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Prediction of patient-specific risk of early preterm delivery using maternal history and sonographic measurement of cervical length: a population-based prospective study

M. S. TO*, C. A. SKENTOU*, P. ROYSTON†, C. K. H. YU* and K. H. NICOLAIDES*
**Harris Birthright Research Centre for Fetal Medicine, King's College Hospital Medical School and †Medical Research Council, Clinical Trials Unit, London, UK*

KEYWORDS: cervical length; preterm delivery; screening

ABSTRACT

Objective *To develop a model for calculating the patient-specific risk of spontaneous early preterm delivery by combining maternal factors and the transvaginal sonographic measurement of cervical length at 22 + 0 to 24 + 6 weeks, and to compare the detection rate of this method to that achieved from screening by cervical length or maternal characteristics alone.*

Methods *This was a population-based prospective multicenter study involving 40 995 unselected women with singleton pregnancies attending for routine hospital antenatal care in London, UK. Complete follow-up was obtained from 39 284 (95.8%) cases. The main outcomes were detection rate, false-positive rate and accuracy of predicting spontaneous delivery before 32 weeks' gestation.*

Results *Spontaneous delivery before 32 weeks occurred in 235 (0.6%) cases. The detection rate of screening for early preterm delivery, at a fixed false-positive rate of 10%, was 38% for maternal factors, 55% for cervical length and 69% for combined testing. There was good agreement between the model estimates and the observed probabilities of preterm delivery.*

Conclusions *This study provides a model that can give an accurate patient-specific risk of preterm delivery. The detection rate of screening by a combination of maternal factors and the measurement of cervical length was substantially higher than that of screening by each method alone. Copyright © 2006 ISUOG. Published by John Wiley & Sons, Ltd.*

INTRODUCTION

Prematurity is the leading cause of perinatal death and handicap, and is responsible for at least half of all neonatal deaths[1,2]. Whilst all births before 37 weeks' gestation are defined as preterm, the vast majority of morbidity and mortality relates to early delivery before 32 weeks[3,4]. Two-thirds of prematurity is attributable to spontaneous birth due to the premature onset of labor or preterm prelabor rupture of membranes (PPROM), and the remainder is a result of delivery for maternal or fetal indications. Although improvements in neonatal care have led to higher survival of very premature infants, a major impact on the associated mortality and morbidity will only be achieved through the development of a sensitive method with which to identify women at high risk of preterm delivery and an effective strategy for the prevention of this complication.

The traditional method of antenatal screening for spontaneous early preterm delivery is based on maternal characteristics, such as age, race and smoking status, and obstetric history. Risk-scoring systems, which attempt to define women as being at high or low risk according to these maternal factors, have been shown to have a low detection rate and a high false-positive rate. Data extracted from a recent systematic review of the literature demonstrated that with the most commonly used risk-scoring system[5], the detection rate of spontaneous delivery before 37 weeks was 38% for a false-positive rate of 17%[6]. An alternative method to identify high-risk women is the sonographic measurement of cervical length at 20–24 weeks of gestation, and several small studies have demonstrated that the risk of preterm delivery is inversely related to the length of the cervix[7–10]. Combined data from the three largest studies, involving a total of 7861 patients, showed that the detection rate of delivery before 35 weeks was 34% for a false-positive rate of about 5%[7–9].

The aim of this study was to develop a model for calculating the patient-specific risk of spontaneous early

Correspondence to: Prof. K. H. Nicolaides, Harris Birthright Research Centre for Fetal Medicine, King's College Hospital Medical School, Denmark Hill, London SE5 8RX, UK (e-mail: fmf@fetalmedicine.com)

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preterm delivery by combining maternal factors and cervical length, and to compare the detection rate of this method to that achieved using maternal factors or cervical length alone.

METHODS

Study design and subjects

This was a prospective study carried out between January 1998 and May 2002 in seven maternity hospitals in and around London, UK. In these hospitals, all women with singleton pregnancies attending for routine antenatal care were offered one ultrasound examination at 11 + 0 to 13 + 6 weeks, for pregnancy dating and early diagnosis of major chromosomal and other fetal abnormalities, and another scan at 22 + 0 to 24 + 6 weeks, for examination of the fetal anatomy and growth. Gestational age was determined from the menstrual history and confirmed from the measurement of fetal crown–rump length at the first-trimester scan. At the time of the second scan the women were given the option of transvaginal sonographic measurement of cervical length (Figure 1) as a screening test for preterm delivery[11].

The sonographers performing the scan had received specialist training and they all had obtained The Fetal Medicine Foundation Certificate of Competence in the technique. Women with major fetal abnormalities, painful regular uterine contractions, or a history of ruptured membranes or cervical cerclage *in-situ* were excluded from screening. The management of the pregnancies was influenced by the findings of the ultrasound scan inasmuch as those with a cervical length greater than 15 mm had normal antenatal care and those with a cervical length of 15 mm or less were invited to participate in a randomized study of cervical cerclage vs. expectant management[12]. All women gave informed written consent to participate in the study, which was approved by the local ethics committee of each participating center and also by the South Thames Multicentre Research Ethics Committee (UK). The study of cervical cerclage demonstrated that it did not reduce significantly the incidence of early preterm birth[12].

Data collection and outcome measures

Patient characteristics, including details of maternal age, race, height, weight, smoking status, history of cervical surgery and details of obstetric history, were obtained from a questionnaire completed by the patient at their first sonogram, and were entered into a computer database. Categories for the classification of maternal race included Caucasian, African-Caribbean, Asian and Oriental, or in cases where none was appropriate, patients had the option of free text. Data on pregnancy outcome, including gestational age at delivery, mode of onset of labor and method of delivery, were collected from the hospital maternity records or general practitioners. The obstetric records of all patients delivering before 37 weeks (< 259 days) were examined to determine if the preterm delivery was iatrogenic or spontaneous. The latter included those with spontaneous onset of labor and those with PPROM.

Statistical analysis

The objective was to predict firstly all preterm deliveries before 37 weeks and secondly the subgroup of spontaneous deliveries before 32 weeks (224 days). Models for the prediction of preterm delivery were developed using logistic regression analysis with backwards elimination of variables that were not significant ($P < 0.05$). Continuous predictors were modeled by fractional polynomials when there was evidence of non-linear association with the outcome[13]. Separate models were built to predict the probability of all preterm deliveries before 37 weeks and spontaneous deliveries before any specified time point during gestation. The patient-specific probability of spontaneous preterm delivery was derived from the product of the chance of such delivery multiplied by the chance of

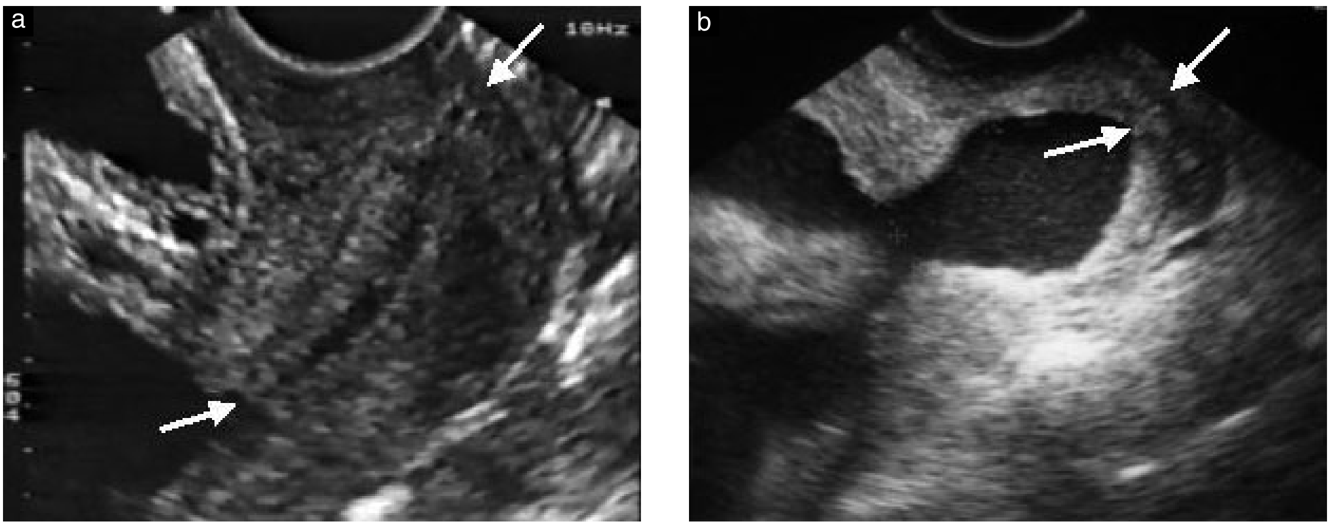

Figure 1 Transvaginal sonographic images of a long (a) and a short (b) cervix.

any preterm delivery. The advantage of this approach is that the model for probability of delivery before 37 weeks was derived from all the data and had considerably higher statistical power compared with models for probability of spontaneous preterm delivery which are based on much smaller sample sizes. Further details on this approach are given in the Appendix.

The detection rate of spontaneous delivery before 32 weeks for a fixed false-positive rate of 10% was used to compare the performance of three sets of models. The first was based on cervical length, the second on maternal demographic characteristics and obstetric history, and the third on the combination of maternal factors and cervical length.

Table 1 Demographic characteristics of the study population of 39 284 singleton pregnancies

Characteristic	*Mean (range) or (n (%))*
Maternal age (years)	29.7 (14.0–50.0)
Gestational age at screening (weeks)	23.1 (22.0–24.9)
Body mass index (kg/m^2)	25.4 (11.0–65.0)
Cigarette smoker	5730 (14.6)
Obstetric history	
Primigravida or pregnancy loss < 16 weeks	20 222 (51.5)
All previous deliveries after 37 weeks	16 556 (42.1)
One or more deliveries at 33–36 weeks†	1415 (3.6)
One or more deliveries at 24–32 weeks†	642 (1.6)
One or more deliveries at 16–23 weeks†	449 (1.1)
Ethnic origin	
Caucasian	27 817 (70.8)
African-Caribbean	7975 (20.3)
Asian	2728 (6.9)
Oriental	414 (1.1)
Mixed	350 (0.9)
Previous knife cone or loop excision	303 (0.8)
Previous minor cervical surgery*	883 (2.2)

*Including laser, cryotherapy and cautery. †Women with more than one preterm delivery were classified according to the one with the earliest gestation.

RESULTS

Cervical length was measured in 40 995 patients, but in 1711 (4.2%) there was no follow-up and these were excluded from further analysis. The maternal demographic characteristics and obstetric history of the study population of 39 284 patients are shown in Table 1. Cervical length was normally distributed, with a mean of 36 mm. The length was 15 mm or less in 368 (0.9%) patients and 129 (35.1%) of these had cervical cerclage.

Delivery before 37 weeks occurred in 5.7% (2244 of 39 284) of cases and in 69.5% (1558 of 2244) of these it was spontaneous. Indications for preterm induction of labor or elective Cesarean section (iatrogenic preterm delivery) included fetal growth restriction, fetal death, antepartum hemorrhage, and maternal medical conditions, such as hypertensive disease, obstetric cholestasis and diabetes mellitus. Spontaneous delivery before 32 weeks occurred in 0.6% ($n = 235$) of cases, of which 45% ($n = 105$) were nulliparous and 29% ($n = 69$) had had one or more previous deliveries at 16–32 weeks.

The probability of delivery before 37 weeks was influenced by maternal age, ethnic group, body mass index, cigarette smoking, previous cervical surgery, and cervical length (Table 2). There was no influence from the presence of cervical cerclage. The magnitude of importance of these factors was expressed as the c-index (area under the receiver–operating characteristics curve). The most important single predictor was cervical length (c-index, 0.612) and the prediction was significantly improved by including obstetric history (c-index, 0.656). Addition to the model of maternal age, ethnicity, body

Table 2 Predictors of preterm delivery; regression coefficients and standard errors (SE) in a logistic regression model to predict the probability of preterm delivery before 37 weeks

Predictor	*Variable/subgroup*	*Regression coefficient*	*SE*	P
Age (linear)	Age in years	0.0096	0.0042	0.02
Ethnicity	Caucasian	0	—	—
	African-Caribbean	0.219	0.055	< 0.001
	Asian + other	0.219	0.077	0.005
Body mass index (BMI)*	1/BMI	200.6	45.2	< 0.001
	(1/BMI) × log(BMI)	−87.5	20.5	< 0.001
Smoking status	Non-smoker	0	—	—
	Smoker	0.371	0.059	< 0.001
Obstetric history	None	0	—	—
	Delivery at 16 to 23 + 6 weeks	0.796	0.143	< 0.001
	Delivery at 24 to 32 + 6 weeks	1.296	0.106	< 0.001
	Delivery at 33 to 36 + 6 weeks	0.919	0.086	< 0.001
	Delivery at term	−0.344	0.053	< 0.001
Previous cervical surgery	None	0	—	—
	Knife cone or loop excision	0.332	0.206	0.04
Cervical length (transformed)	Exp(−0.05 × cervical length)	5.00	0.20	< 0.001
Intercept		−1.031	0.833	—

*Fractional polynomial.

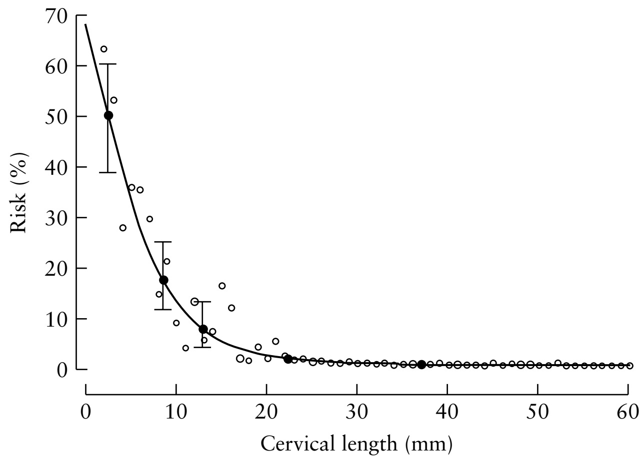

Figure 2 Relationship between cervical length and spontaneous delivery before 32 weeks. Open circles represent the risk for each mm of cervical length and the line represents the fitted curve from a logistic regression model on an exponential transformation of cervical length. Closed circles represent the means; vertical lines represent the 95% CIs.

mass index and history of cervical surgery increased the c-index slightly, from 0.656 to 0.667.

The probability of spontaneous preterm birth was influenced by cervical length (Figure 2), maternal age, and obstetric history. The detection rate of spontaneous delivery before 32 weeks, for a fixed false-positive rate of 5%, screening by maternal factors alone, by cervical length alone and by the combination of maternal factors and cervical length, was 29%, 48% and 57%, respectively, and the respective values for a fixed false-positive rate of 10% were 38%, 55% and 69%. There was good agreement between the model estimates and observed probabilities of preterm delivery, as illustrated by the findings on the prediction of spontaneous delivery before 32 weeks in Table 3.

DISCUSSION

This study, involving 39 284 patients, has established a model that can give an accurate patient-specific risk of preterm delivery. The findings demonstrate that the detection rate of screening for spontaneous early preterm delivery by an integrated approach, combining maternal factors with the measurement of cervical length, is substantially higher compared with screening by each method alone. For a 10% false-positive rate, the detection rate of spontaneous delivery before 32 weeks was 38% for maternal factors, 55% for cervical length and 69% for combined testing.

Table 3 Internal accuracy of model estimates for predicting the probability of spontaneous delivery before 32 weeks

Predicted probability (%)		*Observed probability* (%)*	
Range	*Mean*	*Mean* (n)	*95% CI*
≤ 0.5	0.21	0.19 (63/32 867)	0.15–0.25
0.6–2.0	0.85	1.06 (55/5176)	0.80–1.4
2.1–10.0	4.0	5.0 (50/1002)	3.7–6.5
> 10.0	28.0	28.0 (67/239)	22.0–34.0

*Derived by dividing the number of cases with spontaneous preterm delivery by the total number of patients in each probability range. Results for other gestational ages were similar (data not shown).

The concept of combining factors from the maternal history with the findings of special investigations in the current pregnancy is being applied increasingly in many aspects of obstetric care[14]. For example, in the detection of pregnancies with fetal trisomy 21, the traditional method of screening, based on maternal age and history of previously affected pregnancies, is associated with a detection rate of about 30%, for a false-positive rate of 5%. Combining these maternal characteristics with sonographic findings from examination of the fetus and maternal serum biochemical testing improves the detection rate to 90%, with no increase in false-positive rate[15]. Similarly, in screening for early-onset pre-eclampsia, the combination of sonographic measurement of impedance to flow in the uterine arteries with the traditional approach of eliciting factors in the maternal history, improves the detection rate from about 40% to 80% for the same false-positive rate of 10%[16].

The introduction of the proposed screening test into routine clinical practice will be determined by the extent to which it fulfills the criteria set out by the World Health Organization (WHO) for screening tests[17]. Preterm delivery is certainly an important health problem and screening using our method can identify women at high risk several weeks before the onset of premature labor. Taking a demographic and obstetric history to identify risk factors for pregnancy complications is an integral part of current antenatal care. Sonographic measurement of cervical length is an easy skill to learn for sonographers undertaking routine ultrasound examination in pregnancy, and whilst formal studies of cost-effectiveness are lacking, the infrastructure and equipment needed for screening are readily available in all maternity units. Studies have documented that transvaginal sonography is acceptable to pregnant women and the vast majority do not experience any discomfort[18,19]. Some women will be falsely classified as high risk and consequently may suffer unnecessary anxiety or intervention; however, the high accuracy and specificity of the test ensure that the number affected will be minimal.

An important WHO criterion that remains to be fulfilled is that medical intervention in the high-risk group is shown to be more effective in the prevention of preterm birth compared with the current policy of tocolytic administration in those presenting in preterm labor. Although such administration of tocolytics has been used for several decades, systematic reviews of randomized studies have reported no significant reduction in the number of either total or early preterm deliveries[20]. In contrast, the prophylactic administration of progesterone, given at 20–24 weeks, to women who have previously suffered a preterm birth has been shown to halve the rate of recurrence[21]. However, a strategy in which therapeutic intervention is limited to women with a previous preterm delivery is likely to have a small impact on the overall rate of prematurity, because, as shown in our study, the contribution of such women to the overall rate of spontaneous early preterm birth is less than 30%. A more promising strategy would be to select women for therapeutic intervention by our proposed integrated approach, which, for a screen-positive rate of 10%, could identify about 70% of those destined to deliver very prematurely. However, the extent to which the prophylactic use of progesterone, given to women found at routine screening to have a short cervix, is successful in preventing preterm birth, remains to be determined by ongoing randomized studies.

CONCLUSION

In this study we propose a method for estimating the patient-specific risk of preterm delivery based on maternal history and sonographic measurement of cervical length. For the same false-positive rate, the prediction provided by this integrated approach is substantially higher compared with that of screening by factors in the maternal history or by sonographic measurement of cervical length alone.

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APPENDIX

Further details of statistical modeling

The aim of the analysis was to predict the chance of spontaneous premature delivery (sPTD) at or before any specified time point during gestation and this was accomplished in two stages. The first stage of the analysis was motivated by the following relationship between probabilities:

$$\begin{aligned}&\text{Prob(sPTD at} < X \text{ weeks)}\\&\quad = \text{prob(sPTD at} < X \text{ weeks, given delivery at}\\&\qquad < 37 \text{ weeks)} \times \text{prob(delivery at} < 37 \text{ weeks).}\end{aligned}$$

Expressed in words, the chance of sPTD is the product of the chance of sPTD in preterm deliveries multiplied by the chance of any preterm delivery. Separate models were built to predict the two components on the right-hand side of the equation. The advantage of this approach is that the model for prob(delivery at < 37 weeks) is derived from all the data and has considerable statistical power, whereas models for Prob(sPTD at $< X$ weeks) are based on much smaller sample sizes.

The second stage of the analysis consisted of smoothing the parameters of the model for prob(sPTD at $< X$ weeks, given delivery before 37 weeks) on X. This allowed us to predict the required parameters for any value of X in a parsimonious way. The significant variables for the second stage were selected by backwards stepwise logistic regression. They were 1/age^2, obstetric history (four dummy variables), and transformed cervical length ($e^{-0.05\times \text{cervical length}}$). For values of X in the range 28–36 weeks, the estimated regression coefficients from the logistic model were modeled using a quadratic regression on X, the weeks of gestation. This may be represented by the model:

$$\text{logit } P(X) = \beta_0(X) + \beta_1(X) + \beta_2(X) + \beta_3(X) + \beta_4(X) + \beta_5(X) + \beta_6(X)$$

where $P(X)$ is the probability of sPTD at $< X$ weeks given preterm delivery, and $\beta_0(X)$, $\beta_1(X)$ etc are quadratic functions of X.

The logistic regression equation for the probability Q of preterm delivery for any reason is defined in Table 2. The estimated equations for smoothing the coefficients $\beta_0(X)$, $\beta_1(X)$ etc at different gestational ages X (adjusted for numerical convenience by subtracting 32 weeks) are given in Table 4.

All these analyses were performed using logistic regression. Models were built using backwards elimination of variables not significant at $P < 0.05$. The MFP algorithm[13] was used; in this approach, continuous predictors are modeled by fractional polynomials when there is evidence of non-linear association with the outcome, and non-significant predictors are dropped from the model.

Example

As an example, consider the following case: a woman aged 32 years of African-Caribbean origin, with BMI 30 kg/m^2, obstetric history of previous delivery at 33–36 weeks, cervical length 15 mm, non-smoker, no cervical surgery. Suppose we wish to calculate $P(X)$, the probability of sPTD at $< X$ weeks given preterm delivery, for $X = 28$ weeks. Then from Table 4,

$$\begin{aligned}
\beta_0(28) &= -4.5572 + 0.476371 \times (28 - 32) \\
&\quad + 0.059861 \times (28 - 32)^2 = -5.5049 \\
\beta_1(28) &= 0.5254 - 0.007444 \times (28 - 32) \\
&\quad - 0.014886 \times (28 - 32)^2 = 0.3170 \\
\beta_2(28) &= \cdots = 0.1662 \\
\beta_3(28) &= \cdots = 1.0401 \\
\beta_4(28) &= \cdots = -0.6411 \\
\beta_5(28) &= \cdots = -0.2496 \\
\beta_6(28) &= \cdots = 5.9718,
\end{aligned}$$

from which:

$$\begin{aligned}
\text{logit } P(28) &= -5.5049 + (32/30)^{-2} \times 0.3170 \\
&\quad + 0 \times 0.1662 \\
&\quad + 0 \times 1.0401 + 1 \times (-0.6411) \\
&\quad + 0 \times (-0.2496) + e^{-0.05\times 15} \times 5.9718 \\
&= -3.0465 \\
P(28) &= 0.0454.
\end{aligned}$$

For the probability Q of preterm delivery for any reason, we have from Table 2 of the paper:

$$\begin{aligned}
\text{logit } Q &= -1.031 + 0.0096 \times 32 + 0.219 \\
&\quad + 200.6/30 - (87.5/30) \times \log(30) + 0.919 \\
&\quad + 5.00 \times e^{-0.05\times 15} = -0.4575,
\end{aligned}$$

from which $Q = 0.3876$. Thus, the overall probability of sPTD at < 28 weeks is $0.0454 \times 0.3876 = 0.0176$, or about 2%.

Table 4 Quadratic regressions for each regression coefficient as a function of X, where X is the gestational age in weeks

Variable	*Coefficient*	*Constant*	*Linear term,* X − 32	*Quadratic term,* (X − 32)^2
Intercept	$\beta_0(X)$	−4.5572	0.476371	0.059861
(age/30)$^{-2}$	$\beta_1(X)$	0.5254	−0.007444	−0.014886
Delivery at 16–23 weeks	$\beta_2(X)$	0.5544	−0.026112	−0.030793
Delivery at 24–32 weeks	$\beta_3(X)$	1.5015	−0.044014	−0.039841
Delivery at 33–36 weeks	$\beta_4(X)$	0.1770	0.133579	−0.017738
Delivery at ≥ 37 weeks	$\beta_5(X)$	0.2490	0.02056	−0.026021
$e^{-0.05\times \text{cervical length}}$	$\beta_6(X)$	5.0147	−0.281457	−0.010549