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PROSPECTIVE OBSERVATIONAL STUDY

Cervical Consistency Index: A New Concept in Uterine Cervix Evaluation

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ABSTRACT

Objective: To search an ultrasonographic marker to measure cervix consistency throughout pregnancy quantitatively by transvaginal ultrasonography and compare these values with the current pattern—the cervicometry. In a randomly selected population of pregnant and nonpregnant women using a new cervical consistency index (CCI) and compare these changes with the findings using cervicometry.

Methods: The cervical consistency index (CCI) and cervicometry were measured using transvaginal ultrasonography in a reference population of randomly selected women who were mature enough for reproduction, and women in their first, second and third trimester of pregnancy. Patients with history of cervical conization, two or more dilations and miscarriages, Müllerian abnormalities and history of cervix incompetence were excluded from this study. Furthermore, patients with multiple pregnancies and cervical cerclage were not allowed to participate in this study.

Results: A total of 162 patients were evaluated for cervicometry and CCI. Eighty of these women were not pregnant and the remaining 82 were pregnant. The database was analyzed using EPI-INFO version 6.0. Statistical values, such as the average, median and standard deviation between two groups, were analyzed. Statistically significant differences were found between nonpregnant and pregnant women in the first, second and third trimester regarding CCI with $p < 0.0001$. The cervix of pregnant women loses an average of 1.2% of consistency per week of pregnancy. Cervicometry did not show statistically significant difference among the groups ($p = 0.4459$).

Conclusion: CCI can quantitatively assess cervix consistency in pregnant and nonpregnant women, also found statistically significant differences between these groups and between the different trimesters of gestation, CCI also shows a remarkably circumscribed linear regression trend from early pregnancy. This ultrasound marker may serve in future for the early identification of patients at risk for preterm delivery. On cervicometry, there was no statistically significant differences between groups mentioned above.

Keywords: Cervical consistency index, Preterm labor, Cervical length, Cervix evaluation, Ultrasound.

INTRODUCTION

William Goodell, an American gynecologist (1829-94), was the first person who described the softening of the cervix as one of the changes associated to pregnancy, using the symbol of his name back in the 19th century.[1]

During the last century, Bishop also considered cervix consistency as a factor to determine if the cervix is in favorable conditions for the induction of delivery.[2]

However, to the best of our knowledge, this important cervical characteristic has not been evaluated quantitatively from the ultrasonography standpoint.[3] All the research conducted in the field of echography is based on cervicometry.[4-8] The evaluation of cervical length by transvaginal ultrasound and changes in the internal cervical os are today the basis for identifying the risk of preterm delivery in the world, this is due to other screening strategies proposed as biochemical markers, maternal estriol in saliva, cervicovaginal biochemistry, and evaluation of amniotic fluid are expensive, invasive and are not commercially available everywhere and have low rates of detection.[3] Thus, changes in cervical length measured by transvaginal scan have been inversely related to risk of preterm delivery.[9-12] However, there are controversies about the cut-off and the positive predictive value of the test, especially in low-risk populations.

Cervicometry changes exhibit a physiological pattern where progressive shortening after the 28th week is observed. Furthermore, nomograms have been published in order to predict preterm deliveries based on cervical length.[9-11] However, the initial changes in the cervical ripening do not affect the length, but the consistency, because the cervix must first soften and then shortened, and research on the quantification of this variable has not been published before by any other research groups.

Modifications in cervicometry are few during the first 28 weeks of pregnancy with wide ranges of normality. Sensibility, specificity, positive predictive value and negative predictive value vary greatly according to the type of population. Cervicometry is not very helpful before the 14th week and after the 28th week, according to published research works.[13-17]

The aim of this study was to describe a new technique for measuring the consistency of the cervix by transvaginal ultrasonography (TVU) described as cervical consistency index (CCI) to determine if statistically significant differences occur between nonpregnant patients, pregnant women in the first, second and third trimesters, and compare these results with those obtained with cervicometria in the same population.[18]

MATERIALS AND METHODS

A total of 162 women were examined at Maternal Fetal Medicine Unit, CEDIFETAL, and at the Northern General Clinic in Barranquilla, Colombia, over a period of three months (from 1st April to 30th June, 2009) using transvaginal ultrasonography. These women were evaluated by cervicometry and CCI using a transversal cohort design.

The target population consisted of 80 nonpregnant women at fertile age (17-40 years old) and 82 pregnant women undergoing different trimesters of pregnancy, without history of conization, cervical suture, cervical incompetence or Müllerian malformations. Patients with single pregnancy and no history of preterm delivery were included. The gestational age was determined based on the date of their last menstruation (DLM) and confirmed by the first trimester ultrasound in all of the cases before the scan; patients participating in this study signed a written consent.

Cervix measurements were obtained by a specialist in prenatal ultrasound with over 4000 studies per year, during the last 10 years using the standard technique for cervicometry: Empty bladder, lithotomy position, visualization of cervix under minimum pressure in order to identify the endocervical canal, thus obtaining a clear image. Three measurements of the cervical length were conducted and the lowest of them was considered.

Endocervical funneling was not included in the calculation of cervicometry although it was registered as an ultrasound scan finding.

Measurements were found using a 7 MHz transvaginal probe (Voluson 730 Expert, GE Health care).

CCI was evaluated by applying the following Technique: Technique for CCI

To determine the CCI, examination was performed in five steps as follows:

First step: The cervical length is taken according to standard technique published previously by other authors.[19] It is very important to avoid doing an excess pressure on the anterior lip (Fig. 1).

Second step: Once traced the cervical length, the screen is divided into two, leaving fixed on the left side the cervical length taken previously, and on the right side in real time, a pressure is made softly and progressively on the cervix until there is no visual observation of a greater shortening in the anteroposterior diameter (AP) or the cervix moves due to the pressure. To determine accurately the point of greatest shortening of the

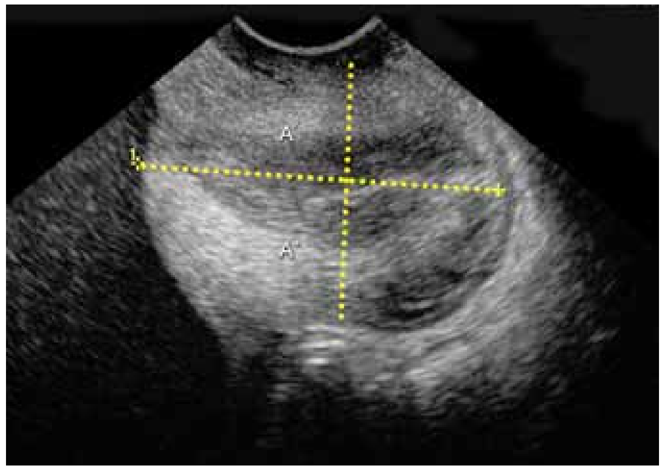


Fig. 1: The cervix must occupy at least 60% at both sides of the display

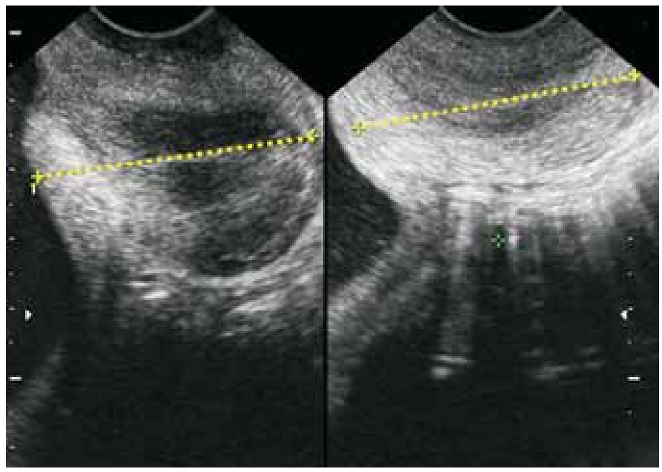


Fig. 2: A line is drawn in the right side, similar to the line used in cervicometry, joining CIO to CEO. The same calculation is conducted in the left side by obtaining the lines A and B

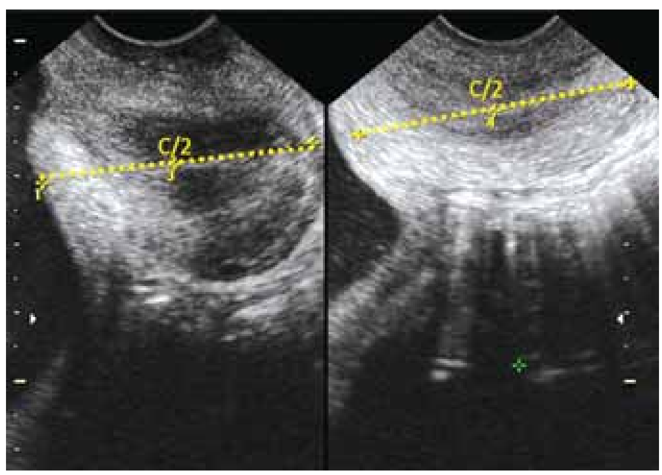


Fig. 3: The middle point of the lines A and B is found and the points X and Y are marked in both the right and the left side of the display respectively

cervix anteroposterior diameter, the cineloop must be used in the equipment. After cervical length was measured on both sides of the screen, it is transported to the center line of the longitudinal axis of the cervix if this does not coincide with the longitudinal axis of the cervical canal as described in Figure 2.

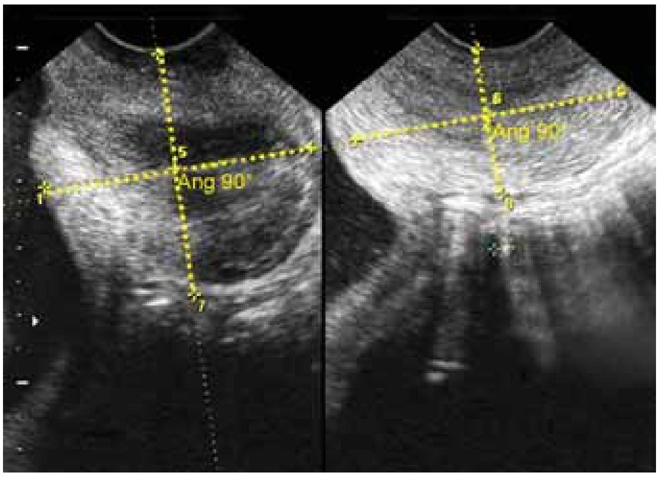


Fig. 4: A perpendicular line is drawn in these points (X and Y) on the right side to measure the distance between the most anterior point of the cervix anterior edge and the most posterior point of the cervix of the posterior edge, passing through the X point. This length is called distance C. The same procedure is followed in the left side of the display thus obtaining the distance D

Third step: A half point of the cervical length transported to the center line of the longitudinal axis of the cervix is calculated (C/2) in both sides of the screen (Fig. 3).

Fourth step: In the half point of the cervical length transported to the center line of the longitudinal axis of the cervix (C/2) is built a perpendicular with an angle of 90º (to measure accurately this angle is used the option angle between 2 lines). On this perpendicular is measured the distance of the most anterior lip point placed anterior to the cervix, until the most posterior point of the lip, posterior of the cervix (AP). Then is made the same procedure on the right side of the screen, obtaining the distance AP´ (Fig. 4).

Fifth step: Finally the AP´ distance is divided by the AP distance and it is multiplied by 100, obtaining this way the CCI, by the equation: CCI = AP´/AP × 100.

In the previous example, AP = 46 mm; AP´= 24 mm. Then, CCI = 24 mm/46 mm × 100; finally, CCI = 52% (see Fig. 4).[18]

The duration of the examinations was 5 to 9 minutes. All 2D ultrasound measurements were repeated two times, and the lowest of the two measurements was used for statistical analysis.

RESULTS

A population of 162 women was studied over a period of 3 months. This population was distributed as follows: Pregnant 80 (49.4%), first trimester 24 (14.8%), second trimester 15 (9.3%) and third trimester 43 (26.5%) (Table 1). The average age was 28.7 years no pregnancy group, 27 first trimester, 23.4 second trimester and 25.2 third trimester (Table 2). Statistically significant differences were found between nonpregnant and pregnant women in the first, second and third trimester regarding CCI with $p < 0.0001$, $r^2 = 0.64$. The following mathematical model is based on those results (Table 3):

CCI = K – [1.202 × (pregnancy age)]
K = 89.53
Pregnancy age: weeks

Table 1: Distribution of patients

	N	*%*
Not pregnant	80	49.4
I trimester	24	14.8
II trimester	15	9.3
III trimester	43	26.5
Total	162	100

Table 2: Age per group

	Median age (years)	*Standard deviation*
Not pregnant	28.733	9.254
I trimester	27.095	5.195
II trimester	23.455	5.803
III trimester	25.256	5.185

p = 0.116

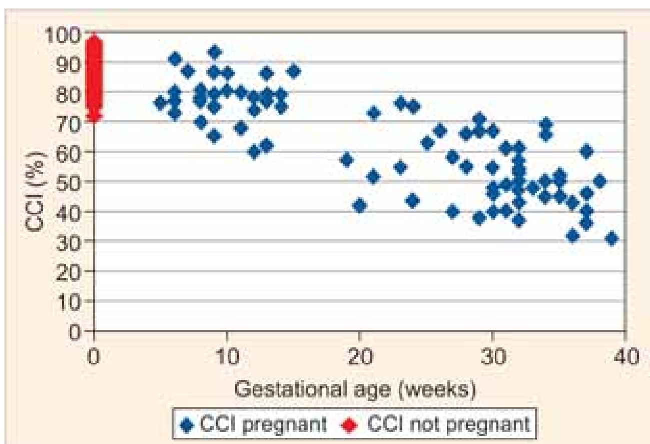
Table 3: Average cervical consistency index per group

	CCI average (%)	*Standard deviation*
Not pregnant	89.53	5.341
I trimester	75.083	14.331
II trimester	68.067	16.158
III trimester	49.581	10.872

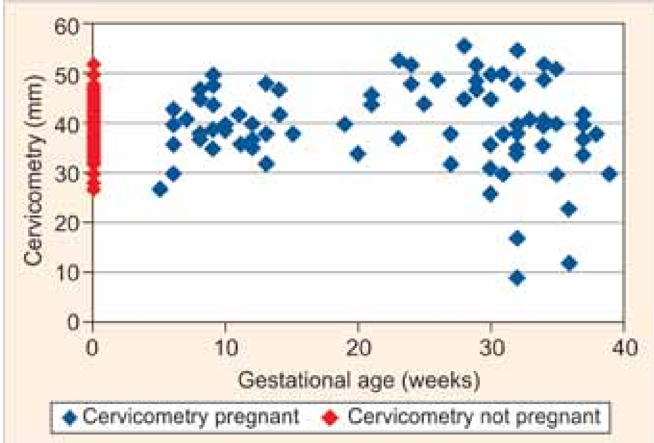
p < 0.0001

The value 'K' corresponds to the average CCI value of nonpregnant women in our population.

The equation above indicates that the cervix of pregnant women loses an average of 1.2% of consistency per week of pregnancy and shows a clear inverse linear relationship with gestational age.



Graph 1: CCI (%) not pregnant (♦), and pregnant (♦) *vs* gestational age (weeks): The dispersion of values found in pregnant patients according to the gestational age. An inverse relation between CCI and pregnancy age is observed



Graph 2: Cervicometry (mm) not pregnant (♦), and pregnant (♦) *vs* gestational age (weeks): The dispersion of values of cervicometry according to gestational age, where no statistical relation is observed between these two variables

Table 4: Cervicometry per group

	Cervicometry average (mm)	*Standard deviation*
Not pregnant	39.286	6.182
I trimester	40.042	5.521
II trimester	42.133	6.069
III trimester	38.070	11.251

p = 0.4459

Table 5: Criteria for the evaluation of effectiveness of a screening test

- Clinically important and prevalent condition
- Safe and well accepted
- Recognize disease in its asymptomatic phase
- A well-described technique, be reliable and reproducible
- The test has validity
- Associated with an intervention that prevents the outcome

Cervicometry did not show any statistically significant difference among the groups, (p = 0.4459) (Table 4). Funneling was present in six patients in the third trimester group.

DISCUSSION

The assessment of cervical consistency was registered only by pelvic examination and not considered of clinical value because of its low reproducibility; however, it has not been described ultrasound technique to measure the consistency of a quantitative and reproducible.[20]

To our knowledge, this is one of the first studies to evaluate the cervical consistency of pregnant and nonpregnant women with TVS.

It is important to assess the consistency of the cervix, because preterm delivery is possibly due to weakness of the cervix to maintain pregnancy and is directly related to the consistency of the cervix.

The cervicometry assumes homogeneity of consistency in relation to cervical length, all the cervix of 25 mm for instance, have the same mechanical strength to support the developing fetus, which according to our result is not true.

The cervix can lose up to 40% of its consistency with no evidence of changes in its length as shown by this work (dispersion Graphs 1 and 2). The advantage of measuring the consistency is given by their predictable behavior and linear regression, as well as in the sequence of events leading to the birth cervix must first soften and then shortened, so the changes in cervical consistency can determine a form of early detection of changes in cervical ripening even want the first trimester of pregnancy which would allow early identification of patients at risk of preterm delivery. The weaknesses of the technique are as follows: First, it requires a new skill to evaluate sonographic cervical consistency, this limitation can be overcome with proper training and second, requires a equipment of high-definition ultrasound transducers over 6.5 MHz. It is also important to introduce the transducer with a good amount of gel into the vagina to reduce the difficulty in identifying the posterior wall of the vagina and not confused with the cervix.

Proper handling of the gain compensation curve is essential to overcome the difficulty described above of course coupled with the use of cineloop as previously described by us,[18] given that the forward and reverse image becomes easier to differentiate the vaginal fornix of cervical tissue. Before looking at changes cervicometry, large variations in the consistency of the cervix could lead to channel shortening cervix (dispersion Graphs 1 and 2). In physiological terms, these changes end with the process of giving birth. Therefore, signs and channel cervicometry represent only the tip of an iceberg of a process initiated in the early stages of pregnancy, as evidenced by our records. These physiological changes in terms of consistency of the cervix and the length measured by the CCI and cervicometry are considered not only in the early diagnosis and monitoring patients at risk of preterm delivery, but also the evaluation of proposed treatments.[21-23] CCI will enable us to detect early stage patients at risk of preterm delivery. Further research involving a larger number of patients are needed to determine the role of CCI in the diagnosis of preterm labor and make decisions if this technique meets all requirements of a screening test, according to the criteria of Grimes[24] (Table 5). Develop a method with which to assess the risk of preterm birth for each patient with cervical ultrasound including cervical length and CCI proposed that cervical length and the CCI are independent variables. This initial study opens the possibility to do research on a new way of assessing changes in the cervix that occur during pregnancy in a clinic. These changes can be very important in predicting preterm birth in preclinical stage, then considering this issue as part of perinatal medicine.

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