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TRANSVAGINAL ULTRASOUND CERVICAL MEASUREMENT FOR PREDICTING PRETERM LABOUR IN SINGLETON PREGNANCIES

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Annotation:

Aim: to estimate the applicability of ultrasound parameters: cervical length (CL), uterocervical angle (UCA) and the index UCA/CL ratio in the second trimester of singleton pregnancies for predicting spontaneous preterm birth (sPTB).

Materials and methods. The study group included 46 pregnant women aged 16 to 43 years. Informed consent was obtained from the patients for the conduct of the study. The main group included 22 women whose pregnancies ended in sPTB at 24-36 weeks of gestation. The control group consisted of 24 patients who had term births. Transvaginal ultrasound was performed at 18-22 weeks of pregnancy using intracavitary transducers with a frequency of 3-13 MHz. Descriptive and analytical statistical methods were used (Shapiro-Wilk test, Student's t-test, Mann-Whitney U test, Pearson's $\chi 2$ test, Fisher's exact test, Spearman's rank correlation coefficients and ROC analyses).

The study was conducted in accordance with the principles of the Helsinki Declaration. The study protocol was approved by the local ethics committee.

Results. In order to assess the prognostic ability and determine the critical (threshold) levels of the studied ultrasonographic indicators measured in the second trimester of pregnancy, ROC analysis was performed to predict sPTB. It was found that the optimal threshold value of CL was $\leq$3.3 mm with an area under the ROC

curve AUC=0.832 (95% confidence interval (CI) 0.693-0.926) at p<0.001, and sensitivity (Se) and specificity (Sp) criteria Se=72.7%, Sp=83.3%. The threshold value of UCA was determined to be an angle >93.2 degrees with an area under the ROC curve AUC=0.799 (95% CI 0.655-0.903) at p<0.001, and sensitivity and specificity criteria Se=81.8%, Sp=70.8%. According to ROC analysis, the most sensitive indicator for assessing the risk of sPTB was the index UCA/CL ratio with an optimal threshold value > 2.66 degree/mm, an area under the ROC curve AUC=0.856 (95% CI 0.721-0.942) at p<0.001, sensitivity and specificity indicators of the criterion Se=95.5%, Sp=66.7%.

Conclusions. Thus, based on the results of our study, we can conclude that a combination of several transvaginal ultrasound cervical measurement in the second trimester (CL, UCA and the index UCA/CL ratio) can provide a higher level of accuracy in predicting the risk of sPTB in singleton pregnancy. We found that the optimal threshold value of CL was ≤3.3 mm, the threshold value of UCA was determined to be an angle >93.2 degrees and for the index UCA/CL ratio an optimal threshold value was established as > 2.66 degree/mm. The index UCA/CL ratio was the most sensitive indicator for assessing the risk of sPTB according to ROC analysis.

The authors declare no conflict of interest.

Key words: Singleton pregnancy, transvaginal ultrasound, cervical length, uterocervical angle, spontaneous preterm birth, predictive markers.

The techniques for diagnosing risk of preterm birth include the patient's history of sPTB; clinical signs including uterine contractions; transvaginal ultrasound parameters and fetal fibronectin. The assessment of cervical function and structural integrity based on the ultrasound CL and UCA described in the several studies [1–7]. It is known that cervical shape and length change gradually from the first to the third trimester. The UCA increases from early to mid-pregnancy, while the CL decreases from early to mid-pregnancy [2, p. 227]. A short CL assessed by transvaginal ultrasound between 16 and 24 weeks of gestation is a reasonably accurate predictor of sPTB. The risk of sPTB is inversely proportional to the CL; those with the shortest

CL have the highest risk of sPTB, regardless of reproductive history. Depending on the population studied and the gestational age at assessment, the clinical cut-off to define a «short» CL has ranged from 15 to 30 mm [7, p. 446].

A wide UCA provides a direct effect of the uterine content on the cervix, whereas a narrow UCA maintains anatomic integrity and exerts less influence on the internal os, which in turn protects from cervical distortion [1, p. 66]. Given that the measurement of UCA is closely related to factors such as gestational week, patient ethnicity, and medical history, which leads to differences in the optimal cut-off point judgment among various studies, the international range of UCA for predicting preterm birth is between 95 and 115 degrees [1-6]. Based on a prospective cohort study, the authors concluded that combined measurement of UCA and CL in patients at threated preterm birth is a more reliable predictor of sPTB, demonstrating cervical ripening prior to active labour onset according to ultrasound findings [1, p. 65, 2, p. 227, 3, p. 157].

Aim: to estimate the applicability of ultrasound parameters: cervical length, uterocervical angle and the index UCA/CL ratio in the second trimester of singleton pregnancies for predicting sPTB.

Materials and methods. The study group included 46 pregnant women aged 16 to 43 years. The main group included 22 women (mean age (M±SD) – 32.5±6.9 years) whose pregnancies ended in sPTB at 24-36 weeks of gestation (median – 32 (30; 35) weeks). The control group consisted of 24 patients (mean age 30.4±5.8 years) who had term births (median 39 (38.5; 40) weeks). The exclusion criteria were: maternal or fetal conditions contraindicating a vaginal delivery; patients with a previous cervical surgical procedure, such as loop electrosurgical excisional procedure (LEEP) or conization; multiple pregnancy; and patients undergoing pessary or cerclage prior to study. Women were also excluded from analysis if they experienced medically indicated preterm birth.

Transvaginal ultrasound was performed at 18-22 weeks of pregnancy on several devices: GemisLogiQ-5 PRO, General Electric, USA; Philips Hd-11 XE, Netherlands; Philips EPIQ 7, Netherlands, using intracavitary transducers with a

frequency of 3-13 MHz. The measurement of ultrasound parameters was carried out using a standardised exam to measure the cervix [5, p. 2]: after bladder emptying, in lithotomy position, with the introduction of the transvaginal probe into the anterior fornix, without exerting pressure on the cervix, obtaining a sagittal cut of the uterine cervix and at least three centimetres of the lower portion of the anterior myometrial wall. The measurement of UCA was added to the routine assessment of the cervix during the second trimester examination. The UCA was defined as the angle between the cervical canal and the lower uterine segment. Visualization included the anterior uterine wall, internal and external cervical os and the isthmus. Two intersecting lines were drawn: one connecting the internal and external os and another parallel to the anterior uterine wall. The angle formed at the internal os represented the UCA [2, p. 225]. The UCA was obtained through three measurements, with the most obtuse UCA being considered among the technically appropriate measurements [5, p. 2].

Descriptive and analytical statistical methods were used (Shapiro-Wilk test, Student's t-test, Mann-Whitney U test, Pearson's $\chi 2$ test, Fisher's exact test, Spearman's rank correlation coefficients and ROC analyses). To assess the prognostic potential of indicators for the risk of sPTB, ROC analysis was performed with the calculation of the area under the ROC curve (AUC) with a 95% confidence interval (95% CI), the discriminatory criterion and operational characteristics (sensitivity (Se), specificity - Specificity (Sp)). A level of $p \leq 0.05$ was considered statistically significant in all tests, with a trend noted at $0.05<p<0.1$.

Informed consent was obtained from the patients for the study.

Results of the study and their discussion. Both study groups were statistically comparable in terms of patient age. We did not find any statistically significant differences in parity, frequency of medical abortions, and miscarriages in the history between the study groups ($p>0.05$). At the same time, there were significant differences in the frequency of sPTB, which occurred in 18.2% of women in the main group and none of the patients in the control group ($p_{FET}=0.045$). A history of a prior sPTB and a short CL are the strongest known risk factors for

recurrent sPTB [7, p. 446].

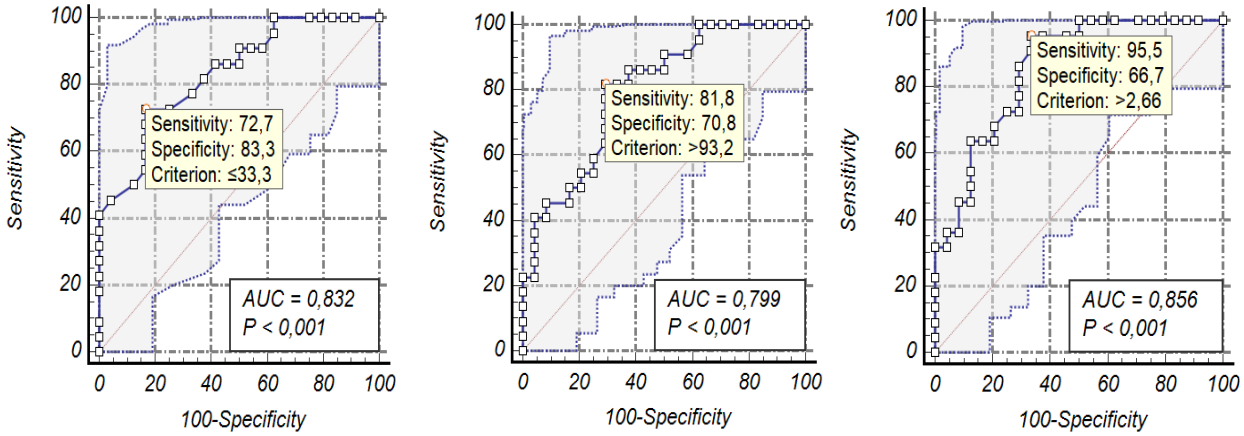
We investigated the prognostic potential of transvaginal ultrasound parameters measured at 18–22 weeks of singleton pregnancy for early diagnosis of sPTB. It was found that the CL in the main group averaged 32.8±1.1 mm. In women in the control group CL averaged 34.4±1.2 mm, which was 4.9% higher than in the main group (p_t<0.001).

These findings do not coincide with the results of other authors. In the observational cohort study [6, p. 4] the CL showed no significant difference between the two groups with sPTB and with at-term birth. The median CL in women with singleton pregnancies who underwent ultrasound examinations between 18^{+0} and 23^{+6} weeks was 36 mm (20–59) in the group with sPTB and 37 mm (14–70) in the group with a term birth (p=0.651).

The results of UCA measurements showed significant differences in the mean UCA values between the two study groups. In women in the main group UCA values averaged 107.2±13.3 degrees, which was 15.1% higher than the corresponding values in women in the control group (93.1±11.7 degrees) at p_t <0.001. Thus, both indicators of transvaginal ultrasound performed in the second trimester of pregnancy are significantly associated with sPTB at gestational age up to 37 weeks: correlation coefficients are rs=0.48, p<0.001 for UCA and rs=-0.57, p<0.001 for CL. This indicates the need to consider both indicators for predicting sPTB.

Given the wide variability and dependence of CL and UCA indicators on gestational age, including in full-term pregnancies, we investigated the predictive role of the index UCA/CL ratio for predicting sPTB. It was determined that the index UCA/CL ratio ranged from 2.59 to 4.08 degree/mm with an average value of 3.27±0.41 degree/mm in women in the main group and exceeded the average values in the control group (2.71±0.34 degree/mm) by 20.7% at p<0.001. An increase in the indicator was also noted in sPTB at gestation periods from 32 to 37 weeks compared to early periods of unfavourable prognosis (<32 weeks) – from 3.06±0.27 to 3.46±0.42 degree/mm (p=0.019). The close relationship between the index UCA/CL ratio and sPTB was also confirmed by correlation analysis data – rs=0.60, p<0.001.

In order to assess the prognostic ability and determine the critical (threshold) levels of the studied ultrasound indicators measured in the second trimester of pregnancy, ROC analysis was performed to predict sPTB. It was found that the optimal threshold value of CL was ≤3.3 mm with an area under the ROC curve AUC=0.832 (95% CI 0.693-0.926) at p<0.001, and sensitivity and specificity criteria Se=72.7%, Sp=83.3% (Fig. 1A).



A – CL, mm B – UCA, degree C – UCA/CL, degree/mm

Fig. 1. ROC curves for determining the optimal values of transvaginal ultrasound indicators for predicting sPTB in singleton pregnancies

The threshold value of UCA was determined to be an angle >93.2 degrees with an area under the ROC curve AUC=0.799 (95% CI 0.655-0.903) at p<0.001, and sensitivity and specificity criteria Se=81.8%, Sp=70.8% (Fig. 1B).

These results differ from the data presented by other authors. An observational cohort study [5, p. 4] including consecutively selected patients with singleton pregnancies who underwent routine examinations between 18^{+0} and 23^{+6} weeks to analyse the risk of prematurity an association was observed between a more obtuse UCA and the occurrence of birth before 37 weeks, with the AUC of 0.636 (p=0.003; 95% CI: 0.546–0.726). The cut-off points of 77.2 degrees demonstrated Se=80% and Sp=29.4% (p=0.003), a positive predictive value (PPV) of 13.6%, and a negative predictive value (NPV) of 91.3%, with a positive likelihood ratio of 1.13 and negative likelihood ratio 0.88. In a subsequent analysis, the cut-off point of 95 degrees was applied, which demonstrated Se=58%, Sp=64.2%, PPV of 18.3%, NPV

of 91.7%, positive likelihood ratio of 1.62, and negative likelihood ratio of 0.62 [5, p. 4].

In prospective observational study [6, p. 576] an obtuse UCA > 98.5 degree predicted sPTB with Se=85%, Sp=79%, AUC=0.86 and odds ratio 21.3 (95 % CI 6.9-65.0). This prospective study [6, p. 577] demonstrates that a mid-trimester UCA exceeding 98.5 degree is a robust, independent predictor of spontaneous pre-term birth in high-risk singleton pregnancies, outperforming the traditional CL threshold of 25 mm.

According to ROC analysis, the most sensitive indicator for assessing the risk of sPTB was the index UCA/CL ratio with an optimal threshold value > 2.66 degree/mm, an area under the ROC curve AUC=0.856 (95% CI 0.721-0.942) at $p<0.001$, sensitivity and specificity indicators of the criterion Se=95.5%, Sp=66.7% (Fig. 1C).

Our results confirmed the findings of the original study. According to a prospective observational cohort study [4, p. 1127] in primigravid women with singleton pregnancies without known risk factors for sPTB from 16^{+0}–23^{+6} weeks of pregnancy until birth UCA and CL were significantly associated with sPTB when adjusting for other variables (adjusted odds ratio: UCA 1.05, 95% CI 1.02–1.07 and CL 0.82, 95% CI 0.75–0.90). Optimal cut-offs were estimated to be 106 degree and 33 mm for UCA and CL, respectively. Authors devised the index UCA/CL ratio was established with an area under the ROC curve AUC=0.781 (95% CI 0.734–0.823), a threshold value of 3.09 degree/mm and improved odds ratios (positive: 3.18, 2.47 and 4.22; negative: 0.63, 0.52 and 0.51 for UCA, CL and UCA/CL, respectively).

Conclusions. Thus, based on the results of our study, we can conclude that a combination of several transvaginal ultrasound cervical measurement in the second trimester (CL, UCA and the index UCA/CL ratio) can provide a higher level of accuracy in predicting the risk of sPTB in singleton pregnancy. We found that the optimal threshold value of CL was ≤3.3 mm, the threshold value of UCA was determined to be an angle >93.2 degrees and for the index UCA/CL ratio an optimal threshold value was established as > 2.66 degree/mm. The index UCA/CL ratio was

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