



DIAGNOSTIC PERFORMANCE OF TRANSPERINEAL SONOGRAPHIC CERVICAL LENGTH MEASUREMENT FOR DIAGNOSIS OF PRETERM LABOR: A DIAGNOSTIC TEST STUDY

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ABSTRACT

OBJECTIVE: To evaluate the diagnostic performance of transperineal sonographic cervical length measurement (TPS-CL) compare with transvaginal measurement (TVS-CL).

MATERIALS AND METHODS: The participants were 107 suspected preterm labor women whom cervical dilatation was < 3 cm. TPS-CL and TVS-CL were measured. The short cervical length (CL) was diagnosed when CL < 3 cm. The diagnostic performance of TPS-CL was evaluated.

RESULTS: Short CL (CL < 3cm) was found in 52.3% by TVS-CL and 51.4% by TPS-CL. TPS-CL had high correlation with TVS-CL ($r = 0.77$). The sensitivity, specificity, positive and negative predictive value, and accuracy of TPS-CL were 78.6% (95%CI 65.6-88.4), 78.4% (95%CI 64.7-88.7), 80.0% (95%CI 67.0- 89.6), 76.9% (95%CI 63.2-87.5), 78.5 % (95%CI 69.5-85.9), respectively.

CONCLUSION: TPS-CL had high correlation with TVS-CL. In case of TVS-CL is unavailable, TPS-CL can be used for preterm labor diagnosis.

KEYWORDS : Cervical Length, Suspected Preterm Labor, Transperineal Ultrasound, Transvaginal Ultrasound

INTRODUCTION

Globally, preterm birth is significant maternal and neonatal problems that is a leading cause of neonatal death and disability. The incidence of premature birth is estimated about 15 million annually and has increased in all countries (Sharvit et al., 2017). This condition causes many problems to the survival neonates such as vision, respiratory, neurological and developmental problems (Nirunsittirat et al., 2016; Society for Maternal-Fetal Medicine . Electronic address, McIntosh, Feltovich, Berghella, & Manuck, 2016). The diagnosis and management of this condition are still problematic such as the diagnostic criteria, tocolytics use.

Cervical length (CL) is an indicator to diagnose preterm labor in developed countries (Sotiriadis, Papatheodorou, Kavvadias, & Makrydimas, 2010; Tsoi, Akmal, Rane, Otigbah, & Nicolaides, 2003; Tsoi, Fuchs, Rane, Geerts, & Nicolaides, 2005). The American College of Obstetricians and Gynecologists (ACOG) recommended the use of CL for the diagnosis and treatment of preterm labor. The short CL ≤ 3 cm is an indication for further investigation by perform fetal fibronectin and CL < 2cm is an indication for preterm labor treatment (American College of & Gynecologists' Committee on Practice, 2016). However, many centers in low-resource countries cannot provide CL measurement from many reasons such as lack of trained personnel or lack of equipment. In many hospitals, ultrasound machine is available without vaginal probe. Therefore, this study was conducted to determine the diagnostic performance in using abdominal convex ultrasonic probe for TPS-CL compare with TVS-CL, in case of TVS-CL is not available.

MATERIAL AND METHOD

This diagnostic test study was conducted in a tertiary care regional hospital from December 2018 through May 2019. This study protocol was approved by the Ethical Research

Committee of Udonthani Hospital (No.40/2561). The inclusion criteria were: 1) women with singleton live preterm (GA 25-36 weeks) pregnancies, 2) who had painful and regular uterine contraction of at least one time in every 10 minutes persisting for more than 30 minutes (Chawanpaiboon, Pimol, & Sirisomboon, 2011) 3). The exclusion criteria were cervix dilated more than 3 cm, placenta previa, abnormal vaginal bleeding, preterm premature rupture of membranes, dead fetus in utero, fetal anomaly, uncertain gestational age, history of previous cervical or uterine surgery, the clear image of TPS-CL or TVS-CL cannot be obtained or unwilling to participate in the study.

The eligible participants were counseled and invited to participate in this study. A written informed consent was obtained after the explanation of study methods to the participants. Then, all participants were examined by digital vaginal examination, by experienced nurses who have worked in the labor room for at least 5 years, to rule out advance labor (cervical dilatation ≥ 3 cm). First, CL was measured transperineally, then transvaginally by trained obstetricians or residents, using a GE Voluson P6 ultrasound machine with a 3.5-5 MHz convex probe and 7-10 MHz transvaginal probe. The patient was examined with an empty bladder. The CL was obtained by measuring from external to internal os in a longitudinal axis. Three measurements were taken and the shortest values was taken as the final CL in both measurements.

Transperineal measurement was done by apply a convex ultrasonic probe, which was covered by a sterile plastic bag, at anterior perineum and between labia majora (Raungron gmorakot et al., 2004). The ultrasonic probe was moved until clear image found. Cut off value for short CL diagnosis was ≤ 30 mm (American College of & Gynecologists' Committee on Practice, 2016; Ness, Visintine, Ricci, & Berghella, 2007). All

staff and residents, who participated in this study, were trained and assessed for standardization of CL measurement in a 1-day course. Then, the participants were managed according to the hospital protocol and the Royal Thai College of Obstetricians and Gynecologists (RTCOG) guideline (The Royal Thai College of the Obstetricians and Gynaecologists, 2015).

STATISTICAL ANALYSIS

The sample size was calculated using the formula for diagnostic test study. The estimated sensitivity of TPS-CL was 80 % with 0.08 acceptable error and 5% significance were used. The calculated sample size was 97, then a 10% dropout rate was added. The total sample size was 107 (Khiewyoo, 2014; Sanoonrat, Srisantiroj, & Yanaranop, 2017).

This study protocol was approved by the Research Ethics Committee of Udonthani Hospital (number No.40/2561). The written informed consent was obtained from all participants before enrolling to this study.

The participants' characteristics are presented in term of frequency and percentage for categorical data. Mean, standard deviation and range were used for continuous data. TVS-CL < 2 cm was used as the gold standard diagnosis of short CL. Diagnostic performance of TPS-CL was assessed including sensitivity, specificity, positive and negative predictive value and accuracy. Statistical analysis was performed using Stata program version 13. P-value <0.05 was considered statistically significant.

RESULTS

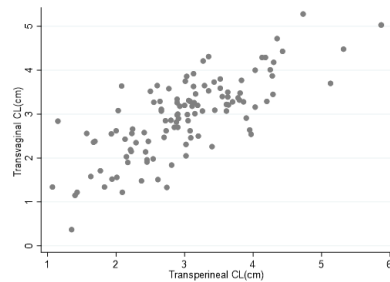
There were 116 participants with suspected threatened preterm labor were examined by TPS-CL and TVS-CL and 9 participants were excluded due to unable to obtain the clear image of TPS-CL. The clear image of TPS-CL and TVS-CL can be measured in 107 (92.2%) and 100.0% of participants, respectively. Their mean age was 25.6 (±SD 7.0) years and 47 (43.9%) women were primigravida. Mean gestational age was 33.2 (±SD 2.5) weeks. Baseline characteristics are presented in Table 1.

Table 1. Basic characteristic of study group.

Characteristics	Total (N=107)	(%)
Maternal age (years), n(%)	25.6+7.0	24.3%
Mean ±SD	26	64.5%
< 20	69	11.2%
20 – 34	12	
≥ 35		
Gestational age at admission (weeks), n(%)	33.2 + 2.5	43.0%
Mean ±SD	46	57.0%
< 34 weeks	61	
>34 weeks		
Primigravida, n (%)	47	43.9%
Body mass index (kg/m2)	25.4 (+4.1)	3.7%
Mean(±SD)	4	25.2%
< 18.5	27	19.6%
18.5 – 22.9	21	37.4%
23 – 24.9	40	14.0%
25 – 29.9	15	
>30		
Previous preterm birth, n(%)	8	7.5%
Previous term birth, n(%)	42	39.3%
Initial dilatation of cervix (cm)	63	58.9%
Closed	44	41.1%
Dilate ≥ 1 cm		

Bishop score	3.8 (+2.5)	74.8%
Mean (±SD)	80	25.2%
< 6	27	
≥ 6		

The mean TVS-CL was 3.0 cm (±SD 0.92) and mean TPS-CL was 3.0 cm (+SD 0.94). The Figure 1 show the correlation of TPS-CL and TVS-CL. Significant correlation of TPS-CL and TVS-CL was demonstrated (r = 0.77)



Abbreviation: CL ; cervical length

Figure 1: The correlation of transperineal and transvaginal cervical length measurement

The prevalence of short CL (TVS-CL < 3 cm) was 52.3% (95%CI: 42.5-62.1), range of CL was 0.4-5.3 cm. TPS-CL found short CL in 51.4%. The sensitivity, specificity, positive and negative predictive value and accuracy were 78.6% (95%CI 65.6-88.4), 78.4% (95%CI 64.7-88.7), 80.0% (95%CI 67.0- 89.6), 76.9% (95%CI 63.2-87.5), 3.6 (95%CI 2.1-6.3), 0.27 (95%CI 0.16-0.46), 78.5 % (95%CI 69.5-85.9), respectively. (Table 2).

Table 2.: Diagnostic performance of transperineal sonographic measurement for short cervical length (< 3 cm) compare with standard transvaginal measurement.

TVS-CL TPS-CL	Short CL (< 3cm)	CL > 3 cm
Short CL(< 3cm)	44	11
CL > 3 cm	12	40
Diagnostic performance	Percent	95%CI
Prevalence of short CL	52.3	42.5-62.1
Sensitivity	78.6	65.6-88.4
Specificity	78.4	64.7-88.7
Positive predictive value	80.0	67.0- 89.6
Negative predictive value	76.9	63.2-87.5
Positive likelihood ratio	3.6	2.1-6.3
Negative likelihood ratio	0.27	0.16-0.46
Accuracy	78.5	69.5-85.9

Abbreviation: TVS: transvaginal sonography, TPS: transperineal sonography, CL: cervical length, CI: confidence interval

DISCUSSION

Preterm labor is sometime difficult to differentiate from false labor pain or Braxton-hicks contraction, especially in case of minimal cervical dilatation. CL measurement has been recommended by many obstetric guidelines as a part of preterm labor diagnosis and management in developed countries (American College of & Gynecologists' Committee on Practice, 2016; Lockwood C, 2018; National Institute for Health and Care Excellence, 2018). However, in low and middle-income countries, an ultrasound machine with transvaginal probe and trained personnel are still unavailable in many hospitals. In some hospitals, ultrasound with convex probe is available but transvaginal probe is not. Data from this study demonstrated that CL measurement by TPS-CL had a high correlation with TVS-CL and can be used with high sensitivity and specificity when compared with TVS-CL. Therefore, TPS-CL can be used in the situation that

vaginal ultrasonic probe is unavailable for evaluating the cervical condition of suspected preterm labor patients.

Data from this study is compatible with Raungrongmorakot K, et al study (Raungrongmorakot et al., 2004) which found significant correlation between TPS-CL and TVS-CL ($r = 0.73$), Meijer-Hoogveen M, et al study which found strong correlation with $r = 0.85$, Larscheid P, et al study which found high correlation with $\text{Lin}'\rho = 0.922$. However, this is the first study that reports the diagnostic performance of TPS-CL in the diagnosis of short CL for preterm labor management.

In this study, the definition of short CL was ≤ 3 cm in accordance with ACOG guideline and Ness A, et al study (American College of & Gynecologists' Committee on Practice, 2016; Ness et al., 2007). However, different cut-off lengths of CL were used in other recommendations. National Collaborating Centre for Women's and Children's Health (NICE) guideline (Sarri, Davies, Gholitabar, Norman, & Guideline Development, 2015), Tsoi E, et al (Tsoi et al., 2003) and Alfirevic Z, et al (Alfirevic, Allen-Coward, Molina, Vinuesa, & Nicolaides, 2007) study recommends that if CL is > 1.5 cm, the diagnosis of preterm birth is unlikely. Palacio M, et al study (Palacio et al., 2007) reported cut-off length of 25 mm in gestational age less than 32 weeks and 15 mm in 32 weeks or later. Therefore, the diagnostic performance of TPS-CL will be different if others cut-off lengths are used.

There are some limitations with this study; first the standardization of observer was done by a workshop, however the inter and intra-observer reliability of TPS-CL and TVS-CL were not measured, therefore reliability problem can be occurred. Second, the TPS-CL and TVS-CL were done by same operator which can have a measurement bias. The further study should be done to compare the outcome of preterm management between using TPS-CL and TVS-CL in the suspected preterm labor cases.

CONCLUSION:

TPS-CL had high correlation with TVS-CL and high sensitivity and specificity when compared with TVS-CL. In case of TVS-CL is unavailable, TPS-CL can be used for diagnosis of short CL in preterm labor diagnosis.

ACKNOWLEDGEMENTS

We gratefully acknowledge Dr.Narong Thadadech, Director of Udonthani Hospital for permission and grant support. Thanks for Udonthani Hospital staff and all participants who participated in this trial.

DISCLOSURE STATEMENT

No author has any potential conflict of interest.

FUNDING

This study was supported by Udonthani Hospital. The study protocol was approved by the Udonthani Research Ethics Committee: No.40/2561

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