ORIGINAL ARTICLE

The role of three-dimensional ultrasound in pregnancies submitted to cerclage

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SUMMARY

OBJECTIVE: *Cervical cerclage is the standard treatment for cervical incompetence (CI); however, there is still a high risk of preterm birth for women who undergo this treatment. The aim of this study was to longitudinally evaluate findings on two-dimensional transvaginal ultrasonography (2DTVUS) and three-dimensional transvaginal ultrasonography (3DTVUS) that could be related to gestational age at birth.*

METHODS: *A total of 68 pregnant women who were treated with cerclage were evaluated by 2DTVUS and 3DTVUS in the second and third trimesters of pregnancy. Log-rank tests and Cox regression analyses were used to identify significant findings related to gestational age at delivery.*

RESULTS: *A cervical length lower than 28.1 mm (p= 0.0083), a proximal cervical length lower than 10 mm (p= 0.0151), a cervical volume lower than 18.17 cm^3 (p= 0.0152), a vascularization index (VI) under 2.153 (p= 0.0044), and a vascularization-flow index (VFI) under 0.961 (p= 0.0059) in the second trimester were all related to earlier delivery. In the third trimester, a cervical length lower than 20.4 mm (p= 0.0009), a VI over 0.54 (p= 0.0327) and a VFI over 2.275 (p= 0.0479) were all related to earlier delivery. Cervical funnelling in the second and third trimesters and proximal cervical length in the third trimester were not related to gestational age at birth. The COX regression analyses showed that cervical volume in the second trimester; FI and VFI in the third trimester were significantly associated with gestational age at birth.*

CONCLUSION: *In women treated with history-indicated cerclage or ultrasound-indicated cerclage, 2nd trimester cervical volume and 3rd trimester FI and VFI are independent significant sonographic findings associated with time to delivery.*

KEYWORDS: *Pregnancy. Obstetric labour, premature. Cervix uteri. Cerclage, cervical. Ultrasonography.*

INTRODUCTION

Cervical incompetence (CI) is diagnosed based on an obstetric history of second [1,2] or early third trimester foetal losses [3], following painless cervical dilation, prolapse or membrane rupture, and expulsion of a live foetus despite minimal uterine activity. This condition is implicated in 10% to 25% of second trimester pregnancy losses. [4]

Cervical cerclage is still a standard technique for treating CI, and some reports have estimated that up to 2% of all pregnancies require cerclage procedures [4] Uncontrolled studies have suggested that infant viability is approximately 25% without cerclage but ranges from 75-90% with cerclage.[3]

However, even after this intervention, these women remain at high risk for preterm delivery. Preterm

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birth rates before 36 weeks vary from 20% – 25% in elective cerclages, 27% – 42% in urgent cerclages, and 53% – 77% in emergent cerclages.[2,5]

Historically, women treated with cerclage receive digital or speculum follow-up examinations, although the usefulness of these procedures has yet to be confirmed by controlled studies.[6,7] In contrast, the introduction of two-dimensional transvaginal ultrasonography (2DTVUS) for visualizing the cervix and stitches has improved and facilitated both the diagnosis and follow-up examination of these patients.[8] Many studies about the use of 2DTVUS in women treated with cerclage and the prediction of preterm birth been published.

In addition, three-dimensional transvaginal ultrasonography (3DTVUS) with power Doppler has recently been studied as an option for evaluating the uterine cervix during pregnancy. Previous studies have demonstrated that 3DTVUS can provide more accurate measurements of cervical volume and cervical length than 2DTVUS.[9-11]

There is evidence that angiogenic factors may play a role in cervical ripening and the birth process, and 3DTVUS with power Doppler could provide more information on cervical morphology and vascularization than 2DTVUS.[12] Theoretically, three-dimensional imaging combined with power Doppler enables the quantitative assessment of volume and Doppler signals of the whole target organ. In contrast, 2DTVUS information on vascularization and blood flow is restricted to a single subjectively chosen 2D plane.[13]

The aim of this study was to longitudinally evaluate the findings of 2DTVUS and 3DTVUS with power Doppler that could be related to gestational age at birth in women treated with cerclage.

METHODS

This was a prospective study of women with a singleton pregnancy who underwent elective cerclage (n= 52) between 12 and 16 weeks of gestation or ultrasound-indicated cerclage (n= 16) between 16 and 24 weeks of gestation. The subjects were followed at the Recurrent Miscarriage Clinic of the Department of Obstetrics and Gynaecology of São Paulo University Medical School between June 1, 2012, and October 30, 2015. This study was approved by the University Ethics Committee (CAPPESq 0851/06). All participants in the study provided written informed consent.

The indication for elective cerclage had a history of two or more second trimester pregnancy losses or preterm births with early cervical dilation without uterine contractions. Cerclage was indicated by ultrasound when there was a history of one second trimester pregnancy loss or early preterm delivery and a current cervical length of 25 mm or lower up to 24 weeks of gestation.

All women who were treated with elective or ultrasound-indicated cerclage during this period were invited to participate in this research.

Elective cerclage (n= 52) was placed at 14.06 ± 1.13 weeks, and ultrasound-indicated cerclage (n= 16) was placed at 19.8 ± 2.98 weeks.

Women were included in the study if they met the following criteria: 1) had a singleton gestation of a live foetus; 2) were treated with elective or ultrasound-indicated cervical cerclage; 3) exhibited no uterine anomalies or cervical conisation; 4) received at least 2 serial transvaginal ultrasound examinations for the assessment of cerclage placement and cervical length, one between 20 and 24 weeks (2nd t) and one between 28 and 32 weeks (3rd t); and 5) had available delivery records. Patients who were treated with emergency cerclage due to prolapsed foetal membranes were not included.

All included patients underwent a McDonald cerclage with a second 5 polyester suture 1 cm below the first stich.

The data obtained included the following: maternal age, race, gestational age at cerclage, cervical length, cervical funnelling, proximal cervical length, cervical vascular index (i.e., vascularization index (VI), flow index (FI), vascularization-flow index (VFI)), cervical volume, and gestational age at birth. The presence of cervical funnelling was defined as a protrusion of membranes into the cervical canal ≥ 5 x 5 mm.

All the exams were performed using a 5 - 9 MHz transvaginal transducer with a 146° field of view (GE Healthcare, Zipf, Austria). The following identical pre-installed settings were used for all patients: a frequency of 3-9 MHz, a pulse repetition frequency of 0.6 kHz, a gain of – 5.0, and a low wall motion filter of 1.

Women were examined in the lithotomy position with an empty bladder. The ultrasound probe was slowly introduced into the vagina, and care was taken to avoid undue pressure on the cervix. After a satisfactory grey-scale image of the cervix had been

obtained, the probe was gradually advanced again with only enough pressure to restore a satisfactory image. A sagittal view of the cervix where the internal os, the cervical canal and the external os could all be observed simultaneously was obtained. The cervical length measurements were performed by the first author, who has five years of experience in ultrasounds, as described by Iams et al.[14] In cases of cervical funnelling, the apex of the funnel was considered the beginning of the closed endocervical canal, and the external os was considered the distal end of the endocervical canal. The location of the cerclage was identified as an echo-dense structure in the cervical stroma. The system was switched to the power Doppler mode and then into the 3D mode. The cervix was centralized within the 3D sector appearing on the ultrasound screen, and data were obtained by holding the transducer stationary while its crystals were mechanically rotated across the sector with a sweep angle of 90°. The fast volume acquisition (i.e., low resolution) setting was always used to minimize periodic flashing artefacts arising from uterine artery pulsation and from foetal movements. The scanned volumes were stored digitally for off-line analysis.

Virtual Organ Computer-Aided Analysis (VOCAL™) software, which is integrated into the Voluson E8 ultrasound system, was used to calculate cervical volume (cm^3) and power Doppler flow indexes.

The calculated Doppler indexes were the VI, FI, and VFI. The VI is the ratio between the colour voxels and the total number of voxels in the volume, where a voxel is defined as the smallest unit of each volume; the VI reflects the percentage of the volume consisting of blood vessels. The FI is calculated as the sum of weighted colour voxels divided by the number of colour voxels. The FI reflects the average energy per colour voxel reflected from the blood corpuscles in the vessels of the volume; the more blood corpuscles, the higher the FI values. The VFI is the sum of weighted colour voxels divided by the total number of voxels, and it reflects both the proportion of tissue consisting of vessels and the number of blood corpuscles in the vessels.

The acquired volumes were manipulated to obtain reformatted multi-planar views of the cervix in the mid-sagittal, axial and coronal planes. All cervical measurements were taken on these multi-planar images, and the results were documented on hard copies. The contour mode in the VOCAL™ program was set to manual, and the longitudinal view was used as reference image. The rotation steps were 30°. When drawing the contours, care was taken not to include the lower uterine segment, the vaginal wall, and particularly the large uterine arteries. Once all contours had been drawn, the volume and power Doppler flow indexes of the cervix were computed automatically.

To minimize interobserver variability, a single sonographer performed all the exams.

The threshold for significance was established at $p < 0.05$.

TABLE 1: DEMOGRAPHIC CHARACTERISTICS AND OBSTETRIC DATA.

	n (%)	Average (± SD)	Median (minimum – maximum)
Maternal Age	66 (100%)	29.32 ± 5.7	30 (17 – 43)
Body Mass Index	64 (97%)	28.03 ± 4.2	28.12 (18 – 39)
Race - Caucasian - Non-caucasian	66 (100%) 31 (47%) 35 (53%)	-	-
Obstetric History - Number of gestations - Early miscarriage - 2nd trimester miscarriage - Term delivery - Preterm delivery - Curettage - Cerclage	66 (100%) 66 (100%) 23 (34.8%) 45 (68.1%) 22 (31.8%) 44 (66.67%) 50 (75.7%) 27 (40.9%)	 4.14 ± 2.02 2.28 ± 1.56 1.86 ± 0.94 1.12 ± 0.33 1.76 ± 0.97 2.58 ± 1.45 1.62 ± 1.06	 4 (2 – 12) 1.5 (1 – 5) 2 (1 – 4) 1 (1 – 2) 2 (1 – 5) 3 (1 – 6) 3 (1 – 6)
Gestational Age at Cerclage - Elective cerclage - Ultrasound-indicated cerclage	 50 (75.75%) 16 (24.25%)	 14.06 19.8	 13.8 (12.28 – 17) 19.6 (15.4 – 25,4)
Gestational Age at Delivery - Elective cerclage - Ultrasound-indicated cerclage	 50 (75.75%) 16 (24.25%)	 36.88 ± 3.87 37.50 ± 2.53	 38 (22.71 – 40.28) 38 (32 – 40.42)
Gestational Age at Delivery < 37 weeks Gestational Age at Delivery < 34 weeks	18 (27.27%) 10 (15.15%)		

A Kaplan-Meier Curve was developed for each sonographic characteristic, and the log-rank test was used for continuous variables to form two groups and maximize the differences between them in the survival curves. A Cox regression model was used to identify risk factors related to earlier delivery. The evaluated time periods were analysed separately. The following were considered co-variables for each time periods: funnelling, proximal cervical length, cervical volume, VI, FI, VFI, and cervical length.

RESULTS

68 women referred for cerclage met the study inclusion criteria. Two patients treated with elective cerclage were excluded from the analysis; one was excluded due to spontaneous miscarriage after cerclage at 19 weeks, and the other was excluded due to foetal death at 20 weeks of gestation. The demographic characteristics and obstetric data of the study population are described in table 1.

The average gestational age ± standard deviation at the first and second ultrasound exams was 22.23 weeks ± 1.33 and 29.87 weeks ± 1.46, respectively.

The sonographic findings of 2DTVUS and 3DTVUS with power Doppler are shown in table 2. Cervical funnelling was present in 16 (26%) patients between 20 and 24 weeks and in 16 (27%) patients between 28 and 32 weeks.

Gestational age at delivery was evaluated as a continuous variable. The Kaplan-Meier curves showed an increased frequency of earlier delivery with a cervical length lower than 28.1 mm (p= 0.0083), a proximal cervical length lower than 10 mm (p= 0.0151), a cervical volume lower than 18.17 cm^3 (p= 0.0152), a VI under 2.153 (p= 0.0044), and a VFI under 0.961 (p= 0.0059) in the second trimester (figure 1). In the third trimester, a cervical length lower than 20.4 mm (p= 0.0009), a VI over 0.54 (p= 0.0327) and a VFI over 2.275 (p= 0.0479) were related to earlier delivery (figure 2). Cervical funnelling between 20 and 24 weeks, and cervical funnelling and proximal cervical length between 28 and 32 weeks were not significant predictors.

The COX regression results showed that for the second trimester ultrasound, a cervical volume ≥ 18.17 was an independent variable that was significantly associated with later gestational age at birth. Furthermore, in the third trimester, a FI ≥ 44.336 and a VFI ≥ 2.275 were associated with gestational age at birth (table 3).

TABLE 2: ULTRASONOGRAPHIC FINDINGS FROM 2DTVUS AND 3DTVUS IN THE SECOND AND THIRD

	n	Average	95% CI	SD	Median	Min - Max
2nd t Cervical Length (mm)	61	29.9	27.7 – 32.1	5.1	31.5	9 – 54
3rd t Cervical Length (mm)	59	26.5	24.1 – 29	9.2	28	6 – 45
2nd t Proximal Cervical Length (mm)	56	13	10.7 – 15.2	8.4	14.1	0 – 34
3rd t Proximal Cervical Length (mm)	59	10.4	8.4 – 12.3	7.5	11	0 – 27
2nd t VI (%)	58	4.6	2.9 – 6.3	6.4	3	0 – 3
2nd t FI	58	37.3	35.5 – 39.1	6.9	36.4	26 – 57
2nd t VFI	58	1.6	1 – 2.2	2.3	1	0 – 16
3rd t VI (%)	59	4.3	2.5 – 6	6.7	3.3	0 - 52
3rd t FI	59	37.5	35.4 – 39.6	8	37.5	17 - 57
3rd t VFI	59	1.4	1.1 – 1.7	1.1	1.2	0 - 5
2nd t Cervical Volume (cm3)	59	33.6	29.3 – 38	16.5	29.9	9 - 100
3rd t Cervical Volume (cm3)	59	35.6	31 - 40	17.6	36.2	7 - 90

2nd t: second trimester; 3rd t: third trimester; CI: confidence interval; SD: standard deviation; Min - Max: minimum - maximum.

TABLE 3: COX REGRESSION MODEL FOR ULTRASOUND PARAMETERS IN THE SECOND AND THIRD TRIMESTERS WITH RESPECT TO GESTATIONAL AGE AT BIRTH.

Variable	Estimate	Standard Error	p Value	HR	95% CI for HR	
					Lower	Upper
2nd t Cervical Volume ≥ 18.17 cm^3	-1.029	0.494	0.037	0.357	0.136	0.941
3rd t FI ≥ 44.336	-1.256	0.423	0.003	0.285	0.124	0.653
3rd t VFI ≥ 2.275	1.120	0.421	0.008	0.285	0.124	0.653

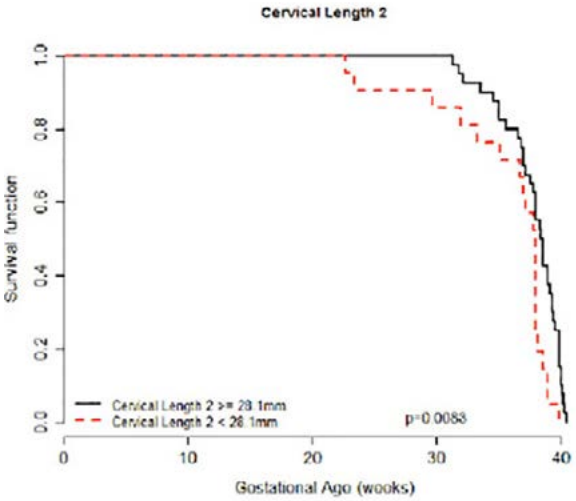

FIGURE 1: Survival curves for gestational age at delivery by cervical characteristics in the second trimester. The p values determined using log-rank tests are p = 0.0083, p = 0.0152, p = 0.0044, p = 0.0059, and p = 0.0151 for a cervical length lower than 28 mm, a cervical volume lower than 18.17 cm3, a VI under 2.153, a VFI under 0.961, and a proximal cervical length lower than 10 mm, respectively.

DISCUSSION

This study aimed at evaluating the usefulness of 2DTVUS and 3DTVUS for investigating gestational age at birth in pregnant women treated with cerclage.

In this group of patients, a second trimester cervical length < 28.1 mm and a third trimester cervical length < 20.4 mm were related to earlier delivery, and these findings are in agreement with current obstetric data. Guzman et al.[15] evaluated 29 women who underwent emergency cerclage at 16 to 26 weeks of gestation and found similar results; these authors found significant differences in postoperative endocervical canal length between patients who delivered at < 36 versus ≥ 36 weeks. Dijkstra et al. [6] studied 32 women treated with elective or ultrasound-indicated cerclage and found a significant relationship between gestational age at delivery and cervical length between 28 and 32 weeks (r= 1.4, p= 0.002). The average cervical length measured between 28 and 32 weeks was significantly different in women who delivered preterm compared with those who delivered at full term (21.0 ± 5.7 compared with 30.3 ± 9.5 mm, respectively; p= 0.002). Song et al.[16] studied a group of 52 pregnant women treated with elective cerclage and found a significant relationship between cervical length after cerclage and gestational age at delivery before 32 weeks. Miller et al.[17] studied 124 women treated with elective cerclage and found a significant relationship between a cervical length of less than 25 mm measured between 18 and 24 weeks and delivery before 34 weeks; however, when these authors considered gestational age as a continuous variable, a cervical length lower than 25 mm was not a significant factor (p= 0.051). In contrast, O'Brien et al.[18], Rust et al.[19] and Hedriana et al.[20] did not find any relationship between cervical length measured after cerclage and gestational age at birth. These findings could be explained by factors of cohort heterogeneity, including a history of second trimester pregnancy loss, a history of diethylstilboestrol exposure in utero, cervical conisation, uterine anomalies and treatment with history-indicated, ultrasound-indicated and emergency cerclage.

A second trimester proximal cervical length < 10 mm was significantly associated with an earlier delivery. Previous studies have already demonstrated this relationship in pregnant women treated with history-indicated[7, 17], ultrasound-indicated[7] and emergency[15] cerclage. However, Hedriana et al.[20] found different results; they measured proximal cervical length at an average gestational age of 26 ± 4.4 weeks (gestational age ± SD) and found that this measurement was not useful for differentiating preterm birth from term birth. The difference between the present study and that study was that we evaluated gestational age as a continuous variable, while Hedriana et al.[20] established the end point as a categorical variable.

A few studies have suggested that compared with 2DTVUS, a 3DTVUS examination would allow a more complete assessment of the cervix.[9, 11] Nevertheless, this is the first study regarding 3DTVUS in women treated with cerclage. Our results showed a significant relationship between a second trimester cervical volume < 18.17 cm^3 and an earlier delivery.

Most studies about cervical volume during pregnancy are related to low-risk patient[7, 12, 21] parity and previous delivery modes[22]. Rovas et al.[12] found no differences in the cervical volume of 677 women during low-risk pregnancy; however, their data showed a significant difference in cervical volume between parous and nulliparous pregnant women. Park et al.[23] found an inverse association between cervical volume measured at 20-24 weeks of gestation and the risk for spontaneous preterm birth before 36 weeks of gestation in pregnant women at a low risk for preterm birth. Similar to our results, they found that the smaller the cervical volume, the higher the likelihood of preterm birth. In a study of 28 pregnant women hospitalized for preterm labour, Rozenberg et al.[24] reported that

cervical volume increases the positive predictive value of preterm birth. This study reported that the optimal cervical volume cut-off point for differentiating full term and preterm birth was 20 mm^3. In contrast, Hoesli et al.[25] did not find a significant difference in cervical volume between pregnant women with low and high risk for preterm birth.

When examining gestational age as a continuous variable, the Kaplan-Meier curves showed that the VI and VFI in the 2nd trimester and the VI and VFI in the 3rd trimester were related to gestational age at birth. We noted that a reduced VI and VFI in the 2nd trimester were related to earlier delivery, in contrast with an increased VI and VFI in the 3rd trimester. Rovas et al.[12] and Yilmaz et al.[21] did not find differences in these cervical indexes when analysing low-risk pregnant women in relation to gestational age at delivery.

There are few studies about cervical vascular indexes and gestational age at delivery. To our knowledge, this is the first study using 3DTVUS with power Doppler to examine women treated with cerclage. De Diego et al.[26] studied 29 women with an asymptomatic short cervix in the 2nd trimester of pregnancy and 71 women with threatened preterm labour; they compared these two groups of women in relation to cervical length, cervical volume, VI, FI and VFI. In the group of women admitted for preterm labour, there was a difference in cervical length (18.3 versus 14.9 mm, p= 0.014) between those with at full term and preterm delivery, respectively, but no differences were found in cervical volume, VI, FI or VFI. The authors also found that cervical volume was lower in women with threatened preterm labour than in asymptomatic women with the same cervical length; in addition, VI and VFI were higher in women with threatened preterm labour, which reinforced the idea that the cervix increases its vascularization and flow to prepare for labour. The different results we found regarding cervical vascular indexes could be due to the cerclage stitch. Cox regression analyses were used to identify which ultrasound variable could be considered a risk factor for preterm birth; the results showed that a cervical volume ≥ 18.17 cm^3 in the 2nd trimester and a FI ≥ 44.336 in the 3rd trimester reduced the risk for preterm birth, whereas a VFI ≥ 2.275 in the 3rd trimester was associated with earlier delivery. While this behaviour was unexpected for FI, it could be explained by the fact that FI is not an indicator of perfusion and cannot provide information on the volume of blood being pumped through a vessel during a particular period. The real meaning of the FI is unclear, and the FI is less predictable than the VI and VFI.[27] Furthermore, Park et al.[23] have already reported an association between small cervical volume (≤ 20 cm^3) and preterm birth

In our study, standardized equipment settings were used to avoid significant effects on our results, and the use of a transvaginal probe to evaluate the cervix theoretically reduces the influence of attenuation on the vascular index.

A methodological difficulty when estimating cervical volume and vascularity using 3D ultrasound is defining landmarks when drawing the contours of the cervix. Rovas et al.[12] and Hoesli et al.[25] have also noted this difficulty. The delineation between the cervix and the lower uterine segment is particularly difficult, especially during early pregnancy and at mid-gestation, when the lower uterine segment is thick and the cervix is often curved. It may also be difficult to clearly distinguish the cervix from the surrounding vaginal tissue.

While we found that according to Kaplan-Meyer curves, the VI and VFI were significantly associated with earlier delivery in women treated with cerclage, the clinical importance of these findings for the vascularization of the cervix has yet to be fully understood.

CONCLUSION

In women treated with history-indicated cerclage or ultrasound-indicated cerclage, 2nd trimester cervical volume and 3rd trimester FI and VFI are independent significant sonographic findings associated with time to delivery.

COMPLIANCE WITH ETHICAL STANDARDS:

The authors declare that they have no conflict of interest.

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

This article does not contain any studies with animals performed by any of the author

Informed consent was obtained from all individual participants included in the study. TF Borghi: Data collection, data analysis, manuscript writing;

MHB Carvalho: Protocol/project development; data analysis; Manuscript writing/editing, supervisor AG Amorim Filho: Protocol/project development; data analysis; S Martinelli: Data collection RPV Francisco: Manuscript writing/editing; M Zugaib: Manuscript writing/editing, supervision

RESUMO

OBJETIVOS: *Determinar quais características ultrassonográficas obtidas por meio da ultrassonografia transvaginal bidimensional (USG TV 2D) e tridimensional (USG TV 3D) associam-se ao parto prematuro em gestantes submetidas à cerclagem profilática e terapêutica.*

MÉTODOS: *Sessenta e seis gestantes com feto único submetidas à cerclagem profilática ou terapêutica e acompanhadas no ambulatório de Aborto Habitual da Clínica Obstétrica do Hospital das Clínicas da Faculdade de Medicina da USP, entre 1º de juho de 2012 e 30 de outubro de 2015, foram avaliadas longitudinalmente, por meio das US TV 2D e US TV 3D associadas ao power Doppler para avaliação do VI, FI e VFI , nos três trimestres da gestação. Os resultados foram avaliados em relação ao parto em idade gestacional (IG) menor que 34 semanas e maior ou igual a 34 semanas, assim como em relação à idade do parto como variável contínua.*

RESULTADOS: *O comprimento do colo uterino (CC) e a distância do ponto de cerclagem ao orifício interno do colo uterino (POI) diminuíram de forma significativa entre o segundo e terceiro trimestres da gestação. O CC, o POI e o afunilamento cervical no terceiro trimestre da gestação tiveram relação com a ocorrência de parto em IG<34 semanas. Na análise de regressão de COX, em que a variável de interesse foi o tempo até o parto, o volume do colo uterino no segundo trimestre e o FI e VFI no terceiro trimestre foram significativos.*

CONCLUSÃO: *Foi possível identificar parâmetros ultrassonográficos do colo uterino bi e tridimensionais que se correlacionam com a idade gestacional do parto.*

PALAVRAS-CHAVE: *Gravidez. Trabalho de parto prematuro. Colo do útero. Cerclagem cervical. Ultrassonografia.*

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