

Patient Acceptability of Universal Transvaginal Cervical Length Screening Program Implementation at HRH Princess Maha Chakri Sirindhorn Medical Center, Thailand

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Background: Preterm birth is a significant problem. It is a leading cause of early neonatal death. Transvaginal ultrasonography for cervical length measurement during second trimester could predict preterm labor. Vaginal progesterone reduced preterm birth incidence in pregnant women with short cervical length.

Objective: To evaluate the acceptance rate of a universal transvaginal cervical length (TCL) screening program implementation.

Materials and Methods: A retrospective cohort study of universal TCL before 24 weeks of gestation at the time of anatomical scan between 18 to 23⁺⁶ weeks from single center from July, 2017 through July, 2018. Pregnant woman with cervical length (CL) ≤ 20 millimeters (mm) were diagnosed cervical shortening and were offered treatment as protocol. Incidence of cervical shortening was assessed. Acceptance rates and factors for declining TCL screening were analyzed. The incidence of preterm birth before 34 weeks and 37 weeks were reported.

Results: Three hundred forty-one Thai pregnant women were enrolled. Of those, 294 (86.2%) accepted TCL screening. Three pregnant woman (1.1%) had a CL ≤ 20 mm. Employed women and women who had income $\geq 10,000$ Baht per month were likely to accept TCL screening (OR, 2.13; 95% CI, 1.14 to 3.98 and OR, 2.85; 95% CI, 1.37 to 5.95, respectively). The incidence of preterm birth was accounted for 8.9 percent in the acceptance and 2.1 percent in denial group.

Conclusion: The universal transvaginal cervical length screening program at HRH Princess Maha Chakri Sirindhorn Medical Center was successfully implemented at 86.2% of acceptance rate.

Keywords: Cervical length; Universal screening; Acceptability; Preterm birth; Prevention

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Preterm birth is a leading cause of death during the first five years of life. In 2015, over a million newborns deaths were related to preterm birth. Its incidence is increasing in countries all over the world. Besides from neonatal death, health effects from preterm birth have an impact on quality of life, both to the newborn and their families. It cast economic burden on families and countries to cope with preterm complications. Preterm birth rate is increasing worldwide. Data from World Health Organization (WHO) shows a preterm birth incidence of 10 percent on average⁽¹⁾. Two thirds

of which is either spontaneous preterm birth or preterm premature rupture of membranes. Thus, efforts are over screening for those who are at risk and prevention of such preterm labor. Preterm labor is associated with several risk factors such as a history of previous preterm labor, low maternal weight, a young maternal age of less than eighteen years-old or maternal age of over forty years -old, premature rupture of membrane, twins pregnancy, smoking or illicit drug usage, maternal medical diseases, maternal infection and maternal congenital genitourinary abnormality⁽²⁾. Anyhow, a history of previous preterm labor is a significant risk factor. Evidence reveals that 15 percent of pregnant women with a history of prior preterm labor will give birth before 35 weeks of gestation⁽³⁾.

Anyhow, over half of preterm birth mothers lack such risk factors. Thus, efforts are towards screening method or protocol in evaluating preterm labor risk among general population, especially in low risk population. Studies have shown that transvaginal ultrasonography for cervical length (TCL) measurement during second trimester of the pregnancy could predict preterm labor. Iams, et al measured cervical length in pregnant women at 24 and 28 weeks of gestation in 2,915 and 2,531 women, respectively⁽⁴⁾. The study shows a statistically significant increase in preterm birth incidence

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with shorter cervical length. Pregnant women with cervical length shorter than 40 mm, 35 mm, 30 mm, 26 mm, 22 mm, 13 mm has higher risk for preterm labor than those with cervical length longer than 40 mm at 1.98, 2.35, 3.79, 6.19, 9.49 and 13.99 odds, respectively. Further studies affirm that short cervical length is a significant risk factor in predicting preterm labor before 37 weeks⁽⁵⁻⁷⁾. Additionally, vaginal progesterone prescription in short cervical length pregnant women helps prevent preterm birth⁽⁸⁻¹⁰⁾. Furthermore, meta-analysis shows that among short cervical length pregnant women diagnosed with transvaginal ultrasonography (cervical length less than or equal to 25 mm), vaginal progesterone reduced preterm birth incidence during 28 to 36 weeks of gestation by 21 percent to 49 percent. It also diminishes respiratory distress syndrome by 53 percent, neonatal morbidity and mortality rate by 41 percent, very low birthweight (birthweight less than 1,500 grams) by 48 percent, and neonatal intensive care admission by 33 percent⁽¹¹⁾. Hence, transvaginal ultrasonography for cervical length measurement as a screening method for preterm birth is used in general pregnant population, in search for short cervical length pregnant women, so that appropriate treatment could be assigned - in hoping for preterm labor reduction. In the meantime, second trimester ultrasonography in asymptomatic pregnant women reveals a short cervical length (shorter or equal to 20 mm) approximately 1.1 percent⁽¹²⁾. It also significantly reduces preterm labor, including those preterm births before 37, 34, and 32 weeks, by 18, 26, and 26 percent respectively⁽¹³⁾. When it comes to cost effectiveness analysis, cervical length measurement by transvaginal ultrasonography in singleton pregnant women, who is at low risk for preterm labor, is cost effective⁽¹⁴⁻¹⁶⁾.

According to a collective data from HRH Princess Maha Chakri Sirindhorn Medical Center (MSMC) during June 2016 to December 2016, preterm birth incidence is approximately six to fourteen percent. Two-thirds of which is a spontaneous preterm birth. The standard protocols include cervical length measurement via vaginal ultrasonography, then, vaginal progesterone is offered for those who are at risk. This has been taken since June 2017. However, such protocol will provide best benefit only if all pregnant women accept the screening method. Nevertheless, vaginal ultrasonography is somewhat invasive. It requires acceptance and cooperation from pregnant women. Thus, we are interested in the acceptability rate of transvaginal ultrasonography for cervical length measurement, factors which effect acceptance or denial decision of such procedure, and the preterm birth rate of those who had transvaginal ultrasonography and those who had not.

Materials and Methods

This is a retrospective cohort study approved by the Strategic Wisdom and Research Institute of Srinakharinwirot University to be a research with exemption from SWUEC (Research number 233/60X). Its data is retrieved from cervical length screening form at MSMC, antenatal care history and labor record from all singleton pregnant women

whose first antenatal visit is prior to 24 weeks of gestation. It is taken during July 2017 to June 2018.

According to the cervical length screening protocol, pregnant women are informed by well-trained doctors and nurses about transvaginal ultrasonography. Patients are given an opportunity to ask for more information before deciding to get included in this protocol. All pregnant women are taken care by standard protocols for both antenatal care and ultrasonography as indicated. For those who agree to be included in the protocol, transvaginal ultrasonography is done along with transabdominal obstetric ultrasonography using the GE Voluson E6 ultrasound machine for a structural scan during gestational age of 18 to 24 weeks without any additional cost. This is performed by obstetricians who have been trained and met standards of The Fetal Medicine Foundation for transvaginal cervical length measurement. Those who has never had preterm labor pain but with a cervical length less than 20 mm, would be offered a 200-milligram (mg) vaginal progesterone once daily.

Exclusion criteria include those with fetal anomaly which requires pregnancy termination prior to 24 weeks of gestation, and those whose first antenatal visit is after 24 weeks. The sample size is calculated by using 85.3 percent ($p=0.85$) of an acceptance rate that was studied by Temming, et al⁽¹⁷⁾ in 2016. A confidence level at 95 percent and an estimation error at 5 percent (type I error = 0.05) are accepted. The calculated sample size is at least 193 persons.

Demographic data includes age, nationality, occupation, income, body mass index before getting pregnant and the gestational age when TCL is taken place. Pregnancy and labor information includes pregnancy and labor complications and gestational age at birth including those who refuse TCL measurement.

The acceptance rate was calculated along with factors that affect acceptance or refusal decisions. The characteristic data were analyzed using descriptive and bivariate statistics. Correlation analysis between acceptance and other factors was done using Pearson Correlation Coefficient. Logistic regression analysis for transvaginal ultrasonography acceptance and other factors was reported in term of the odds ratio (OR) and 95% confidence interval (95% CI). Statistically significant is when the p-value is less than 0.05. Preterm labor before 34 weeks and 37 weeks were reported in each group.

Results

During July 2017 and June 2018, three hundred and forty-one singleton pregnant women had antenatal visit at MSMC. Among these, 294 women, approximately 86.2 percent, agreed to have TCL measurement. Meanwhile, 47 women, approximately 13.8 percent denied such investigation. TCL measurement revealed three cases whose cervical length is shorter than 20 mm – around 1.1 percent. Concerning demographic data of pregnant women in this trial, median age is 28 years with interquartile range (IQR) between 23 to 33 years. Median body mass index (BMI) before getting pregnant is 21.5 kilograms per square meter

(kg/m²) (IQR = 19.2 to 25.2 kg/m²). Precisely 47.2 percent of pregnant women are self-paid for antenatal expenses. Thirty-one percent is unemployed. When it comes to the number of pregnancies, 38.7 percent is the first pregnancy, while 21 cases (6.2 percent) reported history of prior preterm birth. All pregnant women denied smoking or illicit drug usage. Those who agreed to have transvaginal ultrasonography, cervical length measurement was carried out at around 20 weeks of gestation (IQR = 18 to 21 weeks) as shown in Table 1.

Correlation analysis between acceptance and other factors such as age, healthcare coverage, income, occupation, gestation, and body mass index were done. By using Pearson Correlation Coefficient, occupation and income are significantly correlated with transvaginal ultrasonography acceptance as shown in Table 2.

When subgroup analysis was done among factors,

those who were employed, are more likely to give consent for transvaginal ultrasonography than those who were unemployed, or studying (OR, 2.13; 95% CI, 1.14 to 3.98). In addition, those with a monthly income more than 10,000 Baht are more likely to accept transvaginal ultrasonography than those with less income (OR, 2.85; 95% CI, 1.37 to 5.95).

When it comes to labor outcome, those who accepted TCL measurement tends to reach term pregnancy at median gestational age of 38 weeks (IQR 37 to 39 weeks). Approximately 45.4 percent had vaginal delivery. Preterm birth was accounted for 8.9 percent, where 2 percent was giving birth before 34 weeks of gestation and 5.8 percent was giving birth between 34 to 36⁺⁶ weeks of gestation. Among these, 86.4 percent preterm birth is spontaneous.

In addition, pregnant women in denial group also reach term pregnancy. Median gestational age at birth is at 38

Table 1. Demographic data of pregnant women

Demographic data	n=341
Age, median (Interquartile range), years	28 (23 to 33)
Healthcare coverage, number (percent)	
Universal coverage scheme (UC)	28 (8.2)
Social Security Scheme (SSS)	101 (29.6)
Civil Servant Medical Benefit Scheme (CSMBS)	27 (7.9)
Health insurance	2 (0.6)
Self-paid	161 (47.2)
Others, not specified	22 (6.5)
Occupation, number (percent)	
Government and state enterprise officers	24 (7.0)
Permanent employee	100 (29.3)
Employee	67 (19.7)
Student, college student	11 (3.2)
Self-employed	42 (12.3)
Unemployed	61 (17.9)
Others, not specified	36 (10.6)
Monthly income, number (percent)	
No income	14 (4.1)
Less than 5,000 Baht	14 (4.1)
5,000 to 10,000 Baht	44 (12.9)
10,000 to 30,000 Baht	118 (34.6)
30,000 to 50,000 Baht	16 (4.7)
50,000 to 100,000 Baht	3 (0.9)
More than 100,000 Baht	1 (0.3)
No data	131 (38.4)
First gestation, number (percent)	130 (38.1)
History of prior preterm birth, number (percent)	21 (6.2)
BMI before getting pregnant, median (Interquartile range), kilogram per square meter	21.5 (19.2 to 25.2)
Gestational age at transvaginal ultrasonography, median (Interquartile range), weeks	20 (18 to 21)

Table 2 Correlation analysis between acceptance for transvaginal ultrasonography and other factors (Age, healthcare coverage, income, occupation, gestation, body mass index) using Pearson Correlation Coefficient

Variables	Acceptance
Age	
Pearson correlation	-0.005
Sig. (2-tailed)	0.922
n	341
Healthcare coverage	
Pearson correlation	0.014
Sig. (2-tailed)	0.792
n	341
Occupation	
Pearson correlation	0.128*
Sig. (2-tailed)	0.018
n	341
Monthly income	
Pearson correlation	0.255**
Sig. (2-tailed)	<0.001
n	341
BMI before getting pregnant	
Pearson correlation	0.045
Sig. (2-tailed)	0.409
n	341
Gestation	
Pearson correlation	0.058
Sig. (2-tailed)	0.348
n	341
* Correlation is significant at the 0.05 level (2-tailed)	
** Correlation is significant at the 0.01 level (2-tailed)	

weeks (IQR=37 to 39 weeks). Preterm birth is encountered approximately 2.1 percent in this group – all of which is spontaneous in nature.

Discussion

Cervical length measurement as a screening method for preterm labor at MSMC is well accepted. Over 86.2 percent agree to have transvaginal ultrasonography done for cervical length measurement. The acceptance is higher than a study in the USA by Orzechowski et al⁽¹²⁾ – in 2014 – which reveals only 72.3 percent of the acceptance rate. However, the acceptance rate in this present is close approximate to a study by Temming et al⁽¹⁷⁾ which shows an acceptance rate at 85.3 percent even when the social circumstances are quite different. Due to the retrospective essence of this study, specific reasoning of test acceptance and denial are lacking. Chawanpiboom et al⁽¹⁸⁾ reported that maternal

concern about the possibility of abortion is the main reason for refusing TCL screening. The other reasons are concern about pain during the examination and the cost of the TCL screening. Meanwhile, the main reason for requesting the test is concerned with preterm birth. Most pregnant women would request intervention if she knows that it can help to prevent preterm birth. One of several barriers to undergoing TCL screening is lacking the information mentioned above from their physicians. For our protocol, pregnant women have been counseled on the benefits and risks of TCL measurement before a decision. The participants know how TCL is truly measured. The maternal concern issues on its effects – especially the possibility of the procedure-related abortion- have also been discussed. As well, our protocol has set the TCL screening in addition to a routine structural scan without any additional fees. Without concern about the expenses, largely pregnant women indicated they would decide to undergo intervention by themselves⁽¹⁸⁾. Adequate information from attending physicians before a decision-making process and cost-free intervention protocol may have a positive influence on our main outcome.

When it comes to factors which affect acceptance decisions, it appears that different circumstances between Thailand and Western countries play an important role in decision-making. A previous study found that factors which affect such decisions are ethnicity (African American and others), obesity, multiparous, maternal age younger than 35 years old, and maternal smoking⁽¹⁷⁾. For those with the factors mentioned above, transvaginal ultrasonography is likely denied. Meanwhile, the results at MSMC shows that factors which influence such decision are occupation and monthly income. Regarding monthly income, those with an income higher than 10,000 Baht are more likely to accept transvaginal ultrasonography for cervical length measurement. Concerning Thai pregnant women's perspective, a previous study shows that a lack of knowledge of the benefits of TCL and unclear Ministry of Health policies are the main barriers to the acceptance decision. As well as, the person who would influence a pregnant woman's decision is her husband⁽¹⁸⁾. With such knowledge, protocols could be adjusted to improve the acceptance rate for TCL measurement.

According to the prevalence of short cervical length, as previously described as a cervix shorter than 20 mm, is observed in 1.1 percent. There is no different to previous studies by Orzechowski et al⁽¹²⁾ and Temming et al⁽¹⁷⁾ which report short cervical length incidence of 1.1 percent and 1.2 percent respectively.

Regards preterm birth rate, both groups tend to reach term pregnancy at a median gestational age of 38 weeks. Preterm birth – all of which is spontaneous - is accounted for 8.9 and 2.1 percent in the acceptance and denial groups respectively. Nonetheless, the sample size included in this study might be inadequate to provide pregnancy outcomes analysis of TCL in the low-risk population at MSMC. Further study is, thus, suggested.

Table 3. Logistic regression analysis for transvaginal ultrasonography acceptance and other factors such as age, healthcare coverage, monthly income, occupation, and body mass index

Variables	Acceptance 294 (86.2%)	Denial 47 (13.8%)	odds ratio (95% confidence interval)
Age			
<35 years	247 (86.7%)	38 (13.3%)	Reference
≥35 years	47 (83.9%)	9 (16.1%)	1.24 (0.56 to 2.74)
Healthcare coverage			
Self-paid	135 (83.9%)	26 (16.1%)	Reference
At least one coverage scheme	159 (88.3%)	21 (11.7%)	0.69 (0.37 to 1.27)
Occupation			
Employed	208 (89.3%)	25 (10.7%)	Reference
Unemployed, student, college student	86 (79.6%)	22 (20.4%)	2.13 (1.14 to 3.98)
Monthly income			
≥10,000 Baht	128 (92.8%)	10 (7.2%)	Reference
<10,000 Baht	166 (81.8%)	37 (18.2%)	2.85 (1.37 to 5.95)
BMI before getting pregnant			
Normal (18.0 to 24.9)	175 (87.1%)	26 (12.9%)	Reference
Others	119 (85.0%)	21 (15.0%)	1.19 (0.64 to 2.21)

Conclusion

The universal transvaginal cervical length screening program at HRH Princess Maha Chakri Sirindhorn Medical Center was successfully implemented among low risk population at 86.2% of acceptance rate.

What is already known on this topic?

Transvaginal ultrasonography for cervical length measurement during second trimester could predict preterm birth. The preterm birth rate significantly increases in a pregnant woman with short cervical length. Vaginal progesterone prescription in short cervical length pregnant women helps prevent preterm birth.

What is study adds?

Cervical length measurement as a screening method for preterm labor at MSMC is well accepted at 86.2 percent. Cervical length shorter than 20 mm is found only 1.1 percent. The factors that correlated with acceptance of TCL are occupation, and monthly income.

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Potential conflicts of interest

The authors declare no conflict of interest.

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