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A Comparison of Cervical Ruler and Transvaginal Ultrasound for Cervical Length Measurement during Pregnancy

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ABSTRACT

Objectives: To identify and compare the correlation between cervical length measured by transvaginal ultrasound and cervical ruler.

Materials and Methods: A cross-sectional study was conducted in 200 singleton pregnant women who received antenatal care at Chonburi Hospital during September 1, 2018 to June 30, 2019. Transvaginal ultrasound and cervical ruler for cervical measurement were performed during 16 to 24 weeks of gestation. Maternal age, parity, pre-pregnancy weight, pre-pregnancy body mass index, history of abortion, history of preterm birth, smoking behavior, alcohol drinking and drug used during pregnancy were collected. Pearson's correlation coefficient and paired t-test were used to evaluate the correlation and difference between cervical lengths measured by transvaginal ultrasound and cervical ruler.

Results: A total of 200 singleton pregnant women participated in the study. The average cervical length measured by transvaginal ultrasound and cervical ruler were 3.92 ± 0.71 cm. and 3.4 ± 0.73 cm., respectively. The mean difference of both methods was 0.52 cm. (95% confidence interval 0.46 to 0.57, p value < 0.001). The correlation coefficient of cervical length measured by transvaginal ultrasound and cervical ruler was 0.843.

Conclusion: The cervical length measured by cervical ruler was correlated with the cervical length measured by transvaginal ultrasound. However, the average cervical length measured by cervical ruler was statistically significantly lower than those measured by transvaginal ultrasound.

Keywords: cervical length, cervical ruler, transvaginal ultrasound, spontaneous preterm labor.

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การเปรียบเทียบการวัดความยาวปากมดลูกในสตรีตั้งครรภ์ด้วยอุปกรณ์วัดความยาวปากมดลูกเทียบการใช้อัลตราซาวด์ทางช่องคลอด

วริญญา เจียระไนกาญจน์, ธีระ ศิวะดุล

บทคัดย่อ

วัตถุประสงค์: *เพื่อเปรียบเทียบและหาความสัมพันธ์ของการวัดความยาวปากมดลูกในสตรีตั้งครรภ์ด้วยอุปกรณ์วัดความยาวปากมดลูกเปรียบเทียบกับการใช้อัลตราซาวด์ทางช่องคลอด*

วัสดุและวิธีการ: *การศึกษานี้เป็นวิจัยเชิงพรรณนา ณ จุดเวลาใดเวลาหนึ่ง ศึกษาในมารดาตั้งครรภ์เดี่ยวที่ฝากครรภ์ที่โรงพยาบาลชลบุรีในช่วงวันที่ 1 กันยายน 2561 ถึง 30 มิถุนายน 2562 จำนวน 200 ราย โดยใช้อุปกรณ์วัดความยาวปากมดลูกและเครื่องตรวจอัลตราซาวด์ทางช่องคลอด วัดความยาวปากมดลูกในช่วงอายุครรภ์ 16-24 สัปดาห์ โดยมีการเก็บรวบรวมข้อมูลอื่นๆ ได้แก่ อายุมารดา, จำนวนการตั้งครรภ์, ประวัติการแท้ง และการคลอดก่อนกำหนดในครรภ์ก่อน, การสูบบุหรี่ การดื่มแอลกอฮอล์และการใช้สารเสพติดในขณะตั้งครรภ์ และหาความสัมพันธ์ของความยาวปากมดลูกที่ได้จากการใช้อุปกรณ์วัดความยาวปากมดลูกเปรียบเทียบกับการใช้เครื่องตรวจอัลตราซาวด์ทางช่องคลอด*

ผลการศึกษา: *มีมารดาที่ตั้งครรภ์เดี่ยวจำนวน 200 คน เข้าร่วมการศึกษาวิจัยในครั้งนี้ โดยค่าเฉลี่ยของความยาวปากมดลูกที่ได้จากการใช้เครื่องตรวจอัลตราซาวด์ทางช่องคลอดและการใช้อุปกรณ์วัดความยาวปากมดลูก คือ 3.92 ± 0.71 เซนติเมตร และ 3.4 ± 0.73 เซนติเมตร ตามลำดับ โดยมีค่าเฉลี่ยของความแตกต่างระหว่างการวัดทั้งสองวิธีที่ 0.52 เซนติเมตร และมีค่า 95% confidence interval อยู่ที่ 0.46 ถึง 0.57 และ p value < 0.001 และจากการคำนวณโดยวิธี Pearson's correlation พบว่า ค่าความยาวปากมดลูกที่ได้จากการวัดโดยใช้อุปกรณ์วัดความยาวปากมดลูกมีความสัมพันธ์กับค่าความยาวปากมดลูกที่ได้จากการวัดโดยใช้เครื่องตรวจอัลตราซาวด์ทางช่องคลอดอย่างมีนัยสำคัญทางสถิติ โดยค่าสัมประสิทธิ์สหสัมพันธ์ มีค่า 0.843*

สรุป: *ค่าความยาวปากมดลูกที่ได้จากการวัดโดยใช้อุปกรณ์วัดความยาวปากมดลูกมีความสัมพันธ์กับค่าความยาวปากมดลูกที่ได้จากการวัดโดยใช้เครื่องตรวจอัลตราซาวด์ทางช่องคลอด อย่างไรก็ตามค่าเฉลี่ยของการวัดความยาวปากมดลูกโดยใช้อุปกรณ์วัดความยาวปากมดลูกมีค่าน้อยกว่าค่าเฉลี่ยของค่าความยาวปากมดลูกที่ได้จากการวัดโดยใช้เครื่องตรวจอัลตราซาวด์ทางช่องคลอด*

คำสำคัญ: *การวัดความยาวปากมดลูก, อุปกรณ์วัดความยาวปากมดลูก, อัลตราซาวด์ทางช่องคลอด, การคลอดก่อนกำหนด*

Introduction

Preterm birth is defined as a birth delivered at less than 37 weeks of gestation[1]. In 2013, it was reported that over 1 million children died at age under 5 years old due to preterm birth complications[1]. According to World Health Organization (WHO), the rate of preterm birth has increased annually[1] and regarding the report from Siriraj Hospital in Thailand, the preterm delivery rate was increased from 9.44% to 13.7% from 2004 to 2010[2]. In 2018, the incidence rate of preterm birth at the Chonburi Hospital was 16.8%. There are several preventive treatments for pregnant women who are at risk of spontaneous preterm birth, including progesterone supplements[3,4], cervical cerclage[5], and cervical pessary. However, it is necessary to evaluate the risk factors for preterm birth using a safe and accurate procedure[6]. Cervical length measured by transvaginal ultrasound is one of the noninvasive and harmless methods for preterm birth evaluation and prediction[6]; however, some hospitals have limited equipments, specialists, and financial resources.

According to the non-sonographic cervical method in Ross and Beall's study[7], Cervilenz (Fig. 1), a low-cost cervical measurement device, was reported as the potential primary screening test to evaluate cervical length. Lavin showed that Cervilenz measurement which was greater than 20 mm appeared to have high negative predictive value (NPV) for preterm birth prior to 34 weeks[8]. In addition, Baxter mentioned that the use of 30-mm threshold as a successful screening in women with low risk of short transvaginal ultrasound cervical length provided a 98-100% NPV, leading to the reduction of almost 50% of women to receive transvaginal ultrasound[9].

Cervical ruler (Fig. 2) is a simple cervical measurement device initially invented in Thailand developing from the Cervilenz model for general physicians and nurses use to evaluate cervical length as a primary screening test without concerning of the lack of equipments or specialists[10]. A handle of cervical ruler is made from acrylic and silicone which can be used multiple times to reduce cost.

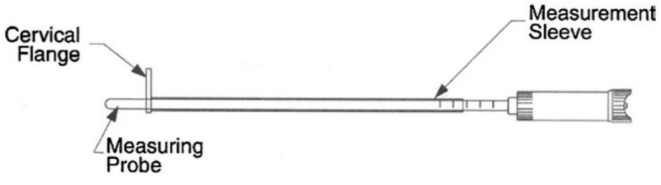

Fig. 1. A schematic drawing of Cervilenz device[7].

Fig. 2. Cervical ruler device invented in Thailand.

The main purpose of this study was to identify and compare the correlation between cervical length measurement of transvaginal ultrasound and cervical ruler.

Materials and Methods

After the Institutional Review Board of Chonburi Hospital approval (Reference Number 39/2561, issued on August 29, 2018), a cross-sectional study was conducted. The data was collected from singleton pregnant women who received antenatal care at Chonburi Hospital between September 1, 2018 and June 30, 2019. All participants obtained general information about the study and provided informed consents.

The exclusion criteria were the pregnant women who had multifetal pregnancy, cervical cerclage, human immunodeficiency virus (HIV) infection, and clinical vaginal bleeding. The demographic data collected in this study included maternal age, parity, pre-pregnancy weight, pre-pregnancy body mass index, gestational age at time of measurement, alcohol consumption, drug use, and smoking behavior during pregnancy. Cervical ruler and transvaginal ultrasound were used to measure cervical length at the gestation age between 16 and 24 weeks.

Cervical length was measured by using two techniques: transvaginal ultrasound as standard technique and cervical ruler. The participants were required to void to empty their bladders before placing into the lithotomy position. Transvaginal ultrasound method[11] was performed by the same performer (maternal-fetal-medicine specialist at Chonburi hospital) in all cases. Transvaginal ultrasound probe was gently placed to identify a longitudinal view of cervix. The cervix was magnified to occupy approximately 50-75% of the image. The caliper was placed between the internal and external os to measure the cervical length. The cervical length was measured 3 times by using transvaginal ultrasound method and used the shortest cervical length as the cut-off value for the standard method in regard to the International Society of Ultrasound in Obstetrics & Gynecology guideline[11].

For cervical ruler method, the device was performed in lithotomy position under the direct visualization after a speculum was inserted. The measuring probe was advanced along the outer aspect of the body of cervix into the lateral fornix until the performer perceived gentle resistance of the vaginal apex. A plastic flange slid against the cervix (Fig. 3) and the cervical ruler was locked in place and the measurement was read on the handle at the end of a device. This method was performed by the same performer (a second-year resident in Department of obstetrics and gynecology) and cervical length was measured 3 times in every case, using the average value as the cut-off value to reduce measurement error. All performers were blinded to the results of both methods.

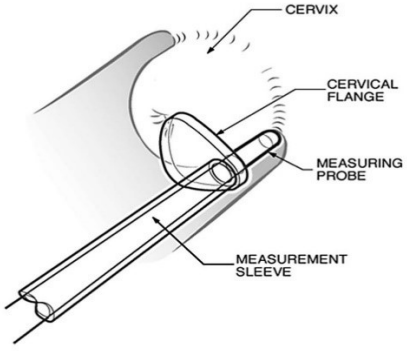

Fig. 3. A schematic drawing, illustrating the proper positioning of the cervical ruler flange against the cervical portion with measuring rod along the lateral aspect of the body of cervix[12].

For statistical analysis, the sample size (N) was calculated regarding the Baxter's study[9], using the type I error of 0.05, type II error of 0.2, and correlation coefficient of 0.25 to calculate the sample size. The total sample size to be included in the study was 181. The statistical analyses were performed using SPSS for Windows Version 22.

The sample demographic data were demonstrated in which the categorical data were reported in terms of frequency and percentage, whereas the continuous data were reported in terms of mean, standard deviation, median, lowest (min) and highest (max) values. The Pearson' correlation coefficients and paired t-test were calculated to determine the correlation between cervical length measured by transvaginal ultrasound and cervical ruler. P value of less than 0.05 was considered as statistically significant.

Results

A total of 200 singleton pregnant women participated in the study. The sample demographic data were described in Table 1.

Table 1. Demographic characteristics (N = 200).

Characteristic	Mean ± SD or n (%)
Gestational age (weeks)	19.56 ± 1.72
Maternal age (years)	24.76 ± 5.84
Pre-pregnancy weight (kg.)	61.81 ± 14.97
Pre-pregnancy height (cm.)	158.86 ± 6.09
Pre-pregnancy BMI (kg/m2)	24.4 ± 5.25
Parity	
0	1 (0.5%)
1	80 (40%)
2	65 (32.5%)
3	34 (17%)
4	17 (8.5%)
5	3 (1.5%)
History of first trimester abortion	
0	155 (77.5%)
1	39 (19.5%)
2	5 (2.5%)
3	1 (0.5%)
History of second trimester abortion	
0	194 (97%)
1	6 (3%)
History of spontaneous preterm labor	
0	193 (96.5%)
1	5 (2.5%)
2	1 (0.5%)
3	1 (0.5%)
History of cervical surgery	0 (0%)
Smoking during pregnancy	1 (0.5%)
Alcohol consumption during pregnancy	0 (0%)
Drug use during pregnancy	0 (0%)

BMI: Body Mass Index

The correlation between cervical length measured by transvaginal ultrasound and cervical ruler was calculated by paired t-test (Table 2), using cervical length measured by transvaginal ultrasound as a gold standard method. The average cervical length measured by cervical ruler was 3.4 ± 0.73 cm and of those measured by transvaginal ultrasound was 3.92 ± 0.71 cm. The mean difference of both methods was 0.52 cm (95% confidence interval 0.46 to 0.57, p value < 0.001).

Table 2. Paired t-test.

	Transvaginal ultrasound (cm)	**Cervical ruler (cm)**	**Difference (95% CI)**	**p value**
Cervical length	3.92 ± 0.71	3.4 ± 0.73	0.52 (0.46, 0.57)	< 0.001

The Pearson's correlation coefficient statistical test (Fig. 4) was performed to assess the correlation between cervical length measured by transvaginal ultrasound and cervical ruler. The correlation coefficient (r) was 0.843. The predicting values of the cervical length measured by transvaginal ultrasound were estimated from the cervical length measured by cervical ruler using the equation (Fig. 5) derived from Pearson's correlation statistical analysis.

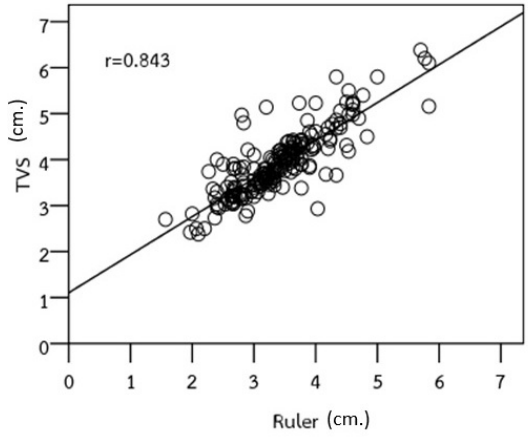

Fig. 4. The estimation of cervical length in cm. measured by cervical ruler (x-axis) and measured by transvaginal ultrasound (y-axis) using Pearson's correlation coefficient.

TVS (cm.) = 1.105 + 0.827 x Ruler (cm.)

Fig. 5. The equation calculated from Pearson's correlation coefficient statistical test.
TVS = value of cervical length in cm. measured by transvaginal ultrasound
Ruler = value of cervical length in cm. measured by cervical ruler

Discussion

Currently, cervical length measured by transvaginal ultrasound is the noninvasive and harmless standard method for evaluating and predicting spontaneous preterm birth in which it can be prevented by progesterone supplements, cervical cerclage, and cervical pessary. However, this standard method has been limited due to lack of equipments, financial resource, and specialists in some hospitals in Thailand. A study conducted by Ross and Beall showed that Cervilenz, a low-cost cervical measurement device, was potential and used as a primary screening test to evaluate cervical length for detecting the risk of spontaneous preterm birth[7]. However, Cervilenz is designed to be a single use which could lead the high cost of medical expenditure in Thailand. A cervical ruler is a new cheap cervical measurement device which is designed for reusable or using multiple times to reduce cost in the hospital due to inadequate financial resource. Additionally, a cervical ruler is designed to facilitate nurses and general physicians to measure cervical length easily. However, it has some limitations among patients with cervical ripening or abnormal shape or position of their cervixes, resulting in diagnosis errors. Currently, a cervical ruler device is in the development and study process; therefore, it cannot be found in the market.

Based on this study, cervical length measurement in singleton pregnant women during gestational age at 16 to 24 weeks using cervical ruler was found to be statistically significant correlated with cervical length measured by transvaginal ultrasound (correlation coefficient was 0.843), which was consistent with the previous studies[7-10]. However, the average cervical length measured by cervical ruler was statistically significantly lower than the average cervical length measured by transvaginal ultrasound (95% confidence interval 0.46 to 0.57, p value < 0.001). The total cervical length can be clearly detectable and measurable by using transvaginal ultrasound; whereas the cervical length measured by cervical ruler can be measured only at the outer aspect of the body of cervix. Therefore, this was illustrated that the average cervical length measured by cervical ruler was less than of those measured by transvaginal ultrasound.

Regarding the findings of previous studies, the cut-off values of the cervical length measured by Cervilenz were reported to predict the risk of spontaneous preterm birth. However, it was unable to estimate the values of cervical length of transvaginal ultrasound by using the measured values from cervical ruler[8]. The equation has been generated to estimate and identify the values of cervical length of transvaginal ultrasound using the measured values from cervical ruler. This procedure is useful for hospitals which lack transvaginal ultrasound or specialists to predict cervical length values of transvaginal ultrasound and can be used for follow-up on the cervical length measurement (Fig. 5).

Conclusion

In conclusion, transvaginal ultrasound is the standard method for evaluating and predicting spontaneous preterm birth, but its limitation still exists in some hospitals with lack of available equipments, financial resource, and specialists. Cervical ruler is low-cost and ease of use cervical measurement device to measure cervical length which correlates with the standard method, but its limitation appears in patients with cervical ripening or abnormal position or shape of their cervixes. This study was a cross-sectional study to identify the correlation between cervical length measured by transvaginal ultrasound and cervical ruler. Further studies are required to identify optimal cut-off value when cervical ruler is performed by general physicians and nurses as primary screening test to evaluate cervical length for predicting the risk of spontaneous preterm birth.

Potential conflicts of interest

The authors declare no conflict of interest. The Zephicure Co., Ltd. provided only the devices for using in the study without any responsibility for the study. The authors are responsible for the content and writing of the paper.

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