Cervical Length Measurement by Transvaginal Sonography in Preterm Pregnant Women for Prediction of Preterm Birth

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Objective: To determine the optimal value of cervical length and the presence of funneling in women with preterm labor to predict preterm delivery.

Material and Method: Transvaginal sonography to determine cervical length and presence of funneling in 69 pregnant women with gestational age between 24 - 36 weeks who had preterm labor and were admitted to the labor room of BMA Medical College and Vajira Hospital.

Results: The cervical length of women with preterm labor ranged between 10.7-61.2 mm (mean \pm SD = $30.1 \pm 9.9 \text{ mm}$). The prevalence of preterm delivery was 43.4 %. The cervical length of 30 mm had the highest diagnostic performances in predicting preterm delivery, with the sensitivity 93.3 %, specificity 82.0 %. About 90% of women with funneling presence had preterm delivery.

Conclusion: The cervical length and presence of funneling in preterm labor women are significantly associated with preterm delivery.

Keywords: Preterm labor, Preterm delivery, Cervical length, Funneling, Transvaginal sonography

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Preterm delivery is the leading cause of neonatal mortality and morbidity (1-2), occurring in approximately 10 % of all pregnancy (3). The clinical diagnosis of preterm labor is generally achieved by means of physical examination; presence of regular uterine contraction and cervical changes (4). Although this approach is objective but may be unreliable due to intra- or inter-observer variations. The criteria for preterm labor are also somewhat different from various authors (4,5) Furthermore, simply pervaginal examination, which assesses mainly the external cervical os and cervical effacement, cannot evaluate the change in the area of internal os or presence of funneling (6-12). Thus certain number of women who are diagnosed as preterm labor would proceed to actual preterm delivery. While the rest might be able to carry on their pregnancy to term or near term, with or without the use of tocolytic agent. This latter group of women, after being hospitalized for a period of time, may be discharged undelivered or have to be retained in the hospital for a close surveillance of preterm delivery. Any means to accurately predict preterm delivery is certainly useful. The precise prognostication will reduce an unnecessary hospitalization or tocolytic agent, and many other in-patients hospital expenditures.

In recent years, the length of cervix in normal pregnancy or those with preterm labor has been extensively study $^{(6-12)}$. The measurement is generally obtained by transvaginal sonography. Many studies reported a mean cervical length of normal singleton pregnant women with gestational age 14-30 weeks ranging between 35-40 mm $^{(12-13)}$. In preterm labor, the cervical length has been shown to be shorter than normal $^{(6-7,9)}$ and the cervical shortening might be helpful as one of the most important parameters to predict preterm delivery in women with preterm labor $^{(14)}$. However, the values of cervical length to predict preterm delivery varied, ranging from 15-30 mm from different

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reports ⁽¹³⁻¹⁹⁾. This wide range of cervical length values might not provide the obstetricians, who are encountering the preterm labor condition, any solid body of evidence to direct the lines of management. Besides, these values were obtained from different ethnic population which might not be applicable to our Thai patients.

In about 25-33 % of patients at risk to have preterm delivery, the internal os are readily open. The presence of funneling has been reported to have better or similar specificity, but with lower sensitivity than the cervical length to predict preterm labor ⁽²⁰⁾.

The aim of our study was to determine whether the cervical length or the wedging of membranes at the cervical internal os, so called "funneling", were good predictive factors for preterm delivery in pregnant women with preterm labor.

Material and Method

Study population

We performed this study after an approval from the Ethics Committee of the institution. Subjects were pregnant women with gestational age between 24-36 weeks who were admitted to the labor room in the Department of Obstetrics and Gynecology, Bangkok Metropolitan Administration Medical College and Vajira Hospital from August 2004 to May 2005.

Gestational age is determined from the women's last menstrual period or by the first ultrasonography before 20 weeks of gestation. True preterm labor is defined as the presence of a regular uterine contraction, associated with cervical effacement and dilatation ⁽⁴⁾. Preterm delivery is defined as birth before 37 completed weeks of gestation ^(4,21). The admission-to-delivery interval is the duration from the date of admission to the date of delivery.

Inclusion criteria were women with: singleton pregnancies, gestational age > 24 weeks and < 36 weeks, membrane intact, having given their inform consent before entering into the study. Exclusion criteria included women who had: cervical dilatation > 3 cm, or had maternal or fetal complications such as severe pre-eclampsia or fetal distress necessitating immediate deliveries.

The obstetric care for women with preterm labor including hospitalization and administration of tocolytic agent, either terbutaline(bricanyl®) or magnesium sulfate, and systemic dexamethasone to promote lung maturity if gestational age < 34 weeks. These cares were determined by the chief resident on duty or the attending staff of the labor room, who were not aware of the ultrasound findings, follows the clinical practice guidelines of the institution.

Transvaginal ultrasonographic measurement of cervical length were performed using a 6-MHz vaginal probe (Toshiba-NEMIO 10, Japan). The measurement was performed by one of the authors (S.K.), within 24 hr after admission, after the women had emptied bladder, and was in the lithotomy position. The internal cervical os was identified in the sagittal plane, and the probe was manipulated until the entire cervical canal was well visualized. The longest distance between the internal and external os was measured as the cervical length. Three measurements were obtained in each patient. The minimum value among the three was used ⁽²⁰⁾. We also observed and recorded the presence of funneling which was defined clearly as > 5 mm of gestational sac bulging into the internal cervical os^(17,20).

Statistical analysis

The diagnosis of true preterm labor in our study was made by the chief resident on duty or the attending staff of the labor room. The main outcomes were cervical length, preterm delivery, interval from admission-to-delivery, and presence of funneling. Data were analyzed by parametric and nonparametric statistics using SPSS statistical software version 11.5 (Chicago, IL) and STATA 7.0 (College Station, Tx). Intra-observer reliability was evaluated with intraclass correlation coefficient. Descriptive statistics were used for demographic data and summarized as mean with standard deviation (SD) or median with range. Categorized variables were compared with the chi-squared test or Fisher's exact test as appropriate. Differences between continuous variables were evaluated with unpaired t-test for variables that were normally distributed and the Mann-Whitney U test for variables that were not normally distributed. Two side-p value of 0.05 was considered as statistical significance. Receiveroperator-characteristic curve (ROC) of cervical length was constructed to determine the appropriate cut-off value to predict preterm delivery. The diagnostic performances were reported as sensitivity, specificity, positive predictive value, and negative predictive value with their 95% confidence interval.

Results

During the study period, 69 pregnant women had true preterm labor and met the inclusion criteria. Two women had history of preterm delivery in their previous pregnancy. One woman had previous episode of preterm labor in this current pregnancy. Mean age of the women was 23.2 ± 5.7 year. More than half were nullipara (59.4% or 41/69). Few numbers of women reported history of smoking (8.7% or 6/69). Mean gestational age of women on the date of admission was 33 weeks 6 days ± 2 weeks 1 days (range, 26 weeks 1 day - 36 weeks). The uterine contractions were present, ranging from 4-7 times in 20 minutes (mean \pm SD, 4.6 ± 0.8).

Quantitative ultrasound examination of the cervical length were feasible in all 69 women with preterm labor in this study. The intra-observer reliability of the three measurements was acceptable with intraclass correlation coefficient of 0.985 (95 % CI; 0.978 - 0.990). Mean cervical length of the whole group was 30.1 mm (10.7-61.2 mm). Funneling changes were present in 14.5 % (10/69) of women.

Nearly half or 32/69 women who had preterm labor received tocolytic drugs. This practice lay on the clinical judgement of the physician in charge, who would give tocolytic agent to an individual when her gestational age < 34 weeks and/or estimated fetal weight < 1500 g. Aside from the gestational age, was the other clinical judgement Intravenous terbutaline (bricanyl®) were used as the first line tocolytic agent in all women. Six of them (6/32 or 18.8 %) did not experience any response to maximal dose of bricanyl®, evidenced by regular uterine contraction or progressive cervical dilatation or effacement. These women subsequently received alternative tocolytic agent as magnesium sulphate.

From 69 women, 30 had preterm deliveries (43.4%), 16 women from the tocolytic group and 14 from the non-tocolytic group. Mean gestational age of women with preterm delivery was 35 weeks \pm 2 weeks compared to 38 weeks \pm 4 days of those with term delivery. The mean birth weight of infants with preterm and term deliveries were 2662 + 96 g. and 3154 + 44 g. respectively. No significant difference of clinical characteristics between women who had term and preterm deliveries in terms of maternal age, history of preterm delivery in previous pregnancy, history of preterm labor in current pregnancy, gestational age on admission, parity and smoking was demonstrated, while frequency of uterine contraction had borderline significant definition (Table 1). Among 32 women treated with tocolytic agents, 16 women finally had preterm delivery (Table 2).

The mean cervical length of women who subsequently had preterm deliveries was significantly shorter than that of women who had term-deliveries, 22.7 ± 7.1 mm versus 35.7 ± 7.6 mm (p<0.001). Almost all women with the presence of funneling had preterm deliveries, 90% (9/10). The numbers and percentages of women with the funneling presence in association

Characteristics	Preterm $(n = 30) N (\%)$	Term $(n = 39) N (\%)$	p value
Maternal age (years) (mean \pm SD)	22.4±5.2	23.9 <u>+</u> 6.1	0.312*
Parity	—	—	
Nulliparous	18 (43.9)	23 (56.1)	0.931**
Mulliparous	12 (42.9)	16 (57.1)	
Smoking status	. ,	. ,	
Smoking	27 (42.9)	36 (57.1)	1.000**
Non-smoking	3 (50.0)	3 (50.0)	
History of previous preterm delivery			
Yes	2 (100)	-	0.185***
No	28 (41.8)	39 (57.4)	
History of previous preterm labor			
Yes	1 (100)	-	0.435***
No	29 (42.6)	39 (57.4)	
Gestational age on admission (weeks)	33w4d <u>+</u> 2w3d	34W1d <u>+</u> w6d	0.255*
$(\text{mean} \pm \text{SD})$			
Number of uterine contractions	4.7 <u>+</u> 0.8	4.4 <u>+</u> 0.6	0.052*
in 20 minutes (mean \pm SD)			

Table 1. Clinical characteristics of women who had preterm compared to term deliveries (N=69)

* Unpaired t-test

** Chi square test

*** Fisher's Exact Test

with the timing of delivery are shown in Table 3.

Patients with shorter cervical length had higher rate of preterm delivery. We found from the Receiveroperator-characteristic curve (ROC) (Fig. 1) that the optimal cut-off-point of cervical length to predict preterm delivery was 30 mm. At this cervical length, the sensitivity was 93.3 % (95 % CI; 87.5-99.2 %), specificity was 82.0 % (95 % CI; 73.0-91.1 %), positive predictive value was 80.0 % (95 % CI; 70.6-89.4 %), negative predictive value was 94.1 % (95 % CI; 88.6-99.7 %), and accuracy was 87.0 % (95 % CI; 79.0-94.9 %). In our study, at the cervical length of < 30 mm, the rate of preterm delivery was 80 % compared to 5.9 % in those whose cervical length > 30 mm. The mean interval from admission to delivery of women whose cervical length were < 30 mm was significantly shorter than those with longer cervical length, 1 week 6 days \pm 2 weeks (range, 1 day - 7 weeks 5 days versus 4 weeks 3 days + 1 week 4 days (range 1 week 3 days - 8 weeks 4 days) (p<0.001). When we re-set the value of cervical length at < 19 mm, the specificity and positive predictive value were 100 % (95 % CI; 100–100 %), while the negative predictive value was 61.9 % (95 % CI; 50.5-73.0 %) and the sensitivity was 20.0 % (95% CI; 10.6–29.4) (Table 4).

We also studied the cervical length factored

by the use of tocolytic agents to predict preterm deliveries. From 37 non-tocolytic agent users, the optimal cut-off-points of cervical length to predict preterm labor was 25 mm with the sensitivity of 92.9 % (95 % CI; 84.6–100 %), specificity and positive predictive value of 100 % (95 % CI; 100-100 %), negative predictive value 95.8 % (95 % CI; 89.6–100 %).

We also determined the diagnostic values of funneling to predict preterm delivery, and found that the sensitivity was 30.0 % (95 % CI; 19.2-40.8 %), with specificity of 97.4 % (95 % CI; 93.7-100 %), positive predictive value of 90.0 % (95 % CI; 82.9-97.1 %), negative predictive value of 64.4 % (95 % CI; 53.1-75.7 %) and accuracy 68.1 % (95 % CI; 57.2-79.1 %)

Discussion

Preterm delivery remains the leading cause of neonatal mortality and morbidity ^(1,2). The current methods to identify patients at risk for preterm delivery among those presenting with signs and symptoms of preterm labor rely on obstetrical history, demographic factors, cervical digital examination ^(4,6,9-11). These methods are neither sensitive nor specific ^(5,9-11,22-23). Presently, lack of clinical tools to distinguish between those women at low-risk and those at high-risk of

Use of tocolytic drug	Preterm (n = 30) N (%)	Term (n = 39) N (%)	Total (n = 69)N (%)
None	14 (37.9)	23 (62.2)	37 (100)
Use tocolytic drug	16 (50.0)	16 (50.0)	32 (100)
Bricanyl®	10 (38.5)	16 (61.5)	26 (100)
Bricanyl [®] then magnesium sulphate	6 (100)	-	6 (100)

 Table 2. The use of tocolytic drugs and preterm delivery

p-value 0.309 by Chi Square Test

Table 3.	Association	of preterm	delivery v	with cervical	length and funnelin

Characteristics	Preterm (n = 30) N (%)	Term (n = 39) N (%)	p value	
Cervical length at level of 30 mm				
< 30 mm	28 (80.0)	7 (20.0)	< 0.001*	
\geq 30 mm	2 (5.9)	32 (94.1)		
Cervical length at level of 19 mm				
< 19 mm	6 (100)	-	0.005**	
\geq 19 mm	24 (38.1)	39 (61.9)		
Funneling				
No funneling	21 (35.6)	38 (64.4)	0.002**	
Presence of funneling	9 (90.0)	1 (10.0)		

* Chi Square Test

** Fisher's Exact Test

Table 4. Diagnostic values of cervical length in all women and according to the use of tocolytic agents

Cervical length	Sensitivity (%)	Specificity (%)	PPV* (%)	NPV** (%)	Area under curve
Cervical length in all patients $(n = 69)$					
< 19 mm	20.0	100.0	100.0	61.9	0.62
< 30 mm	93.3	82.0	80.0	94.1	0.88
Cervical length in tocolytics non-user (n=37)					
< 25 mm	92.9	100.0	100.0	95.8	0.96
Cervical length in tocolytics user $(n=32)$					
< 30 mm	93.8	75.0	79.0	92.3	0.84

* positive predictive value

** negative predictive value

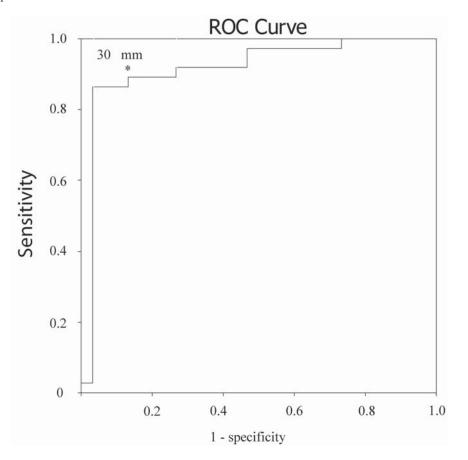


Fig. 1 Reciever-operator-characteristic curve of cervical length to predict preterm delivery

preterm labor in daily medical practice frequency leads to a long hospitalization. This hospital admission is often links to a prescription of tocolytic treatment which has doubtful effectiveness, potential adverse-effects, and is a source of stress, family disorganization, psychological disturbance for women and high cost in hospital. So, many studies attempted to distinguish between those women at low-risk and those at high-risk of preterm labor. Cervicovaginal fetal fibronectin assay has been studied and reported to be effective ^(17,21). However, its application is limited of its expense and unavailability in all areas. Ultrasonography is an idle clinical tool for cervical assessment. Among various techniques of ultrasonography, that required for examiners' experience, such as transabdominal or transperineal or transvaginal approaches, the transvaginal approach appears to be superior than others for prediction of preterm deliveries (8,12,20). Transvaginal ultrasound has many advantages because it provides better resolution and yields more informations than the transperineal, translabial or transabdominal approaches (8,12,20). The procedure of cervical length measurement is easy to perform and yields high reliability and reproducibility. This was also confirmed in our study that only one ultrasonographic examiner was able to measure cervical length after a brief period of training under supervision of the expert ultrasonologist. The measurement were done three times by this examiner, and the intraobserver reliability is acceptable with high intraclass coefficient correlation.

Regarding the optimal value of cervical length in the second and third trimester in normal pregnant women to predict preterm labor, Iams et al reported that normal women with gestational age 24-28 weeks whose had median cervical length of 35 mm would have a greater risk of preterm birth than the women those cervical length exceeds the 75th percentile (approximately 40 mm)⁽¹³⁾. Thongsong et al reported that cervical length in pregnant women gestational 28-30 weeks, the optimal cut-off-point, based on ROC curve, is 35 mm to predict preterm labor with sensitivity 65.9 %, spectificity 62.4 % ⁽²⁴⁾. However, the value in women having preterm labor has not yet been settled and vary from 15-30 mm to predict preterm labor. The definition of preterm labor, gestational ages vary from 35-37 weeks ⁽¹⁴⁻¹⁹⁾.

We conducted our study in women with true preterm labor instead of in women who had routine ultrasonographic screening in second or third trimester as in other studies. Our study focused on the women who actually encountered preterm labor because we thought that our finding of cervical length might support the clinical judgement "to give" or "not to give" tocolytic agent to these women.

In our study, the prevalence of preterm delivery in pregnant women diagnosed with true preterm labor was 43.4 %. This figure was close to 43.5 % in the study of Rizzo et al ⁽¹⁷⁾ whose inclusion criteria were similar to those of our study. Our optimal cut-off value of cervical length to predict preterm labor occurring at gestational age < 37 week was 30 mm which was in the range as those reported from the other studies at 15-30 mm ⁽¹⁴⁻¹⁹⁾. Previous study, Rizzo et al reported the optimal cut-off-point of cervical length to predict preterm delivery was < 20 mm. At this cervical length, the sensitivity was 68.1 %, specificity was 78.7 % ⁽¹⁷⁾. Gomez et

al reported the optimal cut-off-point of cervical length to predict preterm delivery was < 18 mm with sensitivity was 72.7 %, specificity was 75.8 % (14). Vindittelli et al reported the optimal cut-off-point of cervical length to predict preterm delivery was < 30 mm with sensitivity was 83.4 %, specificity was 50.1 % ⁽¹⁸⁾.Those wide range of cervical length from various studies might lie on the inclusion criteria of women entering into each study. Some studies included women with preterm labor who had gestation age ranging from early second trimester at 18 or 20 weeks up to 37 week ^(16,18-19), some study included twins pregnancy. Moreover, different studies had different definition of preterm labor, gestational ages vary from 35-37 weeks⁽¹⁴⁻¹⁹⁾. Gomez et al reported the optimal cut-off-point of cervical length to predict preterm delivery in preterm labor is \leq 18 mm, defined preterm delivery as gestational age at birth < 36 weeks, while the definition in our study was < 37 weeks. Another factor might be the universal use of tocolytic agent in all pregnant women with preterm lobor even in gestational age on admission \leq 36 weeks (15,19) while our study used tocolytic only in gestational age on admission < 34 weeks. These reasons might answer why various studies had various cut-off-points in predicting preterm labor.

Presence of funneling had high specificity of 97.4 % with accuracy at 68.1 % to predict preterm delivery rate of 90.0 %. Our study has higher specificity than previous study that 54.0 % ⁽¹⁴⁾ and 67.2 % ⁽¹⁷⁾. The difference might lie on the definition of funneling presence. Some authors defined the funneling clearly as \geq 5 mm of gestational sac bulging into the internal cervical os while our study had defined as > 5 mmbased on the ROC curve from the study of Rizzo et al. ⁽¹⁷⁾. This exact criteria might give us higher specific rate to predict preterm delivery than other studies. Our study did not evaluate the width of funneling or cervical index [calculated as (funnel length + 1)/cervical length)] because the technique of measurement is difficult, time consuming that we regarded it as impractical to be useful in routine practice, percentage of presence funneling is low.

The interval from admission to delivery of women whose cervical length were < 30 mm was significantly shorter(mean \pm SD, 1 week 6 days ± 2 weeks in preterm delivery, mean \pm SD, 4 weeks 3 days ± 1 week 4 days in term delivery).

To be noted, in 37 women who had not received tocolytic agents, the optimal value of cervical length to predict preterm labor was 25 mm with 100 % specificity and positive predictive value while the sensitivity and negative predictive value were also high at 92.9 % and 95.8 % respectively.

To avoid various complications from tocolytic agents, such as electrolyte imbalance or pulmonary edema, the use of these drugs should be limited to those women at high risk of preterm delivery. The drugs might be withheld as an option to those pregnant women diagnosed preterm labor but are considered as low or moderate risk for preterm delivery. We suggested that pregnant women with cervical length < 30 mm had a higher risk of preterm delivery than whose cervical length \geq 30 mm. Together with the presence of funneling, these factor may help the clinician to discriminate those women with preterm labor at high risk of preterm delivery who would really need the tocolytic agent. Further study to support our findings of cervical length shortening should be conducted in women with preterm labor at lesser risk of preterm delivery eg. those who have cervical length \geq 30 mm to receive tocolytic agent or not.

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การวัดความยาวปากมดลูกโดยคลื่นเสียงความถี่สูงทางช่องคลอดในสตรีที่เจ็บครรภ์คลอด ก่อนกำหนดเพื่อทำนายการคลอดก่อนกำหนด

สุจิรา ขวาแซ้น, ริต้า ไพศาลตันติวงศ์, ไพบูลย์ เจริญชัยนนท์

วัตถุประสงค์: เพื่อศึกษาค่าจุดตัดที่เหมาะสมที่สุดของความยาวปากมดลูกและการโป่งยื่นของถุงน้ำคร่ำลงไปใน ปากมดลูกด้านใน ที่พบจากการตรวจคลื่นเสียงความถี่สูงทางช่องคลอดเพื่อทำนายการคลอดก่อนกำหนด ในสตรีตั้งครรภ์ที่มีภาวะเจ็บครรภ์คลอดก่อนกำหนด

วัสดุและวิธีการ: ทำการวัดความยาวปากมดลูกและประเมินการมีถุงน้ำคร่ำโป่งยื่นลงไปในปากมดลูกด้านใน ด้วยเครื่องตรวจ คลื่นเสียงความถี่สูงทางซ่องคลอด ในสตรีตั้งครรภ์ที่มีอายุครรภ์ 24 - 36 สัปดาห์ มีภาวะเจ็บครรภ์ คลอดก่อนกำหนด และรับไว้เป็นผู้ป่วยใน ที่ห้องคลอด วิทยาลัยแพทยศาสตร์กรุงเทพมหานครและวชิรพยาบาล จำนวน 69 คน

ผลการศึกษา: ค่าเฉลี่ยของความยาวปากมดลูกในสตรีกลุ่มศึกษา เท่ากับ 30.1 <u>+</u> 9.9 มิลลิเมตร (ค่าพิสัย 10.7-61.2 มิลลิเมตร) ความซุกของการคลอดก่อนกำหนดในการศึกษานี้มีค่าเท่ากับร้อยละ 43.4 ความยาวปากมดลูกที่ 30 มิลลิเมตร มีความเหมาะสมที่สุดในการทำนายการคลอดก่อนกำหนด โดยมีความไว ร้อยละ 93.3 ความจำเพาะ ร้อยละ 82 ส่วนการพบการโป่งยื่นของถุงน้ำคร่ำลงไปในปากมดลูกด้านใน มีอัตราการคลอดก่อนกำหนดร้อยละ 90 **สรุป:** ความยาวปากมดลูกและการโป่งยื่นของถุงน้ำคร่ำเข้าไปในปากมดลูกด้านใน มีความสมพันธ์กับการ คลอดก่อนกำหนด