THE LENGTH OF THE CERVIX AND THE RISK OF SPONTANEOUS PREMATURE DELIVERY

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Abstract *Background.* The role of the cervix in the pathogenesis of premature delivery is controversial. In a prospective, multicenter study of pregnant women, we used vaginal ultrasonography to measure the length of the cervix; we also documented the incidence of spontaneous delivery before 35 weeks' gestation.

Methods. At 10 university-affiliated prenatal clinics, we performed vaginal ultrasonography at approximately 24 and 28 weeks of gestation in women with singleton pregnancies. We then assessed the relation between the length of the cervix and the risk of spontaneous preterm delivery.

Results. We examined 2915 women at approximately 24 weeks of gestation and 2531 of these women again at approximately 28 weeks. Spontaneous preterm delivery (at less than 35 weeks) occurred in 126 of the women (4.3 percent) examined at 24 weeks. The length of the cervix was normally distributed at 24 and 28 weeks (mean [±SD], 35.2±8.3 mm and 33.7±8.5 mm, respectively). The relative risk of preterm delivery increased as the length of the cervix decreased. When women with shorter cervixes at 24 weeks were compared with women with values above the 75th percentile, the relative risks of preterm delivery among the women with shorter cervixes were as follows: 1.98 for cervical lengths at or below the 75th percentile (40 mm), 2.35 for lengths at or below the 50th percentile (35 mm), 3.79 for lengths at or below the 25th percentile (30 mm), 6.19 for lengths at or below the 10th percentile (26 mm), 9.49 for lengths at or below the 5th percentile (22 mm), and 13.99 for lengths at or below the 1st percentile (13 mm) ($P<0.001$ for values at or below the 50th percentile; $P=0.008$ for values at or below the 75th percentile). For the lengths measured at 28 weeks, the corresponding relative risks were 2.80, 3.52, 5.39, 9.57, 13.88, and 24.94 ($P<0.001$ for values at or below the 50th percentile; $P=0.003$ for values at the 75th percentile).

Conclusions. The risk of spontaneous preterm delivery is increased in women who are found to have a short cervix by vaginal ultrasonography during pregnancy. (N Engl J Med 1996;334:567-72.)

THE length of the cervix may be useful in predicting the risk of premature delivery, with a shorter cervix predicting a higher risk. Traditional methods to evaluate the cervix in pregnancy are limited and unsatisfactory. Digital examination, the standard method, suffers from large variation among examiners.[1] In contrast, transvaginal ultrasonography is a reproducible method of examination during pregnancy.[2,3] In a multicenter, population-based study, we used vaginal ultrasonography to measure the length of the cervix and examined the relation of this measurement to the risk of prematurity.

METHODS

Study Design and Subjects

This investigation was part of a prospective study of screening tests to predict spontaneous premature delivery conducted by the Maternal Fetal Medicine Network of the National Institute of Child Health and Human Development between October 1992 and July 1994. The patient population at each center was characterized demographically before the study began. The study population was selected to reflect the parity and race of women receiving prenatal care at participating centers, without regard to medical or socioeconomic factors. No center was allowed to recruit more than 20 percent of the study population. The primary outcome was spontaneous preterm delivery, defined as delivery after premature labor or rupture of membranes less than 35 weeks from the last menstrual period (≤34⅙ weeks of gestation). This end point was chosen because neonatal morbidity and mortality occur primarily in infants born before 35 weeks' gestation. Because specific hypotheses were not proposed, sample-size calculations were based on the precision of the odds ratio. We calculated the necessary sample size, assuming that the rate of premature delivery was 3.5 percent, that at least 5 percent of the women would have positive results on any given screening test, and that the odds ratio for premature delivery was 2.0 or more for women with positive results on that screening test as compared with women with negative results. A sample of 3000 women was chosen to give a lower 95 percent confidence limit greater than 1 for this odds ratio.

Women identified before 24 weeks of gestation were recruited and enrolled if they gave informed consent. Subjects were required to have an ultrasound examination after 15 weeks, before enrollment. Gestational age was based on the date of last menses if the age based on that date and that based on the earliest ultrasound measurement of the biparietal diameter of the fetal head agreed within 10 days. If not, ultrasound dating was used. Women whose pregnancies were complicated by multiple gestation, cerclage, placenta previa, or a major fetal anomaly were ineligible. Once the women were enrolled, the only study results available to the women's physicians for patient care concerned fetal death, prolapsed membranes, advanced cervical dilatation (≥2 cm in primigravidas and ≥3 cm in multigravidas), hydramnios, oligohydramnios, and painful regular contractions.

Collection of Data and Ultrasonography

Data collected included information about obstetrical history and sociodemographic variables, results of psychological assessment, blood

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*The members of the network are listed in the Appendix.

assays, culture of cervical or vaginal samples (or both), measurements of pH and fetal fibronectin, and findings on digital and transvaginal ultrasonographic assessment of the cervix. The first study visit was scheduled between 22 and 24⅐ weeks of gestation (referred to here as the 24-week visit), with subsequent visits 2, 4, and 6 weeks thereafter. Transvaginal ultrasonographic assessment of the cervix was performed at the initial visit and at the visit 4 weeks later (referred to here as the 28-week visit).

The ultrasound images were analyzed to assess changes in the cervix that are associated with spontaneous prematurity and to evaluate ultrasonography as an indicator of the risk of premature delivery. The length of the cervix was measured with a transvaginal real-time ultrasound probe placed in the anterior fornix of the vagina while the woman's bladder was empty; this method has an interobserver variation of 5 to 10 percent.[2] Transabdominal images were not used because the size of the maternal bladder has an unpredictable effect on the measurement of cervical length.[3] Digital cervical examination preceded each ultrasound examination. The appropriate sagittal view was identified by the location of the triangular area of echodensity at the external os, a V-shaped notch at the internal os, and a faint line of echodensity or echolucency between the two. Undue pressure on the cervix that might artificially increase its apparent length was avoided by first obtaining an apparently satisfactory image, then withdrawing the probe until the image blurred, and finally reapplying only enough pressure to restore the image. The cervix was measured in this fashion three times along the line made by the interface of the mucosal surfaces, with calipers placed at the notches made by the internal os and external os (Fig. 1). The cervical length we recorded was the shortest measurement that clearly displayed the criteria described above. This measurement was chosen because first measurements are often 3 to 5 mm longer than subsequent measurements, apparently because of the pressure of the probe required to identify the cervix. Each examination was performed during a minimum of three minutes to allow time for development of a "funnel," defined as a protrusion of the amniotic membranes 3 mm or more into the internal cervical os as measured along the lateral border of the funnel (Fig. 2). The presence or absence of a funnel and its length were recorded.

Cervical measurement was standardized by means of operator-training and quality-control programs. A teaching videotape and guide were developed and distributed to each center. Each sonographer submitted for review by an investigator a videotape of 10 cervical sonographic examinations performed in patients who were not study subjects; study subjects were examined only after the sonographer was certified by this process. Sonographers submitted a videotape of five consecutive examinations of study subjects at a time randomly chosen by the data-coordinating center for purposes of quality control. All sonographic images for every study subject were reviewed by a single investigator who was unaware of the outcome of pregnancy, to ensure that measurements were made appropriately and consistently.

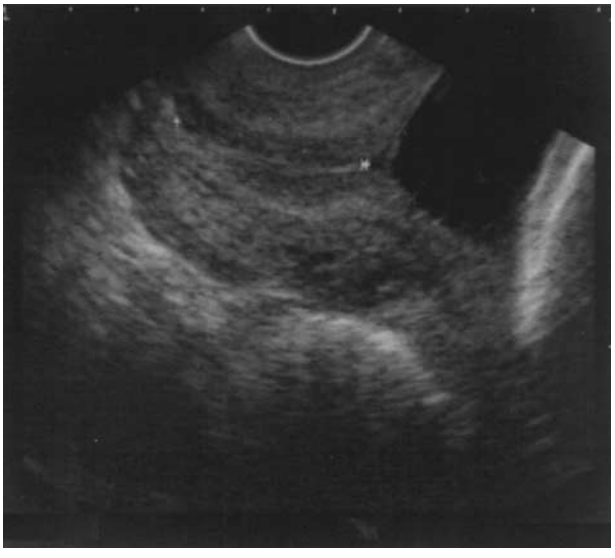

Figure 1. Transvaginal Ultrasound Image of a Normal Cervix.
Calipers have been placed at the internal os (right) and the external os (left).

Figure 2. Transvaginal Ultrasound Image of a Cervix Characterized by Both a Short Length and a Funnel of Amniotic Membrane Protruding into the Internal Os.
The + marks indicate the cervical length, measured from the notch of the external os to the internal os, and the × marks demarcate the funnel cephalad to the internal os. The caudad × caliper overlies the cephalad + caliper.

Statistical Analysis

Cervical length (a continuous variable) and the presence or absence of funneling (a dichotomous variable) were the principal variables used to predict preterm delivery (defined as spontaneous premature delivery before 35 weeks of gestation). Percentiles for cervical length and the presence or absence of funneling were analyzed with the use of chi-square tests. We calculated relative risks and 95 percent confidence intervals by comparing subjects at or below each percentile for cervical length with those above the 75th percentile. Cervical length was analyzed with the use of logistic regression, survival analysis, and receiver-operating-characteristic curves. Correlation of cervical length and the Bishop score (a composite measure of cervical length, dilatation, position, consistency, and degree of descent [station] of the presenting part) was tested by the Jonckheere–Terpstra test.[4]

Results

Study Population

A total of 3073 subjects were enrolled at 10 sites; 73 of this group consented to participate but were exclud-

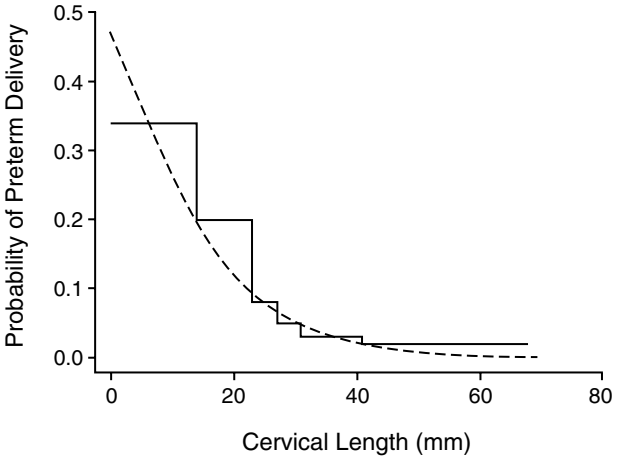

Figure 3. Estimated Probability of Spontaneous Preterm Delivery before 35 Weeks of Gestation from the Logistic-Regression Analysis (Dashed Line) and Observed Frequency of Spontaneous Preterm Delivery (Solid Line) According to Cervical Length Measured by Transvaginal Ultrasonography at 24 Weeks.

ed from the analysis because the length of gestation was greater than the specified limit for the first visit. Of the 3000 subjects examined at the 24-week visit, 71 were lost to follow-up and 14 did not undergo cervical sonography. There remained 2915 subjects (72 actually seen at 22 weeks of gestation, 1523 at 23 weeks, and 1320 at 24 weeks) whose cervixes were measured ultrasonographically at the 24-week visit. Of these women, 384 were not examined again at 28 weeks: 35 of them gave birth before the 28-week visit, 168 withdrew from the study, and 171 did not come to the clinic for the 28-week visit during the specified period (26 to 29 weeks). Another 10 declined to undergo cervical sonography. There were therefore 2531 subjects examined at the 28-week visit (52 actually seen at 26 weeks, 1058 at 27 weeks, 1193 at 28 weeks, and 228 at 29 weeks). Of the 2915 subjects examined at 24 weeks, 42 percent were nulliparous, 28 percent were married, 63 percent were black, 72 percent had not completed high school, and 54 percent had an income below $800 per month.

Sixteen percent (n=458) of the women had previously had one or more preterm deliveries (403 spontaneous and 55 with medical intervention) before 37 weeks of gestation. The frequency of preterm delivery before 35 weeks was 4.3 percent (n=126) among the 2915 subjects examined at 24 weeks. This figure includes the 3.3 percent (n=83) of the 2531 subjects examined at 28 weeks who delivered spontaneously before 35 weeks. The rate of spontaneous preterm delivery ranged from 1.5 percent to 5.1 percent among the centers. Ninety-one subjects (3.1 percent) were treated with parenteral tocolysis, 65 of whom delivered after 35 weeks.

Length of the Cervix in Relation to Preterm Delivery

The mean (±SD) cervical length at 24 weeks was 34.0±7.8 mm for nulliparous women and 36.1±8.4 mm for parous women; the comparable measurements at 28 weeks were 32.6±8.1 for nulliparous women and 34.5±8.7 for parous women. The differences between nulliparous and parous women, although statistically significant, were clinically unimportant. Among parous women, the number of previous deliveries had no effect on the length of the cervix. Data on cervical length in parous and nulliparous women were therefore combined for analysis.

The cervical length was normally distributed at both examinations and decreased slightly from 24 to 28 weeks (mean, 35.2±8.3 mm at 24 weeks and 33.7±8.5 mm at 28 weeks). The mean cervical length was similar among the centers, except for one center that reported significantly longer measurements. Data analysis was performed both with and without the inclusion of the women enrolled at this center, and also for this center alone. Since the exclusion of the center did not change our results or conclusions and since the results were the same for the data from this center alone, combined data are presented here.

The estimated probability of preterm delivery from the logistic-regression analysis and the observed frequency of preterm delivery according to cervical length at 24 weeks are shown in Figure 3. Logistic-regression analysis of data collected at the 28-week visit produced similar results (data not shown). When women with values at or below a particular percentile for cervical length at 24 weeks were compared with those who had cervical-length values above the 75th percentile, the relative risk of preterm delivery was 1.98 (95 percent confidence interval, 1.20 to 3.27) for women at or below the 75th percentile (cervical length, 40 mm), 2.35 (95

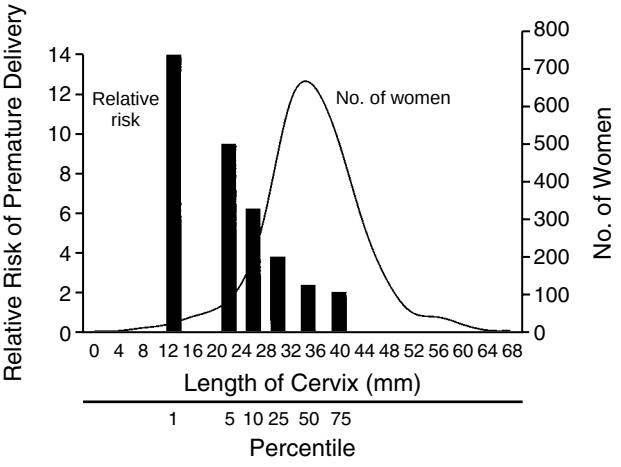

Figure 4. Distribution of Subjects among Percentiles for Cervical Length Measured by Transvaginal Ultrasonography at 24 Weeks of Gestation (Solid Line) and Relative Risk of Spontaneous Preterm Delivery before 35 Weeks of Gestation According to Percentiles for Cervical Length (Bars).

The risks among women with values at or below the 1st, 5th, 10th, 25th, 50th, and 75th percentiles for cervical length are compared with the risk among women with values above the 75th percentile.

percent confidence interval, 1.42 to 3.89) at or below the 50th percentile (35 mm), 3.79 (95 percent confidence interval, 2.32 to 6.19) at or below the 25th percentile (30 mm), 6.19 (95 percent confidence interval, 3.84 to 9.97) at or below the 10th percentile (26 mm), 9.49 (95 percent confidence interval, 5.95 to 15.15) at or below the 5th percentile (22 mm), and 13.99 (95 percent confidence interval, 7.89 to 24.78) at or below the 1st percentile (13 mm) ($P<0.001$ for the comparisons involving values at or below the 50th percentile, and $P=0.008$ for values at or below the 75th percentile).

At 28 weeks, the corresponding relative risks for preterm delivery were 2.80 (95 percent confidence interval, 1.41 to 5.56), 3.52 (95 percent confidence interval, 1.79 to 6.92), 5.39 (95 percent confidence interval, 2.82 to 10.28), 9.57 (95 percent confidence interval, 5.24 to 17.48), 13.88 (95 percent confidence interval, 7.68 to 25.10), and 24.94 (95 percent confidence interval, 13.81 to 45.04) ($P<0.001$ for values at or below the 50th percentile, and $P=0.003$ for values at or below the 75th percentile).

Figure 4 shows the relative risks according to the distribution of cervical-length values at 24 weeks. The association between cervical length and the risk of preterm delivery was evident across the entire range of cervical lengths. Even among women whose cervical length was above the 10th percentile, the risk of preterm delivery increased as cervical length decreased. The logistic-regression analysis indicated that for each increase of 1 mm in cervical length, the odds ratio for preterm delivery was 0.91 (95 percent confidence interval, 0.89 to 0.93).

A change in cervical length between the 24-week and 28-week visits had a small but significant association with the risk of preterm delivery that was independent of the initial cervical length. Among the 56.3 percent of subjects whose cervixes decreased in length between 24 and 28 weeks, the rate of preterm delivery was 4.2 percent, as compared with 2.1 percent among those whose cervixes did not decrease (relative risk, 2.03; 95 percent confidence interval, 1.28 to 3.22). The magnitude of the decrease also had an effect on risk of preterm delivery; the relative risk was 2.80 (95 percent confidence interval, 1.87 to 4.20) for women whose cervixes shortened by 6 mm or more as compared with those whose cervixes changed by less than 6 mm.

The duration of pregnancy according to whether the cervical length was ≤25 mm or >25 mm at the 24-week visit is shown in terms of survival curves in Figure 5. The difference in the duration of pregnancy between women whose cervixes measured 25 mm or less and those whose cervical length was more than 25 mm was significant and continued to widen as gestation progressed. The survival curves for data collected at 28 weeks are similar.

Cervical Ultrasonography to Predict Preterm Delivery

Receiver-operating-characteristic curves suggested 30 mm, 25 mm, and 20 mm as potential threshold values for clinical use, corresponding approximately to the 25th, 10th, and 5th percentiles for cervical length in this study. The sensitivity, specificity, and predictive values of these percentiles are shown in Table 1.

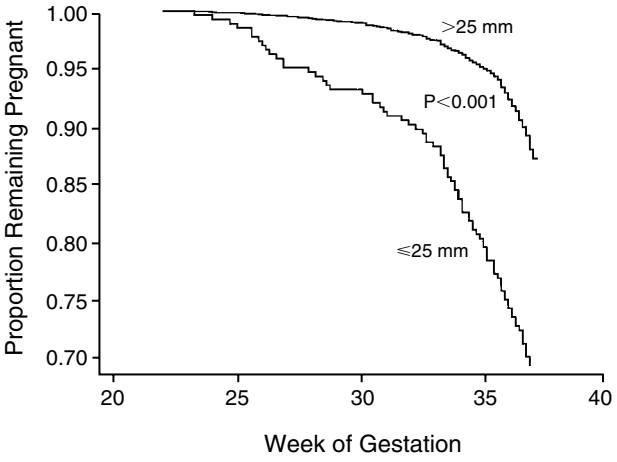

Figure 5. Survival Curves Showing the Duration of Pregnancy among Women Examined at 24 Weeks of Gestation, According to Cervical Length (≤25 mm or >25 mm).

There were 185 subjects at 24 weeks (6.3 percent) and 232 subjects at 28 weeks (9.2 percent) whose cervixes had a funnel at the internal cervical os on ultrasound examination, a finding reported to indicate an increased risk of premature delivery.[5] Among these women, the mean length of the funnel was 16.0±9.1 mm at 24 weeks and 14.3±8.0 mm at 28 weeks. Parity had no effect on the frequency of funneling. Funneling correlated with an increased risk of preterm delivery both at 24 weeks (relative risk, 5.02; 95 percent confidence interval, 3.53 to 7.15) and at 28 weeks (relative risk, 4.78; 95 percent confidence interval, 3.18 to 7.19).

The clinical value of funneling as a predictor of preterm delivery was similar to that of the cervical length (Table 1), but the data on funneling are confounded by substantial variation among centers. Funneling was observed at 24 weeks in no women at one center and in 12.7 percent at another; at these same two centers the values at 28 weeks were 1.3 percent and 21.4 percent. Most centers reported funneling in 3 to 7 percent of subjects at both visits. Variation in the frequency of funneling among centers persisted throughout the study, despite the quality-control measures described earlier. Ultrasound images from centers with the highest and lowest rates of funneling differed in two ways: sonographers at the center with the highest rate appeared to apply less pressure and used a 7-MHz transducer; sonographers at the center with the lowest rate appeared to apply greater pressure and used a 5-MHz transducer. Nevertheless, funneling remained a significant predictor of premature delivery after we controlled for study center and cervical length.

Relation of Cervical Ultrasonography to Digital Examination

Cervical length at both visits correlated significantly ($P<0.001$ by the Jonckheere–Terpstra test[4]) with the

Bishop score, a composite measure that assigns a score of 0 to 3 points to each of five features of the cervix: length, dilatation, position, consistency, and station of the presenting part.[6] Subjects with Bishop scores of 6 or more at 24 weeks (n = 26) and 28 weeks (n = 78) had mean cervical lengths of 23.1 ± 13.3 mm and 25.4 ± 11.2 mm, respectively. The clinical value of the Bishop score is indicated in Table 1.

Discussion

Our findings confirm those of previous studies that have found an inverse relation between the length of the cervix, as measured by ultrasonography during pregnancy, and the frequency of preterm delivery.[3,5,7] The most intriguing finding of our study is that this relation persisted for cervical lengths above the 10th percentile. Women with cervical lengths at or below the 25th, 50th, and 75th percentiles had a significantly greater risk of preterm delivery than those whose cervical lengths were above the 75th percentile. This observation challenges the traditional understanding of the cervix as being either "competent" or "incompetent" and requires reconsideration of the role of the cervix in the pathogenesis of spontaneous premature delivery. In 1961, Parikh and Mehta used digital examination of the cervix to investigate the hypothesis that cervical competence is a continuum; they concluded that degrees of competence did not exist.[8] Our data suggest that these authors were correct in their hypothesis that there was a continuum of cervical competence but that their method of cervical examination led them to the erroneous conclusion, now firmly stated in obstetrical textbooks,[9] that the cervix is either fully functional or nonfunctional (i.e., incompetent).

Our data suggest that the length of the cervix is an indirect indicator of its competence and should be seen as a continuous rather than a dichotomous variable. The length of the cervix is directly correlated with the duration of pregnancy: the shorter the cervix, the greater the likelihood of preterm delivery. Some might argue that this association is tautological — that is, that uterine contractions, whether perceived by the woman or not, shorten the cervix. We offer four observations in response to this proposition. First, the women in this study were outpatients without symptoms of preterm labor at the time of examination. Second, the relation between the length of the cervix and risk of prematurity extended to values well above the 25th percentile for cervical length. Third, survival-curve analysis (Fig. 5) shows increasing divergence of the two curves, rather than a difference established in the days immediately after examination, as might be expected if women with shorter cervixes had occult early labor. Finally, the relation between the length of the cervix and the duration of pregnancy has been observed in successive pregnancies. In a study of 323 women who had previously had a premature delivery,[10] the length of gestation at the time of the earlier preterm delivery was correlated with cervical length in a subsequent pregnancy, suggesting that cervical length operates as a continuous variable in serial gestations. We interpret these observations to mean that there is a continuum of cervical performance that is reflected functionally by the gestational age of the infant delivered prematurely and anatomically by the length of the cervix.

Theories of premature labor based on an understanding of the cervix as uniformly competent may underestimate the importance of the cervix, and overestimate the role of uterine activity, in the pathogenesis of prematurity. Reassessment of the cervix as a structure with variable performance along a continuum supports a theory of spontaneous prematurity as a multifactorial phenomenon in which the causal importance of decreased cervical resistance increases as the length of gestation at the time of the preterm delivery decreases. Uterine activity is known to vary widely among normal pregnancies[11] and could also affect the risk of prematurity in a continuous manner. Just as contraction-based theories of premature labor have led to trials of prophylactic tocolytic agents, our findings raise but do not resolve the question of the appropriate role of cervical cerclage in women with a history of early preterm delivery.[12-14] Perhaps cervical ultrasonography will prove useful in selecting candidates for cerclage.

Obstetricians should be comfortable using the percentile of cervical length as an estimate of the risk of prematurity, since many obstetrical tests are based on percentiles. Although funneling was predictive of prematurity, the ability to identify this phenomenon was not consistent among our 10 study centers. Cervical length was more consistently measured than funneling and performed as well as or better than funneling in

Table 1. Sensitivity, Specificity, and Predictive Value of Cervical Length, Funneling, and Bishop Score for Preterm Delivery before 35 Weeks of Gestation.*

Variable	Cervix at 24 Wk						Cervix at 28 Wk					
	≤20 mm	≤25 mm	≤30 mm	presence of funnel	Bishop score ≥6	Bishop score ≥4	≤20 mm	≤25 mm	≤30 mm	presence of funnel	Bishop score ≥6	Bishop score ≥4
	percent											
Sensitivity	23.0	37.3	54.0	25.4	7.9	27.6	31.3	49.4	69.9	32.5	15.8	42.5
Specificity	97.0	92.2	76.3	94.5	99.4	90.9	94.7	86.8	68.5	91.6	97.9	82.5
Positive predictive value	25.7	17.8	9.3	17.3	38.5	12.1	16.7	11.3	7.0	11.6	25.6	9.9
Negative predictive value	96.5	97.0	97.4	96.6	96.0	96.5	97.6	98.0	98.5	97.6	96.3	96.9

*The rate of spontaneous delivery before 35 weeks was 4.3 percent among the women examined at 24 weeks and 3.3 percent among those examined at 28 weeks.

terms of sensitivity and predictive value. Transabdominal ultrasonography is unsatisfactory for measurement of the cervix because of technical drawbacks that produce inaccurate or poor-quality images.[5,7] Vaginal ultrasonography produced good images in our study and was well accepted by patients. There were no apparent risks associated with the examination. Although the predictive value of ultrasonography was low in this low-risk population, it will rise with the risk of prematurity in the population studied. Ultimately, we expect that cervical ultrasonography will be used to evaluate women with a historical or current risk factor, such as a previous preterm delivery or a Bishop score of 6 or above, and to select candidates for clinical trials to evaluate cerclage.

APPENDIX

In addition to the authors, the participants in the National Institute of Child Health and Human Development (NICHD) Maternal Fetal Medicine Network were as follows: *University of Alabama, Birmingham* — J.C. Hauth, A. Northern, and C. Neely; *Bowman Gray School of Medicine* — E. Mueller-Heubach, M. Swain, and A. Frye; *University of Chicago* — M. Lindheimer, P. Jones, and M.E. Lewis Brown; *University of Cincinnati* — T.A. Siddiqi, N. Elder, T. Coombs, and J. VanHorn; *George Washington University Biostatistics Center* — R. Bain, L. Leuchtenburg, and M. Fischer; *Magee–Women's Hospital* — J.H. Harger, M. Cotroneo, and C. Stallings; *NICHD* — S. Yaffe, C. Catz, and M. Klebanoff; *Ohio State University* — M.B. Landon, J. Schneider, and C. Mueller; *University of Oklahoma, Oklahoma City* — J.C. Carey, A. Meier, and E. Liles; *Medical University of South Carolina* — R.B. Newman, B.A. Collins, T. Metcalf, and V. Odell; *University of Tennessee, Memphis* — B. Sibai, R. Ramsey, and J.L. Fricke; and *Wayne State University* — M. Treadwell and G.S. Norman.

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