

Role of Mid-Trimester Transvaginal Cervical Ultrasound in Prediction of Preterm Delivery

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Summary

Ultrasonographic cervical length assessment is increasingly being utilized clinically to identify women at risk for spontaneous preterm delivery. In a randomised prospective longitudinal study involving 200 women, we measured cervical length and internal os diameter by transvaginal scan at 20 – 24 weeks and analysed their ability to predict preterm birth. The risk of spontaneous preterm delivery increased steeply as cervical length decreased. At cut off value of ≤ 2.5 cm, the cervical length measurements had sensitivity, specificity, positive predictive value and negative predictive value of 77%, 95%, 56% and 98% respectively. However, internal os diameter lacked sensitivity and specificity. Our data suggests that the duration of pregnancy is directly related to length of the cervix: the shorter the cervix, the greater the chance of preterm delivery.

Key Words: Cervical length, Trans-vaginal ultrasound, Preterm delivery

Introduction

The diagnosis of preterm labour remains a major challenge in contemporary obstetrics. Most women who deliver prematurely have no identifiable risk factors and therefore may not benefit from targeted prenatal care. During the past two decades, there have been research indicating the relationship between sonographically determined cervical length and spontaneous preterm birth (SPTB)^{1,2,3}. With the experience now accrued, it is universally agreed that shorter the cervical length, greater the risk of SPTB. Digital palpation of the uterine cervix is limited by large variations perceived among examiners and has low sensitivity and low positive predictive value⁴. Transvaginal ultrasonography has the potential to provide precise, objective and repeatable measurements of cervical length, by its virtue of higher transducer frequency and better quality image. It is superior to transabdominal ultrasound which has a

lower transducer frequency and where measurements are affected by extent of bladder filling⁵.

We performed transvaginal ultrasound for assessing the cervix at 20-24 weeks of gestation in antenatal women who were undergoing a routine screening by transabdominal scan for fetal anomalies. The cervical findings were analyzed for their significance in predicting SPTBs.

Materials and Methods

This was a prospective randomised study involving 200 low risk singleton pregnancies done in the Department of Obstetrics and Gynecology at Dr T.M.A.Pai Hospital, Udipi between June 2003 to May 2004. This hospital serves as one of the teaching hospitals in maternity for undergraduate and postgraduate students studying at Kasturba Medical College, Manipal.

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Sample size determination:

We wanted to know whether midtrimester cervical measurements significantly differ in those who are likely to deliver preterm compared to normal population. The published mean and standard deviation for midtrimester cervical measurements are 35.2mm and 8.3mm respectively¹. We hypothesized that a mean cervical length of 25mm would be significantly different from the norm. With a desired level of power of 90% and level of significance 0.05, the sample size was calculated using the formula;

$$n = \left[\frac{(z\alpha - z\beta)\sigma}{\mu_1 - \mu_0} \right]^2$$

where $z\alpha = 1.96$ (critical value that divides the central 95% of z distribution from 5% in the tails),
 $z\beta = 1.28$ (critical value that separates the lower 10% of distribution from upper 90%)
 $\sigma = 8.3$ (standard deviation)
 $\mu_1 - \mu_0 = 10.2$ (difference of two means)

Accordingly minimum sample size of women with cervical measurement less than 25mm, was seven and considering preterm prevalence rate of 7%, it was calculated that minimum of 100 subjects would be needed for the study. We decided to recruit 200 patients keeping in mind unexpected dropouts and need for early induction if any complication arose such as PIH, IUGR etc.

Exclusion criteria for patient recruitment were as follows:

1. History of first trimester bleeding
2. Presence of obstetric or medical disorders complicating the pregnancy such as pregnancy induced hypertension, essential hypertension, renal diseases etc which might influence the gestational age at delivery
3. Presence of uterine malformations and fibroids
4. Twins, hydramnios, fetal malformations
5. Cervical length less than 2 cm*

The cervical parameters (total length and internal os diameter) were measured with a 5 Mhz vaginal probe. After the woman emptied her bladder, the length of the cervix was measured with the probe placed in the anterior fornix of the vagina. The appropriate sagittal view of cervix was obtained by simultaneous imaging of external and internal os. The cervical canal was seen as a translucent line connecting these two points. The

distance between the external and internal os was taken as cervical length. The cervical canal width was measured in sagittal plane in the region of internal os. All these measurements were repeated thrice and the averaged readings were taken for statistical analysis. In initial part of the study, the measurements were done by two senior staffs (the author himself and his next senior, for first twenty cases) to study interobserver variation and we observed that measurements were reproducible within 2mm and this was in accordance with standards reported for cervical measurements⁶.

Of these 200 women, 24 were lost for follow-up; pregnancy had to be iatrogenically terminated in eight women before term because of antenatal complications like late onset IUGR, hydramnios, severe PIH, preterm PROM etc. However, this did not effect the minimum required sample size. The remaining 168 women were followed up regularly till delivery. Twenty three (14%) of them had symptoms of preterm labour. Of these thirteen (7.7%) delivered preterm and ten (6%) responded to bed rest and tocolytics and they continued till term.

Data was analysed using computerized statistical package SPSS v 7.5. Chi square test and student t test were used to find the statistical significance of the observations.

* The hospital ethical committee did not approve recruitment of women with cervixes less than 2 cm, fearing high risk of pregnancy wastage and as such it was our policy to perform prophylactic cervical encirclage in these patients

Results

The incidence of spontaneous preterm births was 7.7 % (13/168) in the present study. The mean \pm standard deviation (SD) of cervical lengths measured at mid-trimester was 3.54 ± 0.58 cm in primigravidae (n=72) and 3.50 ± 0.62 in multigravidae (n=96) which was statistically insignificant (p=0.605).

Table I shows mid-trimester cervical parameters in preterm and term groups.

For women who delivered preterm the cervical length measured 2.30 ± 0.23 cm and those who delivered at term, the corresponding value was 3.62 ± 0.50 cm.

T test for independent group was used to analyze the data. The cervical lengths were significantly lower in those who delivered preterm. However, internal os diameter did not differ in preterm and term group.

Receiver Operator Characteristics (ROC) curve analysis was done to choose best cut points (i.e. the values with maximum sensitivity and lowest false positive rate). The cut off values were 2.5cm and 0.5cm for cervical length and internal os diameter respectively. Table II shows sensitivity, specificity, positive and negative predictive values for these parameters in assessing preterm risk. It is evident that internal os diameter is a poor predictor of spontaneous preterm birth.

Table III shows relative risk of preterm labour according to different cervical length measurements by TVS. It will be seen that risk increases steeply as length decreases. The extrapolated risk was calculated to be 9.3, if cervical length were less than 2cm. As current literature cites the same, no women were recruited for study if cervical length was less than 2cm and they were offered prophylactic McDonald's stitch^{7,8}.

Table IV shows percentage of ongoing pregnancies at different gestational periods. It will be seen that when cervical length was less than 2.5cm, only 33% delivered beyond term, where as at more than 2.5cm, 87.5% of women could achieve term delivery. It can also be concluded that two-thirds of women with mid-trimester cervical length less than 2.5cm deliver preterm unless certain precautions are taken.

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 the pregnancy, and the frequency of SPTB^{1,2,3}. Our data suggests that the duration of pregnancy is directly correlated to the length of the cervix; the shorter the cervix, the greater the likelihood of preterm delivery. High specificity (95%) and negative predictive values (98%) makes this method of cervical examination as one of the important tools to screen otherwise low risk pregnant population. Table V shows observations made by other authors in this aspect.

Table I: Cervical parameters in preterm and term patients (in cms)

	Preterm (n=13)		Term (n=155)		statistics	
	Mean	SD*	Mean	SD	T-value	Significance
Cervical length at 20-24 weeks	2.30	0.23	3.62	0.50	17	P<0.05
Internal os diameter at 20-24 weeks	0.60	0.23	0.56	0.11	0.62	NS

*SD = Standard Deviation

Table II: Accuracy of cervical length and internal os diameters in predicting preterm risk

Parameter	Sensitivity	Specificity	Positive predictive Value	Negative predictive Value
Cervical length ≤2.5 cm	77%	95%	56%	98%
Internal os diameter >0.5 cm	54%	37%	7%	91%

Table III: Relative risk of preterm birth according to cervical length

Cervical length (in cms)	Relative risk
2.0-2.2	7.8
2.21-2.4	6.5
2.41-2.6	2.6
2.61-2.8	0.7
>2.8	0.09

Table IV: Percentage of ongoing pregnancies at each gestational age (Survival analysis)

Gestational Age	Cervix ≤ 2.5 cm	Cervix >2.5 cm
32 weeks	94.5%	99.3%
33 weeks	83.3%	98.7%
34 weeks	72.2%	98.0%
35 weeks	55.6%	97.3%
36 weeks	44.4%	96.7%
37 weeks	33.3%	87.3%

($\chi^2=2.44503E-07$, P<0.001)

Table V: Measurement of Cervical length by ultrasound in low risk women and preterm delivery (PTD) rate according to different cutoff values

Author	Year	N	Gestation (weeks)	Cut off (mm)	Definition of PTD	% Prevalence PTD	% Sensitivity	% Specificity	% PPV	% NPV
Anderson et al. ⁹	1990	113	<30	<39	<37	15	76	59	25	93
Tongsong et al. ¹⁰	1995	730	28-30	≤35	<37	12	66	62	20	93
Iams et al. ¹	1996	2915	24	<20	<35	4	23	97	26	97
Taipale et al. ³	1998	3694	18-22	≤25	<37	2.4	6	100	39	99
Heath et al. ²	1998	2702	23	≤15	≤32	1.5	58	99	52	99
Hasson et al. ¹¹	2000	6877	14-24	≤15	≤32	3.6	8	99	47	97
Present study	2004	168	20-24	≤25	<37	7.7	77	95	56	98

Though many studies suggest that dilated internal os (funneling) is predictive of prematurity, we could not establish this relation in the present study^{12,13}. We recommend prophylactic encirclage for all women with mid-trimester cervical length less than 2cm for the reason discussed earlier.

Prevalence of preterm labour in our hospital ranges between 6 to 8%. We are aware that risk scoring strategies have been devised to assess a woman's potential for preterm birth based on her socioeconomic status, clinical history, lifestyle, and past obstetric and current perinatal complications. Unfortunately, there is insufficient evidence from randomized trials of preterm preventive programs to suggest that the use of

prospective risk scoring can reduce the incidence of preterm delivery¹⁴. Other gadgets like detection of fetal fibrinectin in cervical secretions¹⁵ and home uterine activity monitoring systems¹⁶ have been proposed, but they are extremely costly, not available in our set-up and it is not clear whether they can actually affect the rate of preterm delivery. We believe that combining transvaginal ultrasound measurement of cervical length at the time of routine midtrimester scan can be a helpful strategy to identify women at risk and preventive measures such as bed rest, restriction of activity, avoidance of coitus etc may be advised from the very beginning and will also provide enough room for tocolytics, steroid therapy and transfer to tertiary neonatal care units.

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