

Thai Journal of Obstetrics and Gynaecology
July 2018, Vol. 26, No.3, pp. 166-174

OBSTETRICS

Estimating the Date of Confinement: A 3-year Retrospective Study in Ramathibodi Hospital

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ABSTRACT

Objectives: To estimate limits of agreement (LOA) between the actual date of delivery (ADD) and four different methods for estimated date of confinement (EDC) based on last menstrual period (LMP).

Materials and Methods: This retrospective cross-sectional study was conducted in the pregnant women who delivered at Ramathibodi Hospital, Bangkok, Thailand during 2013-2015. The inclusion criteria were term pregnancy, singleton, spontaneous onset of labor, certain date and duration of LMP, regular menstrual cycles, no recent use of hormonal contraceptives in past 3 months, ultrasound scan in mid-trimester was performed and all newborns were evaluated full-term by pediatricians. Exclusion criteria was wrong date recalled after redating with ultrasound scan in mid-trimester. Four methods for EDC: Naegele's rule using the 1st day of LMP, Naegele's rule using last day of LMP, pregnancy wheel, and pregnancy calculator application were compared with ADD. The discrepancies between EDC and ADD were defined as the LOA and its 95% confidence interval (95%CI). Statistical comparison was performed by using Bland and Altman's method.

Results: There were 1,883 pregnant women who met the criteria. LOA of ADD was 5.2 days before predicted EDC by pregnancy calculator application. Predicted EDC using last day of LMP by Naegele's rule was differ from LOA of ADD more than other methods (-8.8 days). Different days in each month affect predicted EDC except by application method.

Conclusion: Pregnancy calculator application based on LMP is the preferred method for predicting EDC when compared with Naegele's rule and pregnancy wheel in women who can certainly remember her LMP.

Keywords: EDC, Estimated date of delivery, Naegele's rule, pregnancy wheel, pregnancy calculator application

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การคาดคะเนกำหนดคลอด การศึกษาย้อนหลัง 3 ปีในโรงพยาบาลรามธิบดี

ณัฐพร ภูไพบูลย์, สมมาตร บำรุงพืช, ณัฐพงศ์ อิศรางกูร ณ อยุธยา

บทคัดย่อ

วัตถุประสงค์: เพื่อศึกษา limits of agreement ระหว่างวันคลอดจริงกับกำหนดคลอดจากการคำนวณที่แตกต่างกัน 4 วิธี โดยนับจากประจำเดือนครั้งสุดท้าย

วัสดุและวิธีการ: การศึกษาย้อนหลังในหญิงตั้งครรภ์ที่คลอดในโรงพยาบาลรามธิบดี ช่วงระหว่างมกราคม พ.ศ.2556 ถึง ธันวาคม พ.ศ.2558 โดยมีเกณฑ์การคัดเลือกคือ หญิงตั้งครรภ์เดี่ยว ครบกำหนด เจ็บครรภ์คลอดเองตามธรรมชาติ จำวันและระยะเวลาของประจำเดือนครั้งสุดท้ายได้แม่นยำ ประจำเดือนมาสม่ำเสมอ ไม่มีประวัติใช้ฮอร์โมนคุมกำเนิดในช่วงสามเดือนก่อนการตั้งครรภ์ ได้รับการอัลตราซาวด์ในช่วงไตรมาสที่สองของการตั้งครรภ์ และทารกอายุครบกำหนดคลอดจากบันทึกของกุมารแพทย์ เกณฑ์การคัดออกคือ กำหนดคลอดที่เปลี่ยนโดยอัลตราซาวด์ในช่วงไตรมาสที่สองเนื่องจากจำประจำเดือนครั้งสุดท้ายผิด จากนั้นคำนวณวันคลอดโดยสี่วิธี คือ 1. กฎของ Naegele โดยใช้วันแรกของประจำเดือนครั้งสุดท้าย 2. กฎของ Naegele โดยใช้วันสุดท้ายของประจำเดือนครั้งสุดท้าย 3. วงล้อหมุน 4. แอปพลิเคชัน นำมาเปรียบเทียบกับวันคลอดจริง ความแตกต่างระหว่างกำหนดคลอดที่คำนวณได้กับวันคลอดจริงกำหนดให้เป็นระดับข้อตกลง และความเชื่อมั่น 95 เปอร์เซ็นต์ เปรียบเทียบค่าทางสถิติโดยใช้วิธีของ Bland และ Altman

ผลการวิจัย: จากหญิงตั้งครรภ์ที่คลอดทั้งหมด 1,883 รายที่เข้าเกณฑ์ วิธีคำนวณกำหนดคลอดโดยใช้แอปพลิเคชันใกล้เคียงวันคลอดจริงมากที่สุด คือ หลังวันคลอดจริง 5.2 วัน ในขณะที่วิธีคำนวณโดยกฎของ Naegele จากวันสุดท้ายของประจำเดือนครั้งสุดท้ายห่างจากวันคลอดจริงมากที่สุด คือ หลังวันคลอดจริง 8.8 วัน จำนวนวันที่ต่างกันในแต่ละเดือนมีผลต่อการคำนวณกำหนดคลอด แต่จะไม่มีผลกระทบต่อวิธีคำนวณโดยใช้แอปพลิเคชัน

สรุป: แอปพลิเคชันคำนวณกำหนดคลอดจากประจำเดือนครั้งสุดท้ายเป็นวิธีที่ดีกว่าเมื่อเทียบกับการใช้กฎของ Naegele และวงล้อหมุนในหญิงตั้งครรภ์ที่จำประจำเดือนครั้งสุดท้ายได้แม่นยำ

คำสำคัญ: กำหนดคลอด, กฎของ Naegele, วงล้อคำนวณวันคลอด, แอปพลิเคชันคำนวณวันคลอด

Introduction

The accurate determination of gestational age is very important in prenatal care and the time of delivery management. These include screening for fetal aneuploidy, intervention at the limit of fetal viability, the administration of corticosteroids for fetal lung maturation, and the elective induction of labor in some indicated conditions in order to decrease both mother and fetal morbidity and mortality e.g. hypertension, diabetes, and postterm pregnancy. Nowadays, the ultrasound measurement of embryo or fetus in the 1st trimester is the most accurate method to establish or confirm gestational age⁽¹⁾. However, last menstrual period (LMP) is still important in clinical practice, physicians use various methods to calculate estimated date of confinement (EDC) from LMP depending on their preferred methods, such as Naegele's rule, pregnancy wheel or pregnancy calculator application. The discrepancies of EDC between each method can affect the management and the outcome of pregnancy.

In general, gestational age will be corrected by ultrasound if EDC discrepancies are more than determined days⁽²⁾, the reliability of ultrasound will be decreased depending on the time of first ultrasound performed. At Ramathibodi hospital, if the height of fundus from physical examination correlates with gestational age by certain LMP, obstetricians usually wait until mid-trimester to perform ultrasound screening for fetal anomaly and correcting the gestational age. However, in some parts of Thailand, especially in the setting of community hospitals, insufficient resources and healthcare providers are the major problems and ultrasound may be performed later than usual in some women. This results in the discrepancies between EDC by LMP and ultrasound which can be extended to more than 14 days, especially in the case of suboptimally dated pregnancies⁽³⁾.

The duration of pregnancy is 280 days from the onset of LMP or 266 days from the date of conception. Naegale's rule assumes a 28-day-cycle with ovulation on day fourteen. By adding 7 days to the first day of the last menstrual period and counting back 3 months

the expected date of confinement can be obtained. But the duration of pregnancy by Naegale's rule is not always exactly 280 days, due to the number of days in each month⁽⁴⁾. The largest published cohort study of 427,582 singleton pregnancies in Sweden showed that the average duration from LMP to vaginal birth was 281 days (mean), 282 days (median), and 283 days (mode)⁽⁵⁾.

As Baskett et al. stated, Naegale did not the first person who invented the rule^(6,7). It may have been the famous Hermann Boerhaave (1668-1738), Professor of Botany and Medicine at Leyden University, who first set down this calculation. Franz Carl Naegele (1778-1851), Professor of Obstetrics at the University of Heidelberg, also quoted Boerhaave's section in his 1812 textbook. Baskett et al., commented that their wording "counting from the last menstrual period" lacked of precision, so that one could interpret conception as the occurrence either seven days after the start or after the end of the last period. Bedford, the Professor of Obstetrics and Diseases of Women and Children in the University of New York, did so in his 1872 text, he had taken the date to which the seven days should be added as the end of the period⁽⁸⁾. The calculation "from the last menstrual period" remained unclear until the late 19th and early in the 20th century, the standard American texts advocated Naegele's rule which were interpreted as adding seven days to the start of the last menstrual period⁽⁹⁾.

In common obstetric practice, a pregnancy wheel is usually used for calculating the gestational age based on the normal duration of pregnancy of 280 days. In addition, pregnancy calculator application becomes more widespread along with the introduction of smartphones and tablets. The convenience and functionality of these devices offer their popularity among users.

Despite the accuracy of pregnancy dating by ultrasound, physicians commonly use alternative methods for assessing gestational age at each antenatal care visit. But there remains doubtful which methods would be the best among these methods for the estimated delivery date calculation based on LMP.

This study aimed to determine the precision of four methods: by Naegele's rule using the 1st day of LMP, by Naegele's rule using last day of LMP, using pregnancy wheel, and using pregnancy calculator application, in predicting term gestation when compared with the actual date of delivery.

Materials and Methods

From January 2013 to December 2015, data from total 7,514 unselected deliveries in Ramathibodi Hospital were retrospectively collected. The inclusion criteria were term pregnancy (gestational age 370/7-416/7 weeks), singleton, spontaneous onset of labor, certain date and duration of LMP, regular menstrual cycle with interval 21-35 days (LMP, previous menstrual period and duration of period were recorded), no recent use of hormonal contraceptives in past 3 months, ultrasound measure for gestational age in mid-trimester was performed and all newborns were evaluated full-term by pediatricians. From the remaining 2,767 women, 884 women were excluded due to wrong date recalled after redating with ultrasound scan in mid-trimester. The final study population thus comprised of 1,883 women, as shown in Fig. 1. No pregnancy from assisted reproductive technology was included in this study.

EDC were calculated by 4 methods for each woman: (1) Naegele's rule by the 1st day of LMP (2) Naegele's rule by the last day of LMP (3) pregnancy wheel and (4) pregnancy calculator application.

The duration of normal pregnancy was defined as 280 days. The accuracy in predicting the EDC was calculated for term deliveries only because preterm delivery was a unique condition that caused by various pathologic processes which may affect to the results. For this reason, this group was not included in the study.

Naegele's rule was used to calculate EDC by adding 7 days and counting back 3 months from the 1st day of LMP (EDC1) and calculated from the last day of LMP (EDC2). EDC Wheel was calculated by using pregnancy wheel based on the normal duration of pregnancy of 280 days. We use only one wheel by one observer to reduce inter-observer variability. There

were 365 tick marks in the wheel and numbers of tick marks were corresponded with the month. If a wheel EDC was midway between two dates, the later date was used. However, there was no scoring system for pregnancy wheel. Finally, the manual pregnancy wheel that was commonly used in antenatal clinic manufactured by Obimin AZ[®] was chosen for this study. The pregnancy calculator application was used to calculate EDC App by using the 280 day rule from 1st day of LMP. According to APPLICATIONS Scoring System⁽¹⁰⁾, ACOG EDD calculator was selected for this study because of the highest score among all of the other pregnancy calculator apps (score 13 out of 16)⁽¹¹⁾.

Sample size was calculated using data from pilot study of 40 women to estimate limits of agreement (LOA) between predicted EDC and actual date of delivery (ADD). The sample size can be estimated based on the equation for estimation of lower limit (LL) and upper limit (UL) of 95% confidence interval (95%CI) of LOA, with varying delta (confidence interval width). The estimated SD of delta (ADD-EDC2) is 9.38. Delta equaled 2 was chosen and sample size of 760 women were calculated.

Describe data by means or median where appropriate for continuous data and frequency for categorical data. Estimated limits of agreement and its 95% CI were calculated by Bland and Altman's method^(12,13). Duration of pregnancy was defined as duration between LMP and predicted EDC. All analyses were performed by STATA 14.2.

The study was approved by the Center of Ethical Reinforcement for Human Research, Faculty of Medicine Ramathibodi Hospital, Mahidol University (ID 05-59-25).

Results

Demographic characteristics are shown in Table 1. Mean age was 29.1 years (SD 5.8 years) and mean pre-pregnant BMI was 21.3 kg/m² (SD 3.6 kg/m²). Most women were primigravida (61.7%). Mean birthweight of newborn were 3,137.9 g (SD 372.8 g) and percentage of newborn's sex was comparable (49.8% vs 50.2%).

Table 1. Demographic characteristics.

| Characteristics | No. | Percent |
|---|---------------------|---------|
| Age (years), mean \pm SD | 29.1 \pm 5.8 | |
| Prepregnant BMI (kg/m ²), mean \pm SD | 21.3 \pm 3.6 | |
| Parity: | | |
| 0 | 1,162 | 61.7 |
| 1 | 542 | 28.8 |
| \geq 2 | 179 | 9.5 |
| Route of delivery: | | |
| Normal labor | 1,233 | 65.5 |
| Cesarean section | 572 | 30.4 |
| Vacuum extraction | 53 | 2.8 |
| Forceps extraction | 25 | 1.3 |
| Newborn: | | |
| Birth weight (grams), mean \pm SD | 3,137.9 \pm 372.8 | |
| Sex | | |
| Male | 938 | 49.8 |
| Female | 945 | 50.2 |

Fig. 2. shows difference in days between predicted EDC1 and average ADD presented as LOA and 95%CI in Bland-Altman's plot. The mean difference was -6.0 days (average ADD occurred before predicted EDC1 for 6 days) with 95%CI -20.1 to 8.1 days. Fig. 3. presents LOA and 95%CI of all 4 methods. Average ADD usually occurred before predicted EDCs. LOA was about 5 days before predicted EDC by pregnancy calculator application with a range of -19.3 to 8.8 days which was closer to LOA of ADD than other methods. LOA by pregnancy wheel and Naegele's rule using the 1st day of LMP were relatively equal 6 days before predicted EDC (-5.9 and -6.0 days, respectively). The use of the last day of LMP by Naegele's rule was differed from LOA of ADD more than other methods (-8.8 days).

Seasonal variability in mean duration of pregnancy by each method was observed but this was found to be consistent with EDC by pregnancy calculator application (Fig. 4).

Discussion

Accurate determination of gestational age is very

important in prenatal care. There were many methods used in predicting EDC based on LMP. The discrepancy of EDC between each method may confound the physicians and lead to inaccurate gestational age determination. The results in this study suggested that EDC by using pregnancy calculator application was the most accurate whereas EDC by using the last day of LMP was the least accurate among 4 methods when compared with ADD.

In population of women whose the LMP were known, EDC based on LMP were 3.3 days earlier⁽¹⁴⁾. Oslen et al claimed that if 283 days were added to the LMP would render the EDC based on LMP estimates more accurate⁽¹⁵⁾. Similarly, the mode (283 days) estimated in duration of pregnancy from the Swedish birth registry was felt to be more accurate than the mean value (280 days) as it reduced the influence of pathological pregnancies at the extreme of prematurity⁽⁵⁾. Baskett et al., concluded that original Naegale's rule may have to add seven days to the end instead of the beginning of the LMP⁽⁶⁾.

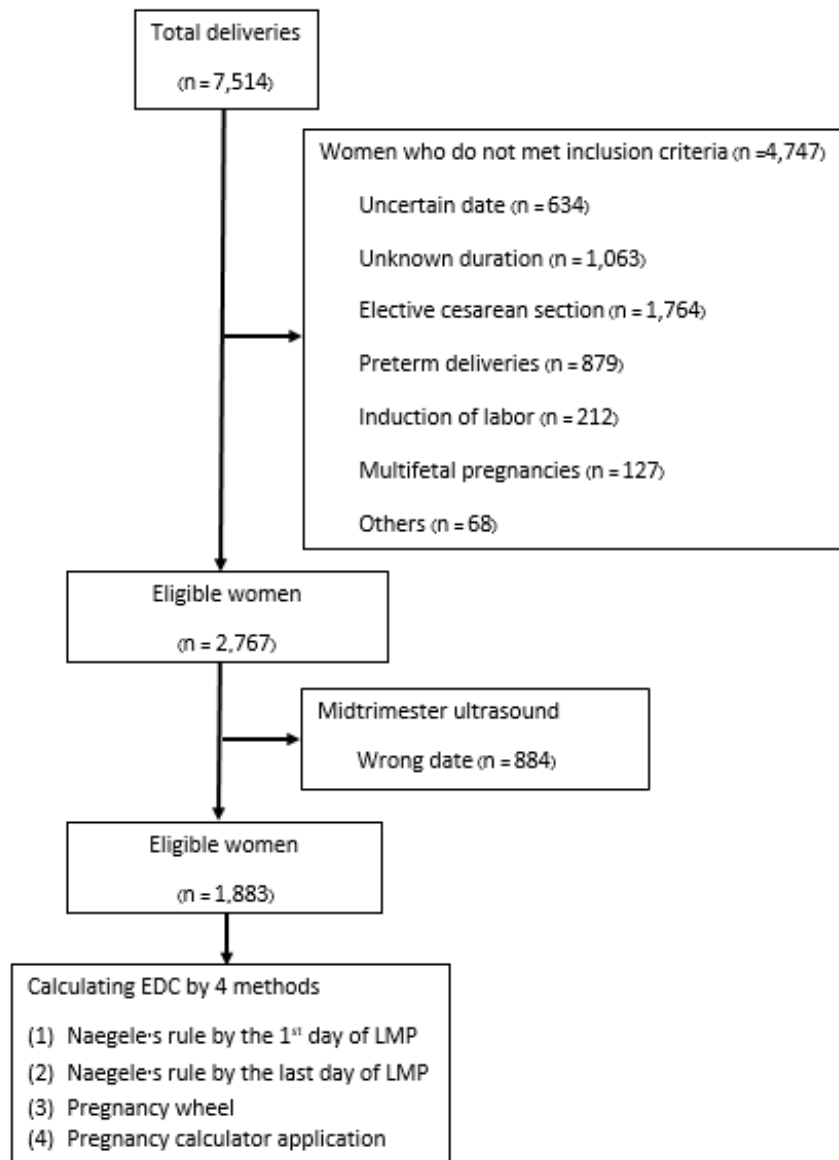


Fig. 1. Flow chart of analytic sample selection.

The results of this study did not support Baskett et al.'s conclusion. EDC by Naegele's rule calculated from last day of LMP was different from ADD when compared with EDC calculated from 1st day of LMP (8.8 vs 6.0 days). This may result from last day of LMP were varied in individuals, uncertain duration of menstrual cycle and amount of menstruation which effected in marked variations in range of EDC.

Ross found discordance between the EDC

determined by wheels and the computerized program up to five days⁽¹⁶⁾, whereas McParland et al quote the inter-wheel variation was up to seven days between different manufacturers⁽¹⁷⁾. Hutchon et al compared an obstetrical wheel and ultrasound dating among seventeen obstetricians and concluded that concordance and accuracy would be improved with a computer-based system⁽¹⁸⁾. Linda et al., evaluated electronic applications and paper pregnancy wheels

and found that the largest discrepancy was four days short of 280 days in the later group⁽¹⁹⁾.

This study results showed that predicted EDC by pregnancy calculator application was close to ADD more than other methods, similar to previous studies. Seasonal variability was clearly seen from Naegele's rule calculation which was similar to pregnancy wheel. Because of calculation by adding and subtracting method was imprecise by different number of days in

a month while the length of pregnancy always consistent with 280 days in pregnancy calculator application. Moreover, applications have no limitation like pregnancy wheel. As noted by McParland and Johnson⁽¹⁷⁾, the alignment of wheels may not be concentric, and central mounting may be loosen, even though this was not detected by inspection. Physicians should be aware of the potential error of both Naegale's rule and pregnancy wheels.

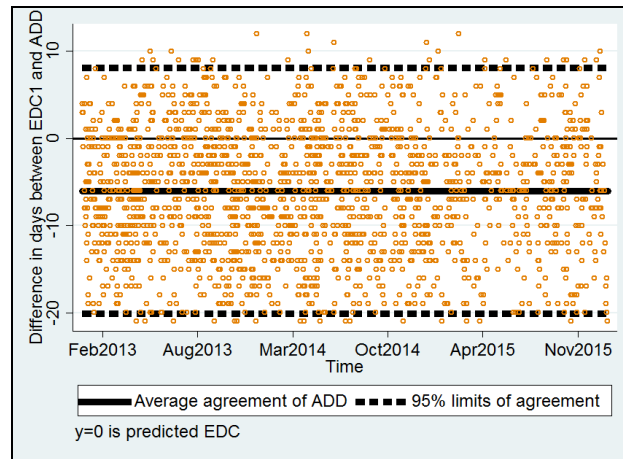


Fig. 2. Difference in days between predicted EDC1 and average ADD.

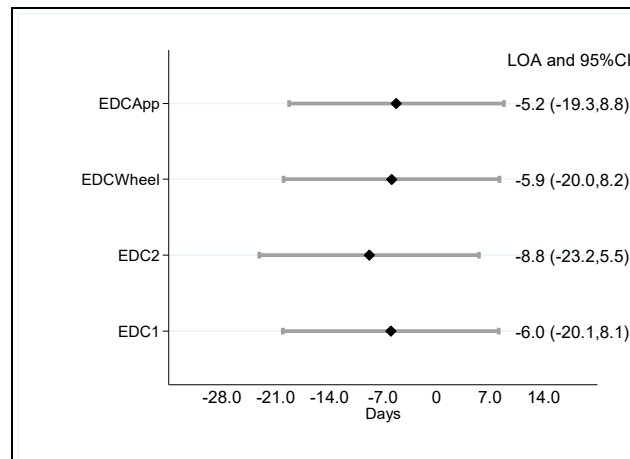


Fig. 3. Limits of agreement between actual date of delivery and predicted EDCs. EDC1; Naegele's rule by the 1st day of LMP. EDC2; Naegele's rule by the last day of LMP, EDC Wheel; pregnancy wheel, EDC App; pregnancy calculator application, Day 0 = predicted EDC.

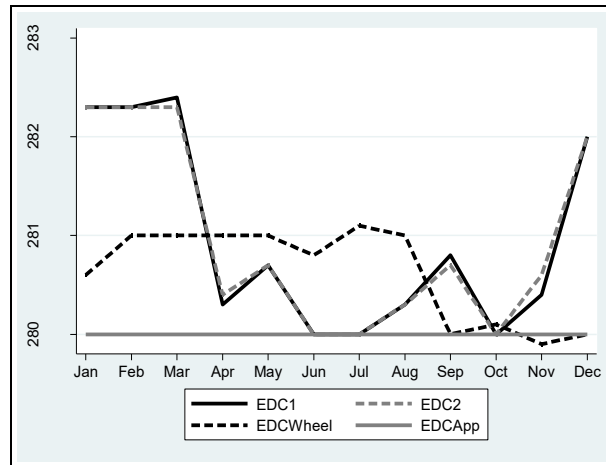


Fig. 4. Seasonal variability in mean duration of pregnancy by each method. EDC1; Naegele’s rule by the 1st day of LMP. EDC2; Naegele’s rule by the last day of LMP, EDC Wheel; pregnancy wheel, EDC App; pregnancy calculator application.

However, several factors may limit the accuracy of EDC based on LMP, such as women who do not have regular 28-day cycle due to variability in the length of the follicular phase, the fertile window which may not day 14, variations of the duration between fertilization and implantation, and uncertain date of their last period⁽²⁰⁾. Therefore, physicians should be aware of predicting EDC based on LMP alone and ultrasound redating is necessary for EDC confirmation. Nevertheless, limitation of healthcare resource in Thailand, especially in countryside, only few women had ultrasound scan in the first trimester for indicated obstetric conditions such as first trimester bleeding, uncertain menstrual date, etc. This suggests that LMP is still important in predicting EDC in common clinical practice in Thailand.

The strength of this study were enrollment only women who can certainly remember her LMP and previous menstrual period which can identify regularity of menstrual cycle and duration of period, and all of them were performed ultrasound screening in the mid-trimester to confirm EDC. But there were some limitations included retrospective study, exclusion of more than 70% of women because of uncertain date and intervention for delivery and did not include a leap

year in this study.

Conclusion

Pregnancy calculator application was preferred for predicting EDC based on LMP when compared with Naegele’s rule and pregnancy wheel in women who could certainly remember her LMP.

Acknowledgements

We are grateful to Assoc. Prof. Dr. Ammarin Thakkinstian and Sukanya Siriyotha, Clinical Epidemiology and Biostatistics Section, Faculty of Medicine Ramathibodi Hospital, Mahidol University for their contribution in the statistical analysis. We would like to thank all the staff of the Department of Obstetrics and Gynaecology, Faculty of Medicine Ramathibodi Hospital, Mahidol University for their support in this study.

Potential conflicts of interest

The authors declare no conflict of interest.

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