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# Thai Journal of Obstetrics and Gynaecology

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Thai Journal Obstetrics and Gynaecology (TJOG) is the official journal of The Royal Thai College of Obstetricians and Gynaecologists (RTCOCG). This is a double-blind peer-reviewed journal aiming to promote academic knowledge and provide a forum for publication in Obstetrics and Gynaecology. Manuscripts submitted to TJOG will be accepted on the understanding that the author must not have previously submitted the paper to another journal or have published the material elsewhere.

**Type of Paper:** Special (invited) article, Original article, Case report

**Frequency:** 4 issues per year (January-March, April-June, July-September, October-December)

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**ISSN:** 0857-6084 (Since 1989)

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TJOG is the official journal of RTCOCG. This is a double-blind peer-reviewed journal aiming to promote academic knowledge and provide a forum for publication in Obstetrics and Gynaecology. First issue of TJOG (Volume 1) was published in June 1989.

Improvement of TJOG has been documented. TJOG was accepted for indexing by the Thai Journal Citation Index (TCI) in December 2010 and indexed in the ASEAN Citation Index (ACI) in September 2015. TJOG also received the National Journal Award from the 3rd TCI-Scopus-TRF Journal Awards on December 15, 2016.

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# Thai Journal of Obstetrics and Gynaecology

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## Reviewer acknowledgement 2020

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## EDITORIAL

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I am pleased to announce that Thai Journal of Obstetrics and Gynaecology (TJOG) has received funding for the quality development of Thai journals in the project TCI-TSRI-Scopus Collaboration Project phase 2 to create professional editors' career path and develop research quality through the process of developing and improving the quality of research articles in Thai academic journals in the Scopus database. The journal editorial team would like to thank the TCI-TSRI-Scopus Collaboration Project, Thai-Journal Citation Index Center, and the local board for their constructive feedback contributing to the journal quality improvement.

This fourth issue of TJOG contains many interesting articles. The special article in this issue is **"The Systematic Work Up to Identify Etiology of Non-immune Hydrops Fetalis: A perspective view of pathologist"**.

RTCOC Annual Meeting 2020 will be held during 14-16 October 2020 at The Royal Golden Jubilee Building, Soi Soonvijai, Bangkok, Thailand. The theme of this meeting is **"50 Years Golden Jubilee RTCOG: New Normal"**. All RTCOG members are cordially invited to participate this scientific meeting.

Wish to see you at RTCOG Annual Meeting 2020 at Royal Golden Jubilee Building, Soi Soonvijai, Bangkok, Thailand.

**Prof. Vorapong Phupong, M.D.**  
**Editor in Chief**

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## SPECIAL ARTICLE

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# The Systematic Work Up to Identify Etiology of Non-immune Hydrops Fetalis: A perspective view of pathologist

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### ABSTRACT

Non-immune hydrops (NIH) is an important condition in health service. Many etiologies of NIH have been described, but the definite cause of NIH in many cases is still reported as “unknown.” This finding may be partly explained by the inadequate investigation. The article summarized the possible etiology of NIH and the needed investigation to establish cause of NIH from the view of pathologist.

**Keywords:** Hydrops fetalis, non-immune hydrops fetalis, etiology

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## Introduction

Hydrops fetalis is the condition with excessive fluid accumulation in two or more fetal compartments. The accumulation of fluid can occur in tissue such as fetal subcutaneous tissue or in body cavities such as pericardial effusion, pleural effusion, and ascites<sup>(1)</sup>. The reported overall incidence of hydrops fetalis is 1 in 1,500 to 4,000 pregnancies. However, this number may be lower than the actual incidence because hydrops fetalis can spontaneously resolve in some cases<sup>(2, 3)</sup>.

## Etiology

There are two categories of hydrops fetalis: immune and non-immune. Immune hydrops fetalis is due to red blood cell alloimmunization in which Rhesus

(Rh) D antibody is the most common cause. At the present, the blood test of red blood cells antibodies is routinely performed in antenatal care and anti-D immunoglobulin is also widely available, so the incidence of immune hydrops fetalis is much lower and accounts in only 10% of overall hydrops fetalis. The incidence is also varied among population because Rh-negative is found in up to 15% of Caucasian population, while less than 1% of Asian population are Rh-negative<sup>(4-7)</sup>.

Non-immune hydrops (NIH) is much more common than immune hydrops and there are many etiologies that cause this condition. The prevalence and etiologies are different among countries, depends on the ethnic which is prone to hemoglobinopathy and

genetic disorders as well as endemic area of some infectious disease. The etiologies can be divided into four groups: maternal, fetal, placental, and idiopathic; which can be overlapping between groups. However, it is easier to classify by structures and pathophysiology as follows:

#### ***Cardiovascular abnormalities***

This category is considered to be the most common cause of NIH in many studies, especially from western countries, and accounts for 17-35%<sup>(8, 9)</sup>. The abnormalities can be structural malformation which is the majority of cases; or other less common conditions such as arrhythmia, tumor, physical dysfunction from infection, inflammation, cardiomyopathy, and vascular anomaly. The common reported cardiac malformation in NIH are hypoplastic left heart and endocardial cushion defect<sup>(9, 10)</sup>. Cardiac or intrathoracic vascular malformation leads to increased venous pressure, resulting in volume overload and finally causes heart failure. The prognosis of NIH due to structural cardiac malformation is very poor with high rate of intrauterine fetal death. In contrast, fetal tachyarrhythmia is the most treatable cardiac cause by transplacental medical therapy<sup>(9)</sup>.

#### ***Chromosomal abnormalities***

Chromosomal abnormalities in NIH are varies among the studies, depending on the availability of investigation and financial resources. The reported prevalence is ranging from less than 10% and up to 70% in some series<sup>(8, 9, 11)</sup>. The most common reported cases are Turner syndrome (45,X) and Down syndrome (trisomy 21). Other common aneuploidies include trisomy 13, trisomy 18, and triploidy. The mechanism of hydrops in this group is explained by the increased rate of cardiovascular malformation, lymphatic dysplasia (e.g. cystic hygroma), and abnormal myelopoiesis in such cases.

#### ***Hematologic abnormalities***

Any hematologic abnormality causing fetal anemia can lead to hydrops. The most common etiology in this category is hemoglobinopathy which is inherited transmission. Alpha thalassemia or hemoglobin Bart hydrops are frequently found in Southeast Asia countries and considered to be the most common

etiology of overall hydrops in this region<sup>(12, 13)</sup>. Other less common causes in this group consist of hemolysis, massive fetomaternal hemorrhage, abnormal in red blood cells productivity, and infection (e.g. parvovirus B19).

#### ***Infectious diseases***

Intrauterine infection is a common cause of NIH and accounts for 4-15%. The hydrops can be occurred from viral, bacterial, or parasitic infection. The frequently identified diseases are parvovirus B19, cytomegalovirus, syphilis, and toxoplasmosis<sup>(14, 15)</sup>. The pathogenesis of hydrops in cases with intrauterine fetal infection is associated with several mechanisms including endothelial cell damage, increased capillary permeability, anoxia, myocarditis, and anemia. In western countries, parvovirus is the most commonly reported infectious cause of NIH. However, syphilis is more commonly found than parvovirus in Asian countries<sup>(16-19)</sup>.

#### ***Thoracic abnormalities***

This category comprises of multiple conditions, particularly involving with mass effect in thoracic cage either directly compress by lesion or complication such as effusion that impairs venous return and cardiac output. The examples of diseases in this group include congenital cystic adenomatoid malformation (CCAM), vena caval obstruction, bronchopulmonary sequestration, mediastinal tumor, and congenital hydrothorax. Among of these etiologies, chylothorax is the most common cause of isolated effusion that leads to NIH, occurring from lymphatic obstruction<sup>(20, 21)</sup>.

#### ***Urinary tract abnormalities***

Structural urinary tract malformation is quite rare to be etiology of NIH. Huge intraabdominal tumor can cause NIH by the mass effect that interferes with venous return. Congenital nephritic syndrome has also been reported as a cause of NIH due to hypoproteinemia<sup>(22)</sup>.

#### ***Hepatobiliary and Gastrointestinal tract abnormalities***

The examples of abnormality in this group are diaphragmatic hernia, small bowel volvulus, gut obstruction, intestinal malrotation, liver tumor, biliary atresia, and meconium peritonitis. The mechanism of hydrops is varied depends on the etiology. The cause of NIH in cases with intraabdominal masses is explained

by obstruction the venous return. In contrast, NIH in cases of gut obstruction is due to decreased osmotic pressure from protein loss, while arteriovenous shunting is the main mechanism of high cardiac output failure in case with hepatic hemangioma<sup>(23)</sup>.

#### ***Placental and cord lesions***

The reported associated conditions with NIH include chorangioma, umbilical arterial aneurysm, umbilical venous thrombosis, angiomyxoma of cord, and amniotic bands<sup>(24)</sup>. Small chorangioma is identified in approximately 1% of pregnancies and does not have clinical significance. Therefore, the lesion that is larger than 5 cm can cause fetal hydrops due to high arteriovenous shunt<sup>(25)</sup>.

#### ***Inborn errors of metabolism and other genetic conditions***

This group has been occasionally reported in the past and account for only 1-2% of NIH. The most well known example is lysosomal storage disease<sup>(26)</sup>. However, the recent studies showed increased prevalence of lysosomal storage disease if a comprehensive workup for this condition was performed<sup>(27, 28)</sup>. The proposed pathogeneses are visceromegaly leading to decrease or obstruction of venous return; decreased erythropoiesis; and hypoproteinemia.

### **Workup of nonimmune hydrops fetalis<sup>(29, 30)</sup>**

There are several guidelines, but the completion of every step is controversial and limited by the available resources of each center. Autopsy is still considered as a necessary procedure and strongly recommended in all cases of fetal death or termination of pregnancy that diagnosis is unknown prenatally<sup>(30)</sup>. Pathologist has an important role in summarizing the evidence and establish the final diagnosis. However, most cases were submitted for pathologic examination without adequate clinical information including the results of previous investigations. In order to accurately identify the cause of NIH, collaboration between obstetrician and pathologist is needed. The investigations that should be performed are as follows:

#### ***Clinical evaluation***

Detailed maternal history is very important and should be informed the pathologist prior to autopsy examination. The history that should be focused includes ethnicity, consanguinity, maternal past history and reproductive history, previous hydrops or fetal death, infectious disease exposure, traveling, use of medication, and 3-generation pedigree.

#### ***Sonographic examination***

Besides of determining the structural malformation; several etiologies can be confirmed or excluded by targeted ultrasound examination such as cardiac arrhythmia and fetal anemia. Middle cerebral artery Doppler study is essential to assess fetal anemia. Arterial Doppler is also important as it reflects the redistribution of fetal cardiac output to the blood flow in descending aorta and umbilical artery. However, changes in umbilical artery Doppler occur later than venous Doppler and cardiac function alteration. Absent or reversed end diastolic blood flow in the umbilical artery is associated with increased cardiac afterload and frequently seen in cases with poor prognosis<sup>(10)</sup>.

#### ***Testing for hemoglobinopathy and other hematologic abnormalities***

Routine maternal blood tests include complete blood count (CBC), ABO blood type, and antigen status. Hemoglobin electrophoresis and glucose-6-phosphate dehydrogenase (G6PD) deficiency screening are depending on the ethnic origin. Antibody screening can be done by indirect Coombs test. If fetal bradyarrhythmia is present, SS-A, SS-B antibodies should also be performed. Kleihauer-Betke smear is useful in cases that suspected of fetomaternal hemorrhage.

#### ***Investigation for fetal infection***

There are several laboratory tests for infectious diseases that associated with fetal hydrops. Nowadays, two main categories are performed; serologic test and infectious agent detection<sup>(14, 31)</sup>. Serology is sensitive, but rather non-specific because it often cannot determine the definite time of infection. Classically, immunoglobulin (Ig) G and IgM are measured in which two samples from different period are required to determine seroconversion or rising in titer. IgM reflects a recent infection, but it may persist for a long time in some cases. In the other hand, IgM can also not be

detected at the time of fetal hydrops because seroconversion was rapidly occurred earlier. Maternal toxoplasmosis, rubella, cytomegalovirus, herpes simplex (TORCH), and parvovirus B19 serologic test are generally done one time when hydrops was diagnosed in which the interpretation of laboratory result may be limited. It will be more useful if prior immune status of these infectious diseases is tested as baseline since the first trimester. If available, more sensitive molecular methods (such as polymerase chain reaction (PCR) or reverse transcription polymerase chain reaction (RT-PCR)) to detect infectious agents are recommended, but the procedure to collect specimen is much more invasive than routine maternal serologic test.

#### ***Karyotype and genetic studies***

As some chromosomal abnormalities may not have obvious structural malformation; fetal chromosomal analysis should be offered in all cases whether the anomalies are detected or not by sonography<sup>(32)</sup>. The prenatal diagnosis can be done by classic karyotype, fluorescence in situ hybridization (FISH), or chromosomal microarray analysis via chorionic villus sampling, amniocentesis, placental biopsy, or fetal blood sampling. Therefore, screening non-invasive prenatal testing can detect only some chromosomal abnormalities, so it is not considered as an adequate testing in cases of fetal hydrops.

#### ***Studies of inborn errors of metabolism***

Although inherited metabolic disorders (such as lysosomal storage diseases, Gaucher disease, and Niemann-Pick disease) are rare, but it is critical because of the high recurrence due to autosomal recessive inheritance. In such cases, the pathologist should be informed in order to carefully histologic examine of the placenta, liver, spleen, and bone marrow. Panels of causative storage diseases can be tested in only few specialized laboratories. However, this condition should be concerned in cases of NIH that cannot find any cause of hydrops or cases that have recurrent hydrops in a family<sup>(27, 28)</sup>.

#### ***Placental pathologic examination***

Placental examination should be performed in all cases of fetal hydrops. Some common infectious

disease can be demonstrated in the placenta, but it is quite non-specific in most cases. Clinical information is needed to be evaluated at the time of examination to determine whether the pathologic feature is compatible with suspected condition or not. Additional immunohistochemical study may have a role in detection of infectious agent, but it is expensive and available in only some laboratories.

#### ***Autopsy***

Autopsy is strongly recommended for every case that the prenatal diagnosis is still unknown. Review of all clinical data and investigation is necessary for good planning of autopsy to collect specimen for further studies. Besides of routine autopsy examination, detailed photography should be taken for retrospective review of dysmorphic structures. Fetal X-rays are optional in cases that suspected of skeletal dysplasia. Fetal blood, tissue, deoxyribonucleic acid (DNA), and amniotic fluid supernatant should be collected and frozen at -70°C. In some centers, a potentially dividing fetal cell line (amniocytes, skin biopsy) is also collected for future biochemical or molecular genetic testing. Extensive sampling from various sources to test for tissue-specific enzymatic activity or gene expression should be considered in the indicated case<sup>(33)</sup>.

## **Conclusion**

NIH has several etiologies. In order to identify definite cause of NIH, it needs the collaboration between obstetricians and pathologists to combine the clinical information and plan of investigation.

## **Potential conflicts of interest**

The author declares no conflict of interest.

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## OBSTETRICS

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# Face Recognition of Newborn by Mother during Immediate Postpartum Period: An observational study

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### ABSTRACT

**Objectives:** To determine the proportion of new mothers who could correctly recognize their newborns' face during immediate postpartum period for the mother-newborn identification method.

**Materials and Methods:** A prospective observational study of healthy mothers and infants, who delivered vaginally without complications was conducted. Each mother was let to have a skin-to-skin contact with her newborn for 15 minutes. Then, she was tested if she could recognize her newborn's face at two hours postpartum by picking the photo among other five different ones. The mother who could correctly identify the photo of her own baby was deemed as capable of recognizing hers.

**Results:** Among 88 participants, 54 (61.4%) could correctly identify the photos of their newborns while 34 (38.6%) could not. When the data between these two groups were compared with multivariate analysis, there was a statistical difference in maternal age, adequacy of skin-to-skin contact protocol, and level of maternal education. The older mothers had a higher rate of recognition than the younger ones (adjusted odds ratio 1.115; 95% CI 1.013-1.227;  $p = 0.026$ ). Also, those who completed 15 minutes of skin-to-skin contact protocol had a higher rate of recognition (adjusted odds ratio 4.209; 95% CI 1.570-11.285;  $p = 0.004$ ). In addition, those who graduated from a secondary school or higher had a higher rate of recognition (adjusted odds ratio 5.518; 95% CI 1.490-20.433;  $p = 0.011$ ).

**Conclusion:** The newborn's face recognition by mother was imprecise accuracy. However, we suggest using this process for establishing mother-infant bonding rather than mother-newborn identification method.

**Keywords:** face recognition, memory, postpartum, newborn.

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## การศึกษาเรื่องความสามารถในการรับรู้และจดจำใบหน้าทารกแรกเกิดในมารดาหลังคลอดทันที

กมลพร เชาวีวัฒนกุล, นพพร โรจน์เพ็ญเพียร, พรรณวรา ปรีตกุล

### บทคัดย่อ

**วัตถุประสงค์:** เพื่อทราบสัดส่วนมารดาที่จำใบหน้าทารกของตนเองได้หลังคลอด

**วัสดุและวิธีการ:** การสังเกตในกลุ่มมารดาและทารกที่คลอดทางช่องคลอด ไม่มีภาวะแทรกซ้อน ได้รับการดูแลทารกแบบเนื้อแนบเนื้อเป็นเวลา 15 นาที ประเมินความสามารถในการจำใบหน้าทารกที่สองชั่วโมงหลังคลอด โดยการเลือกรูปภาพทารกของตนเองจากรูปภาพทารกอีก 5 ภาพที่แตกต่างกัน

**ผลการศึกษา:** ผู้เข้าร่วมวิจัย 88 คน 54 คน (61.4%) จำใบหน้าทารกของตนเองได้ และ 34 คน (38.6%) จำไม่ได้ เมื่อเปรียบเทียบข้อมูลระหว่างมารดาทั้งสองกลุ่ม พบว่า มีปัจจัยที่แตกต่างกันอย่างมีนัยสำคัญ คือ อายุ การโอบกอดแบบเนื้อแนบเนื้ออย่างเพียงพอ และระดับการศึกษาของมารดา โดยมารดาที่อายุมากจำใบหน้าทารกได้มากกว่ากลุ่มที่อายุน้อย (adjusted odds ratio 1.115; 95% CI, 1.013 to 1.227;  $p = 0.026$ ) มารดาที่ได้รับการโอบกอดแบบเนื้อแนบเนื้อครบ 15 นาทีที่จำใบหน้าทารกของตนเองได้มากกว่า (adjusted odds ratio 4.209; 95% CI, 1.570 to 11.285;  $p = 0.004$ ) และมารดาที่จบการศึกษาชั้นมัธยมศึกษาหรือสูงกว่านั้นจำได้มากกว่า (adjusted odds ratio 5.518; 95% CI, 1.490 to 20.433;  $p = 0.011$ )

**สรุป:** ความถูกต้องในการจำใบหน้าทารกของมารดามีความไม่แน่นอน การโอบกอดแบบเนื้อแนบเนื้อ ควรปฏิบัติเพื่อเสริมสร้างสายสัมพันธ์ระหว่างมารดาและทารกมากกว่าใช้เป็นวิธีการระบุตัวตนระหว่างมารดาและทารก

**คำสำคัญ:** การจดจำใบหน้า, ความจำ, มารดาหลังคลอด, ทารก

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## Introduction

Facial recognition is imperative for the establishment and maintenance of social communication. It involves complex neuropsychological processes and is an exclusive ability of primates<sup>(1)</sup>. Humans are classified as face processing expertise, with abilities to remember and identify the faces of many different individuals. They are generally sensitive to subtle differences in facial features<sup>(2)</sup>. When a newborn is presented to a new mother immediately after delivery, a common practice is to reveal the face of the newborn along with the gender. There is a general presumption that this practice may play a role in the mother-newborn identification as the mother should be able to remember the face of her newborn. However, there is a lack of scientific evidence to support such practice. A study by Eidelman reported that only 37% of the new mothers correctly identified their newborns, which was a surprisingly low accuracy<sup>(3)</sup>. However, the study by Eidelman was conducted in 1987, when the intrapartum and postpartum care might be different from the present, especially in the aspect of early skin-to-skin contact and early bonding which was not widely practiced during the past decades<sup>(4)</sup>. Early skin-to-skin contact was known to correlate with the release of oxytocin during the immediate postpartum period<sup>(5)</sup>, and oxytocin had distinct effects on memory performance for facial identity<sup>(6)</sup>. Therefore, it is possible that the proportion of mothers who could directly identify their baby would be higher in contemporary postpartum care. The objective of this study was to determine the proportion of new mothers who could correctly recognize the faces of their newborns during the early postpartum period.

## Materials and Methods

We conducted a prospective observational study at HRH Princess Maha Jakri Sinrindhorn Medical Center, Nakorn Nayok, Thailand, during March to October 2018. The Human Research Ethics Committee at Srinakharinwirot University exempted this study from the full review (registration number SWUEC 352/60X). Healthy singleton pregnant women, who were 18 years old or above with gestational age of at least 37 weeks,

vaginally delivered a baby of 2,500 - 3,500 grams, and had a normal cognitive function, were recruited for the study. The study excluded those who had significant intrapartum and postpartum complications which may affect consciousness such as preeclampsia with severe features, eclampsia, abruptio placenta, placenta previa, prolapsed cord, ruptured vasa previa, and those who had postpartum hemorrhage. Newborns with Apgar score at 5 minutes after birth of less than 6 and who had noticeable facial marks (eg. birthmark, forceps mark) were also excluded from the study.

The consenting participants received standard intrapartum and postpartum care, including skin-to-skin contact of mother-infant pair for 15 minutes. However, in some mother-infant pairs, the duration for a skin-to-skin contact might be shorter than 15 minutes, depend on their maternal/infant mental and physical stability. The face recognition of newborn by mother was assessed two hours after delivery when the baby was brought back to the mother after initial assessment by a pediatrician. Each mother was tested her ability to recognize her newborn's face by picking the photo of her newborn's face among other five possible ones. The mother who could correctly identify the photo of her own baby from a pool of other 5 distractors was deemed as capable of recognizing hers.

All photos used in this research were in digital format taken with iPad Pro camera. The digital photos of five random babies were prepared in advance to be used as "distractors". Full face photos of each baby, which their skin tones were not detectably different, were taken with the baby facing directly to the camera, in neutral expression (eye opened, not crying). All five photos of different babies were taken on an identical background and clothing (by swaddling the baby with head covered). When preparing the photo of the participant's newborn, we used the identical process with the preparation of the distractors. The research assistants were clearly informed about the photos preparation procedure and were trained until the standard of the procedure was met. The photo of the correct newborn was mixed with other five distractors to form a digital album. All photos in the album were

presented to the mother and asked to choose the correct one of her newborn.

We assessed facial recognition at two hours after delivery, when the baby was back with the mother after initial physical examination and evaluation by a pediatrician. Before the baby was brought to the mother, the mother has chosen a photo on a tablet device which she believed to be her newborn from a pool of six different newborn's face photos. To ensure that the photo of the correct newborn was presented in the option of the six photos, the research assistant checked if the mother's last four digit of the hospital number corresponded with the code on one of the six photos in the album.

To ensure that the mother was in good consciousness, the recent memory of the mother was assessed using words recall test, modified from the Montreal Cognitive Assessment test (MoCA test)<sup>(7)</sup>, which required the mother to recall five words (face, velvet, church, daisy, red) within the next five minutes. The mother was informed about the instruction of choosing one of the photos which resembled her newborn in her opinion. However, in case that she felt none of the photos was her newborn, the "unable to recognize" was also an available option. She could spend as much time as she needs to make a decision without any rush. The mother who could correctly choose her newborn photo was categorized in "recognize" group. Meanwhile, the mothers who were unable to recognize any of the photo or chose the incorrect photo of distractors was categorized in "unrecognize" group.

With regard to sample size calculation, we estimated that 65% of the mothers would correctly recognize their newborns. With the population size of 100,000, 10% margin of error, and 95% confidence interval, the sample size of 88 participants were needed.

The statistical analysis was performed using SPSS version 25 (IBM Corp., Armonk, NY, USA). Kolmogorov–Smirnov test was used to test the normality of the distribution of data in ratio scale. The association between newborn's face recognition by mother and maternal & newborn characteristics and intrapartum factors were assessed by using chi square test, Mann-

Whitney U test, or t-test. Multivariate logistic regression analysis was used to evaluate the association between newborn's face recognition by mother and the factors which might have effects. Other statistical methods were used including percentage, mean, standard deviation, median, interquartile range, 95% confidence interval and odds ratio. The statistical significance was considered when  $p$  value  $< 0.05$ .

## Results

Among 139 eligible mothers, 94 consented to participate in the study. Six were excluded due to neonatal hypothermia and neonatal respiratory distress which could interfere the proceed of skin-to-skin contact of mother and infant. The remaining 88 participants were accounted for data analysis. Mean age of the mothers was  $27.17 \pm 5.60$  years. Seventy-three (83.0%) of the mothers graduated from a secondary school or higher, fifteen (17.0%) graduated from a primary school or lower. Twenty-one (23.9%) had incomes of less than 15,000 baht per month, while 67 (76.1%) earned more. Median time of skin-to-skin contact of maternal-newborn after the delivery was 15 minutes with interquartile range was 10 to 15 minutes. Demographic characteristics were showed in Table 1.

All participants passed the recent memory screening test using MoCA test before choosing the photos of their babies. In this study, we found that 54 mothers could correctly identify the photo of their newborns which equals to 61.4% and 34 mothers could not recognize their newborns at two hours after delivery which is 38.6%. Mean age of mother in recognized group was higher than unrecognized group ( $28.06 \pm 5.61$  vs  $25.76 \pm 5.35$  year-old, respectively). There were 57 (64.8%) mother-infant couples who completed the skin-to-skin contact protocol while other 31 mothers (35.2%) did not. In addition, there were 42 (73.7%) mothers who had completed the skin-to-skin contact protocol and could recognize their babies. However, there were 12 (38.7%) mothers who did not complete this protocol but could still recognize their babies. There were 49 (67.1%) mothers who graduated from a secondary school or higher that recognized their newborn's face. In contrast, 5 (33.3%) mothers who graduated from a primary



school or lower could correctly recognize her newborn's face. The data was shown in Table 2 (The factors that

were not a significant association did not show in the table).

**Table 1.** Demographic characteristics.

Characteristics	N
<b>Mothers factors</b>	
Age: mean $\pm$ SD (years)	27.2 $\pm$ 5.6
Education < secondary school (%)	15 (17.0%)
$\geq$ secondary school (%)	73 (83.0%)
Incomes < 15,000 baht (%)	21 (23.9%)
$\geq$ 15,000 baht (%)	67 (76.1%)
Gravid: median (IQR)	2 (1-3)
Parity: median (IQR)	2 (1-3)
Abortion: median (IQR)	0 (0-0)
<b>Newborn factors</b>	
Birth body weight: mean $\pm$ SD (grams)	3,016.7 $\pm$ 297.6
Apgar score at 1 minute: median (IQR)	9 (8-9)
<b>Intrapartum factors</b>	
Opioids use Yes (%)	2 (2.3%)
No (%)	86 (97.7%)
Oxytocin use Yes (%)	53 (60.2%)
No (%)	35 (39.8%)
Duration of labour: median (IQR), hrs	5.75 (4-8)
Duration of second stage: median (IQR), min	13 (7-19.75)
Estimated blood loss: median (IQR), ml	150 (100-250)
Mother-newborn STSC duration: median (IQR), min	15 (10-15)

SD: standard deviation, IQR: interquartile range, STSC: skin-to-skin contact

**Table 2.** The association of significant factors and newborn's face recognition by their mothers.

Factors	Newborn's face recognition by mothers	
	Recognized group N = 54	Unrecognized group N = 34
Maternal age: mean $\pm$ SD, years	28.1 $\pm$ 5.6	25.8 $\pm$ 5.4
Adequate STSC		
Yes, n (%)	42 (73.7%)	15 (26.3%)
No, n (%)	12 (38.7%)	19 (61.3%)
Maternal education		
$\geq$ secondary school, n (%)	49 (67.1%)	24 (32.9%)
< secondary school, n (%)	5 (33.3%)	10 (66.7%)

STSC: skin-to-skin contact, SD: standard deviation

We compared demographic data and intrapartum factors between two groups of mothers, those who could correctly recognize their newborns and those who could not. There were some statistical differences in the characteristics of the two groups by using multiple logistic regression analysis. This included maternal age, maternal educational level, and adequacy of skin-to-skin contact between the mother and the newborn. No statistical difference was observed in the characteristics of parity, baby birth weight, Apgar score, intrapartum opioid usage, intrapartum oxytocin usage, labor duration, second stage of labor duration and estimated blood loss.

In the detail of significant characteristics, the older mothers had a significant higher rate of newborn recognition than the younger mothers (adjusted odds ratio 1.115; 95% CI 1.013-1.227;  $p = 0.026$ ). The mothers who completed 15 minutes of skin-to-skin contact protocol had a statistically significant greater ability to recognize their babies (adjusted odds ratio 4.209; 95% CI 1.570-11.285;  $p = 0.004$ ). Concerning maternal education, those who graduated from at least a secondary school also had a statistically significant higher rate of newborn's face recognition (adjusted odds ratio 5.518; 95% CI 1.490-20.433;  $p = 0.011$ ) (Table 3).

**Table 3.** Factors influencing the face recognition of the newborns by their mothers.

Factors	Crude OR	95%CI	p value	Adjusted OR <sup>†</sup>	95%CI	p value
Maternal age (years)	1.080	0.996-1.171	0.064	1.115	1.013-1.227	0.026*
Adequate STSC						
Yes	4.433	1.745-11.266	0.002*	4.209	1.570-11.285	0.004*
No	1	-	-	1	-	-
Maternal education						
≥ secondary school	4.083	1.256-13.280	0.019*	5.518	1.490-20.433	0.011*
< secondary school	1	-	-	1	-	-

<sup>†</sup> Adjusted by maternal age, baby birth weight, estimated blood loss, adequacy of skin-to-skin contact, maternal educational level, and maternal incomes

OR: odds ratio, STSC: skin-to-skin contact, \* statistically significant, 95%CI: 95% confidence interval

## Discussion

Sixty-one percent of the mothers in the present study were able to accurately recognize their newborns. This was much higher than the previous study conducted by Eidelman et al in 1987, which reported only 37% of the mothers correctly recognized their newborns. The result of this study was contradictory to the general belief that mothers could accurately recall the faces of their own babies immediately after birth. It should be noted that the newborn is considered a face of a stranger according to the mother, and remembering unfamiliar faces is a great challenge to human perception and memory systems.

Previous research had shown that neural activity

used for remembering a familiar face differ from those of an unfamiliar face<sup>(8, 9)</sup>. When seeing a face of a stranger, the brain generally shows an activity in the lateral fusiform gyrus. On the other hand, when a familiar face is seen, the brain activity shows domination on the anterior temporal region<sup>(10)</sup>. According to previous studies, facial recognition was strikingly poor for unfamiliar faces<sup>(11)</sup> with 69.5% of correct identification of unfamiliar faces. Our current study reflected the mothers could correctly recognize their newborns' faces at such equivocal percentage. Also, changes of facial features of the newborn over time, due to tissue edema of the face which may be alleviated at later hours of life, could interfere with the recollection of the newborn's

face by the mother.

Maternal age, maternal educational level, and adequacy of skin-to-skin contact were statistically different between the “recognize” and the “unable to recognize” groups. According to Germine et al’s study in 2010, psychologists found that the ability to recognize and remember faces continually and slowly increased throughout the age of 20s and reached a peak at the age of 30 to 34 years old. After this, face recognition skills declined slowly<sup>(12)</sup>. For those with adequate skin-to-skin contact, the mothers were more likely to correctly recognize their babies. According to the study of Phillips in 2013, oxytocin was often referred as the “love hormone” that was shown to increase relaxation, attraction, facial recognition, and maternal caregiving behaviors<sup>(13)</sup>. Also, the mothers who graduated from a secondary school had a higher capacity to correctly recognize her newborn’s face. This was because the performance in reasoning domain of cognitive function was related to higher educational level<sup>(14)</sup>.

In contemporary medicine, many currently used mother-infant identification methods are effective enough to prevent baby mix-up in hospitals. At our hospital, the bracelet tag indicating maternal name and hospital number are placed on the newborn wrist and ankle. Biometrics data of the infant including palmprints, fingerprints and footprints may also be used as an identification procedure<sup>(15-17)</sup>. Despite the ongoing progress and widespread use of facial recognition technology, research on its use for newborns is still lacking. We, therefore, suggest that further research to explore the use of facial recognition technology for newborns, specifically in terms of its practicality and accuracy, should be undertaken.

There were some limitations in this study. First, the assessment of facial recognition by asking a mother to choose a photo of her newborn’s face might be lack of reality. It would be more appropriate to evaluate the ability to recognize the baby by using the selection of the actual newborn from the pool of other five newborns. However, considering the ethical issues, presenting other newborns as distracters were prohibited and not appropriate, so such an assessment method could not

be implemented. Second, there might be some specific characteristics that affect maternal recognition of her newborn’s face such as layer of eyelids, sex of the newborn which did not control in this study. Third, there was not a confirmative process whether the correctness of mother’s recognition of her newborn’s face was based on her memory or by accident. The last limitation was the duration of skin-to-skin contact was not controlled to archive 15 minutes as suggested in the hospital protocol. Although we strongly believed that the duration of skin-to-skin contact was an essential factor for boosting the rate of newborn facial recognition, controlling the duration may pose a challenge of not prioritizing the maternal need for how long she would like to hold her child. Some mothers might feel too exhausted to hold the child for the full 15 minutes and it was our responsibility to respect the patients’ decisions. However, when a subgroup analysis was done, the mothers who completed the 15-minute skin-to-skin contact could correctly recognize her baby at the higher rate than those with shorter duration. This finding supports our hypothesis that the longer the period of time mothers contact with newborns during the immediate postpartum is, the higher the rate of recognizing the newborns is.

In summary, given the equivocal accuracy of facial recognition of the newborns by their mothers presented in this study, we suggest that the practice of introducing the face of newborns at time of birth should not be viewed as a process for mother-infant identification but rather as an action to establish the bonding between them.

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## Potential conflicts of interest

The authors declare no conflict of interest.

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## OBSTETRICS

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# Factors Affecting the Decision to Participate in Down Syndrome Screening of Pregnant Women at HRH Princess Maha Chakri Sirindhorn Medical Center

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### ABSTRACT

**Objectives:** To evaluate the factors which affect Thai pregnant women's decision to participate in prenatal Down syndrome (DS) screening, including their knowledge and attitudes.

**Materials and Methods:** An analytic cross sectional study of 326 self-administered questionnaires from Thai pregnant women who attended their first antenatal care clinic at HRH Princess Maha Chakri Sirindhorn Medical Center (MSMC) between June and December 2018 were collected. The participants' knowledge and attitudes on DS and DS screening tests, including their acceptance in prenatal DS screening, were examined. Factors which affected their decision to whether or not participate in screening were also evaluated.

**Results:** The mean age of the participants was  $29.1 \pm 5.6$  years. Regarding their knowledge on DS, 30.7% of the participants were classified as having good knowledge. However, only 7.4% of the participants were classified as having good knowledge on prenatal DS screening. The percentages of the participants with positive, neutral and negative attitudes on DS and DS screening were 12.9%, 42.9% and 44.2%, respectively. Multivariate logistic regression revealed that pregnant women with an education level of bachelor degree or higher and familial income of  $\geq 30,000$  Baht per month were more likely to accept DS screening, but these did not reach statistical significance. Most participants (297/326, 91.1%) in our study agreed to participate in DS screening, with the majority (116/297, 35.6%) selecting integrate test. Also, most agreed that the cost of screening test should not exceed 5,000 baht and the test should be done in general provincial hospital. Over half of the participants (179/326, 54.9%) believed that pregnant women's personal health coverage should be responsible for the cost.

**Conclusion:** An education level of bachelor degree or higher and familial income of  $\geq 30,000$  baht per month are potential factors associated with the pregnant women's decision to accept DS screening.

**Keywords:** Down syndrome, screening, factors, acceptance, knowledge, attitude.

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# ปัจจัยที่มีผลต่อการตัดสินใจเข้ารับการตรวจคัดกรองทารกกลุ่มอาการดาวน์ของสตรีตั้งครรภ์ไทยที่ศูนย์การแพทย์สมเด็จพระเทพรัตนราชสุดา ฯ สยามบรมราชกุมารี

มรุต วณิชชานนท์, อรสา เหมะจันทร์

## บทคัดย่อ

**วัตถุประสงค์:** เพื่อศึกษาปัจจัยที่มีผลต่อการตัดสินใจเข้ารับการตรวจคัดกรองทารกกลุ่มอาการดาวน์ของสตรีตั้งครรภ์ไทย ซึ่งรวมไปถึงความรู้และทัศนคติต่อภาวะดาวน์และการตรวจคัดกรองทารกกลุ่มอาการดาวน์

**วัสดุและวิธีการ:** เป็นการศึกษาวิจัยเชิงวิเคราะห์โดยให้สตรีตั้งครรภ์ไทยผู้ซึ่งมาฝากครรภ์ครั้งแรกที่ห้องตรวจครรภ์ของศูนย์การแพทย์สมเด็จพระเทพรัตนราชสุดา ฯ สยามบรมราชกุมารี จำนวน 326 ราย ตอบแบบสอบถามหลังจากรับฟังการให้คำปรึกษาและแนะนำเรื่องการตรวจคัดกรองทารกกลุ่มอาการดาวน์ โดยทำการเก็บข้อมูลตั้งแต่เดือนมิถุนายน ถึง ธันวาคม 2561 ในการศึกษาดังกล่าวได้มีการเก็บข้อมูลในส่วนของความรู้และทัศนคติของทั้งกลุ่มอาการดาวน์และการตรวจคัดกรองทารกกลุ่มอาการดาวน์ รวมไปถึงการตัดสินใจของสตรีตั้งครรภ์ที่เข้าร่วมงานวิจัยในการเข้ารับการตรวจคัดกรองและเหตุผลประกอบ นอกเหนือจากปัจจัยเหล่านี้แล้วยังมีการศึกษาเกี่ยวกับปัจจัยอื่นๆซึ่งมีผลต่อการตัดสินใจเข้ารับการตรวจคัดกรองอีกด้วย โดยข้อมูลได้ถูกรวบรวมและวิเคราะห์โดยใช้สถิติ Chi-square และ logistic regression analysis

**ผลการศึกษา:** สตรีตั้งครรภ์ที่เข้าร่วมงานวิจัยมีอายุเฉลี่ยเท่ากับ  $29.17 \pm 5.6$  ปี โดยสัดส่วนของสตรีตั้งครรภ์ที่มีความรู้เกี่ยวกับภาวะกลุ่มอาการดาวน์และการตรวจคัดกรองทารกกลุ่มอาการดาวน์อยู่ในเกณฑ์ที่ดีคิดเป็นร้อยละ 30.7 และ 7.4 ตามลำดับ ในเชิงทัศนคติสัดส่วนของสตรีตั้งครรภ์ที่เข้าร่วมงานวิจัยซึ่งมีทัศนคติในแง่บวก เป็นกลางและแง่ลบคิดเป็นร้อยละ 12.9, 42.9 และ 44.2 ตามลำดับ ปัจจัยที่มีแนวโน้มที่จะมีผลต่อการตัดสินใจเข้ารับการตรวจคัดกรองทารกกลุ่มอาการดาวน์ของสตรีตั้งครรภ์ได้แก่การจบการศึกษาระดับปริญญาตรีขึ้นไปและรายได้ครอบครัวที่มากกว่าหรือเท่ากับ 30,000 บาทต่อเดือนถึงแม้ว่าจะไม่มีนัยสำคัญทางสถิติ สตรีตั้งครรภ์ในการศึกษาส่วนมากเลือกที่จะเข้ารับการตรวจคัดกรองทารกกลุ่มอาการดาวน์ (ร้อยละ 91.1) โดยร้อยละ 35.6 ของผู้ที่ตัดสินใจเข้ารับการตรวจทั้งหมดเลือกวิธี integrate test นอกเหนือจากนี้สตรีตั้งครรภ์ส่วนมากเห็นด้วยว่าราคาของการตรวจคัดกรองไม่ควรเกิน 5,000 บาทและการตรวจคัดกรองควรทำในโรงพยาบาลจังหวัดหรือโรงพยาบาลศูนย์ในส่วนของผู้รับผิดชอบค่าใช้จ่ายในการตรวจคัดกรอง สตรีตั้งครรภ์ส่วนมาก (ร้อยละ 54.9) เห็นด้วยว่าควรขึ้นอยู่กับสิทธิของการรักษาของตน

**สรุป:** ปัจจัยซึ่งมีแนวโน้มที่จะมีผลต่อการตัดสินใจเข้ารับการตรวจคัดกรองทารกกลุ่มอาการดาวน์ของสตรีตั้งครรภ์ไทยได้แก่การจบการศึกษาระดับปริญญาตรีขึ้นไป และรายได้ครอบครัวที่มากกว่าหรือเท่ากับ 30,000 บาทต่อเดือน

**คำสำคัญ:** กลุ่มอาการดาวน์, การคัดกรอง, ปัจจัย, การยอมรับ, ความรู้, ทัศนคติ

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## Introduction

Down syndrome (DS) or trisomy 21 represents the most common genetic cause of moderate to severe mental retardation and the most common chromosomal abnormality of the newborn. However, it is most compatible with survival compared with other autosomal trisomies<sup>(1, 2)</sup>. Its incidence is around 1 in 700 to 800 live births<sup>(2)</sup>. It is associated with characteristic physical features and multiple congenital anomalies, involving organs such as the heart, gastrointestinal tract, thyroid gland, eyes and ears<sup>(3,4)</sup>. However, the most concerning problems are developmental delay and mental retardation as these may imply significant social costs due to the special care needed<sup>(2,4)</sup>. In Thailand, around 1,000 cases of DS are delivered yearly<sup>(5)</sup>. At HRH Princess Maha Chakri Sirindhorn Medical Center (MSMC), a university hospital located in Nakhon Nayok province of Thailand, there are approximately 1,800 to 2,000 deliveries per year which result in 0-3 DS cases if no screening strategy.

Generally, the risk of a pregnant woman having a DS fetus increases steeply when maternal age is 35 years or older<sup>(1,3)</sup>. The American College of Obstetricians and Gynecologists (ACOG) has been recommending that DS screening should be offered to all women who are pregnant regardless of age since 2007<sup>(6,7)</sup>. Over the past years, a wide range of prenatal screening tests for DS have been developed with predictive rates obtained either with a single test or a combination of several tests. Thus, this allows an offering of multiple options for pregnant women to select based on their informed choices. Prenatal DS screening tests are non-invasive, and those with positive screening results are offered a diagnostic test such as amniocentesis, chorionic villus sampling or cordocentesis to determine fetal karyotype<sup>(7-9)</sup>.

A variety of factors may influence the

pregnant woman's decision to accept a screening test including her knowledge and attitude towards both DS and the screening tests. At present, most studies concerning the pregnant women's knowledge and attitudes of DS, its screening tests and the factors which affect their decision to accept screening have been carried out in Western countries<sup>(10-13)</sup>. Although knowledge and attitude may directly influence their decision, factors such as maternal age<sup>(12,13)</sup>, ethnicity<sup>(12,13)</sup>, religion, education level<sup>(13)</sup> and familial income may also be crucial. In addition, previous miscarriage<sup>(11,12)</sup>, previous antenatal counseling on prenatal testing<sup>(11-12,14)</sup> and number of antenatal visits<sup>(11)</sup> have been shown to associate with screening uptake.

In Asian countries, including Thailand, extensive studies of pregnant women's knowledge and attitudes towards DS and screening have been widely carried out<sup>(5,15-17)</sup> but the evaluation of significant factors affecting their decision to undertake screening is lacking. Previously, two large cross-sectional studies were carried out in Thailand's university hospitals examining the knowledge and attitudes of pregnant women<sup>(5,15)</sup>. Unfortunately, these studies were conducted for almost a decade at the time when prenatal DS screening was firstly introduced in Thailand. Since that time, many issues dealing with Thailand's social context have changed, such as the extended use of social media and the internet to gain information and more effective genetic counselling which have been increasingly offered in various medical institutions.

At MSMC, genetic counselling has been offered to all pregnant women at their first visit to our antenatal clinic beginning in 2012. This includes information on the available DS screening tests, the appropriate gestational age for testing considering every available option, each individual test's detection rate and cost. In recent years, there have been approximately 150-200 pregnant

women who visited our first antenatal care clinic per month. However, only about 12-14% of those attending our clinic decided to undergo a DS screening test. Thus, the primary objective of this study was to evaluate the factors which affect Thai pregnant women's decision to participate in prenatal DS screening, including their knowledge and attitudes. The secondary objectives were to evaluate their decisions and preferences of screening tests, reasons for making a decision, affordable cost, preferred place for testing and responsibility of screening payment.

## Materials and Methods

This analytic cross-sectional study was conducted among pregnant women who attended antenatal care clinic at MSMC, Faculty of Medicine, Srinakharinwirot University, Ongkharak, Nakhon Nayok, Thailand, between June and December 2018. It was approved by the research Ethics Committee of the Faculty of Medicine, Srinakharinwirot University (registry number: SWUEC/E-025/2561). After the informed consents from all participants were obtained, they were asked to complete the questionnaires during the first antenatal visit. This was done immediately after the routine patient education program was offered to all new attendants at our antenatal care (ANC) clinic. The inclusion criteria were all pregnant Thai women who were 18 years of age or older who came for the first antenatal visit at MSMC. Participants who could not read or write Thai, were unable to fully complete the questionnaire by themselves, or whose fetus was already diagnosed with any structural anomalies were excluded. The sample size for the study was calculated by Yamane's formula<sup>(18)</sup>, and the data of the number of Thai pregnant women aged 18 years or older who made a first ANC visit at MSMC in 2017 which matched the inclusion and exclusion criteria of the current study was 1,772. Based on this, a total of 326 completed

questionnaires were required and used to analyze. To account for possible attrition of 20%, 408 questionnaires were collected.

The questionnaire, which consisted of five parts, was adapted from previous studies<sup>(5,10)</sup>. Part I consisted of the participants' demographic information including their age, ethnicity, religion, current residence, level of education, familial income, gravida, parity, personal and familial history of having a DS child, history of any previous fetal congenital anomaly, and the type of health coverage. Part II included information on the routes by which the participants have received counselling or information about DS and 10 items which focused on their knowledge about DS. Part III comprised of information on the routes by which the participants have received counselling or information about DS screening and 15 items which focused on their knowledge about DS screening tests. Part IV contained 15 items which focused on the participants' attitudes. The participant's opinion on each question was expressed based on five Likert scales: strongly disagree, disagree, uncertain, agree, and strongly agree. Finally, Part V of the questionnaire focused on the participant's decision to whether or not accept the DS screening test. If the participant chose to accept the DS screening, the preferable screening method was asked. To aid the participant's decision-making process, a table of four screening tests available at our ANC clinic (first trimester screening, quad test, integrate test, and non-invasive prenatal test (NIPT)) along with their suitable gestational age range for testing, detection rate and cost was provided. If the participant's gestational age at the first antenatal visit was too advanced, her opinion on the preferable choice of screening was asked instead. In addition, the final part included information on the participant's economic capability of payment, the preferred screening location and total cost support.

The questionnaire used in our study was evaluated for validity in the knowledge about DS and its screening tests by three maternal fetal medicine specialists. Using Cronbach's alpha statistic, the reliability of the questionnaire was calculated based on a pilot study of 50 volunteers to be 0.83.

Data collection and analyses in this study were done using Statistical Package for the Social Sciences, Windows version 22.0 (SPSS Inc., Chicago, IL, USA). Baseline demographic data and characteristics of all participants were expressed as percentages or as a means with a standard deviation (SD). The total knowledge score on DS and DS screening was summed after giving a score of -1 for incorrect answer, 0 for do not know, and 1 for correct answer in each question. The correct and incorrect answers were based on scientific knowledge which the participants should be aware before antenatal DS screening. The possible sum score of knowledge on DS ranged from -10 to 10. All participants were categorized into three levels: poor (defined as score  $\leq 1$ ), intermediate (defined as score 2-4) and good (defined as score 5-10). Whereas, the possible summed score of knowledge on DS screening ranged from -15 to 15. The participants were also categorized into three levels: poor (defined as score  $< 2$ ), intermediate (defined as score 3-7) and good (defined as score 8-15).

For the analysis of attitude, the scores for each participant was summed, giving -2 for strongly disagree, -1 for disagree, 0 for uncertain, 1 for agree and 2 for strongly agree. Therefore, the possible summed score ranged from -30 to 30. All participants were categorized into three groups of attitudes: negative (defined as score of -30 to 8), neutral (defined as score of 9-14) and positive attitude (defined as score of 15-30).

Each dependent factor in our study was categorized as dichotomous variables including

maternal age ( $< 35$  vs  $\geq 35$  years old), religion (Buddhism vs others), current residence (Bangkok & nearby vs others), education (bachelor degree or higher vs lower than bachelor degree), family income per month ( $< 30,000$  vs  $\geq 30,000$ ), history of having a child with DS (yes vs no), history of having a child with congenital anomaly (yes vs no), health coverage (payment by other vs. self-paid), knowledge on DS and DS screening (good vs. intermediate to poor), and attitude (positive vs neutral to negative). Factors affecting the Thai pregnant women's decision to accept DS screening were initially analyzed using the chi-square test and the prevalence rate ratio was expressed for each factor. Then, univariate and multivariate logistic regression models were constructed to identify factors which were independently and significantly associated with the pregnant women's acceptance to participate in DS screening. The p value of  $< 0.05$  was considered as statistically significant in all tests performed in this study.

Finally, this study analyzed the final decision on the acceptance of antenatal DS screening and presented it as the percentages of participants who agreed, disagreed, or felt uncertain about screening. In addition, the percentages for the reasons why the participants chose to agree, disagree or felt uncertain, the affordable cost of screening, the preferred places for screening, and economic support preference were also presented.

## Results

Demographic characteristics of the 326 participants based on the complete questionnaires are presented in Table 1. Mean  $\pm$  SD for maternal age was  $29.1 \pm 5.6$  years. One participant had a previous history of having a DS child while one participant had a history of a child having congenital anomaly.

**Table 1.** Participant demographic characteristics (n = 326).

Characteristics	N (%)
Age (years)	
18-34	262 (80.4)
≥ 35	64 (19.6)
Ethnicity	
Thai	326 (100.0)
Chinese	0 (0.0)
Others	0 (0.0)
Religion	
Buddhist	283 (86.8)
Muslim	38 (11.7)
Others	5 (1.5)
Current residence	
Bangkok & nearby	199 (61.0)
Others	127 (39.0)
Level of Education	
High school or less	178 (54.6)
Bachelor degree	127 (39.0)
Higher than bachelor degree	21 (6.4)
Family income (Baht/month)	
< 15,000	93 (28.5)
15,000 - 29,999	158 (48.5)
≥ 30,000	75 (23.0)
Nulliparous	136 (41.7)
Primigravida	118 (36.2)
History of having a DS child	1 (0.3)
History of having a child with congenital anomaly	1 (0.3)
Family history of Down syndrome/mental retardation	
Yes	0 (0.0)
No	325 (99.7)
Unknown	1 (0.3)
Type of health coverage	
Self-paid	113 (34.7)
Civil servant medical benefit scheme	37 (11.4)
Social security scheme	153 (46.9)
Government universal coverage	22 (6.7)
Others	1 (0.3)

Concerning the knowledge on DS and DS screening, the percentages of the correct, incorrect, and do not know answer for each individual question were calculated. The three most common routes in which the participants gained their knowledge about DS were from a physician (82.2%), a medical provider (73.3%), and social media or the internet (57.4%). Medical providers included registered nurses, practical nurses and public health officers. The number of the participants who had good, intermediate and poor knowledge on DS were 100/326 (30.7%), 196/326

(60.1%) and 30/326 (9.2%), respectively. The majority of the patients (75.2%) were aware that DS is a genetic disease, and that the risk of having a fetus with DS increases as the maternal age advances (89.6%). Furthermore, most participants understood that children with DS need someone to take special care of them (93.9%) and that they could be trained (85.9%). For the knowledge on DS screening tests, most participants gained their knowledge from a physician (90.2%), a medical provider (77.3%), and social media or internet (38.7%). The number of the participants who had

good, intermediate and poor knowledge on DS screening were 24/326 (7.4%), 241/326 (73.9%) and 61/326 (18.7%), respectively. The majority appreciated that DS screening could be performed during the prenatal period (96.0%) and the time at which it could be performed depends on the screening method (90.5%). In addition, almost all pregnant women in this study were aware that the tests are performed only to screen for disease or abnormalities of the fetus (97.2%).

In our study, the number of patients with positive, neutral and negative attitudes were 42/326 (12.9%), 140/326 (42.9%) and 144/326 (44.2%), respectively. Most participants appreciated that the DS screening tests could be beneficial to all pregnant women regardless of their age (92.6%), and that the performance

of these tests could relieve the anxiety of the pregnant women (92.6%).

The factors affecting the Thai pregnant women's decision to participate in DS screening from our study are shown in Table 2. One participant of 326 who was unsure whether or not she would participate in DS screening was not included in this non-parametric chi-square test. The only statistically significant factor was having a family income of  $\geq 30,000$  Baht per month. Pregnant women with age  $> 35$  years old, who are a Buddhist, an education level of bachelor degree or higher, a previous history of having a DS child or child with congenital anomaly, and a good knowledge on DS and DS screening, were more likely to accept a DS screening test but without statistical significance.

**Table 2.** Factors affecting the decision to accept DS screening (n = 326).

Characteristics	Acceptance		Prevalence rate ratio	95% CI	p value
	Deny	Accept			
Age (years)					
$\geq 35$ (%)	4 (6.2)	60 (93.8)	1.036	0.962-1.117	0.407
$< 35$ (%)	25 (9.5)	237 (90.5)			
Religion					
Buddhism (%)	23 (8.1)	260 (91.9)	1.068	0.942-1.210	0.245
Others (%)	6 (14.0)	37 (86.0)			
Current residence					
Bangkok & nearby (%)	18 (9.1)	180 (90.9)	0.995	0.928-1.066	0.878
Others (%)	11 (8.6)	117 (91.4)			
Education					
Bachelor degree or higher (%)	2 (3.1)	62 (96.9)	1.080	1.017-1.147	0.070
Lower than bachelor degree (%)	27 (10.3)	235 (89.7)			
Family income (Baht/month)					
$\geq 30,000$ (%)	2 (2.7)	73 (97.3)	1.091	1.030-1.155	0.031*
$< 30,000$ (%)	27 (10.8)	224 (89.2)			
Previous history of having DS child					
Yes (%)	0 (0.0)	1 (100.0)	1.098	1.061-1.136	1.000
No (%)	29 (8.9)	296 (91.1)			
Previous history of having a child with congenital anomaly					
Yes (%)	0 (0.0)	1 (100.0)	1.098	1.061-1.136	1.000
No (%)	29 (8.9)	296 (91.1)			
Health coverage					
Payment by others (%)	21 (9.9)	192 (90.1)	0.970	0.907-1.038	0.402
Self-paid (%)	8 (7.1)	105 (92.9)			
Knowledge on DS					
Good (%)	6 (6.0)	94 (94.0)	1.047	0.980-1.118	0.222
Intermediate to poor (%)	23 (10.2)	203 (89.8)			
Knowledge on DS screening					
Good (%)	2 (8.3)	22 (91.7)	1.007	0.888-1.141	1.000
Intermediate to poor (%)	27 (8.9)	275 (91.1)			
Attitude					
Good (%)	5 (11.9)	37 (88.1)	0.962	0.856-1.081	0.398
Neutral to negative (%)	24 (8.5)	260 (91.5)			

CI: confidence interval, DS: Down syndrome

In Table 3, the logistic regression analysis of factors affecting the pregnant women's decision to accept DS screening is shown. Bivariate logistic regression showed that pregnant women with familial income  $\geq$  30,000 Baht per month and education level of bachelor degree or higher are more likely to accept DS screening,

but only the income factor was statistically significant. Multiple logistic regression showed that again, both familial income  $\geq$  30,000 Baht per month and education level of bachelor degree or higher are more likely to accept DS screening; however, both factors did not reach statistical significance.

**Table 3.** Logistic regression analysis of factors affecting the decision to accept DS screening. (n = 326)

Characteristics	Crude OR <sup>a</sup>	95% CI	p value	Adjusted OR <sup>b</sup>	95% CI	p value
Familial income (Baht/month)						
$\geq$ 30,000	4.400	1.021 - 18.952	0.047*	4.293	0.994 - 18.549	0.051
< 30,000						
Education						
Bachelor degree or higher	3.562	0.824 - 15.388	0.089	3.453	0.795 - 14.987	0.098
Lower than bachelor degree						

CI: confidence interval, OR: odds ratio

<sup>a</sup> Estimated by binary logistic regression, <sup>b</sup> Estimated by multiple logistic regression, adjusted for religion, education, familial income and knowledge on DS.

Finally, Table 4 represents the participants' decision to whether or not accept DS screening, the reasons for agreement or disagreement to participate, their affordable costs, the preferred locations for screening and their preference for total cost support. For those patients who accepted to participate in DS screening, the percentages for the individual tests they would prefer are also shown. Of those who agreed to undergo DS screening (297/326,

91.1%), the two most common choices were integrate test (116/326, 35.6%) and cell-free fetal DNA test (87/326, 26.7%). The majority of the participants who chose to screen for DS wished to evaluate the risk of having a DS fetus and determine the fetal sex. For those who denied to participate in DS screening (28/326, 8.6%), most were worried about the high cost of the price and fear of the venipuncture pain.

**Table 4.** Decision for acceptance of Down syndrome screening. (n = 326)

	N (%)
Agreed to participate in DS screening	297 (91.1)
(1) First trimester screening	63 (19.3)
(2) Quad test	31 (9.5)
(3) Integrate test	116 (35.6)
(4) Cell-free fetal DNA testing / NIPT	87 (26.7)
Denied to participate in DS screening	28 (8.6)
Unsure about participation in DS screening	1 (0.3)
Affordable costs of screening (Thai Baht)	
< 500	11 (3.4)
501 - 5,000	248 (76.1)
5,001 - 10,000	46 (14.1)
10,001 - 20,000	21 (6.4)
Preference for total cost support	
Self-paid	39 (12)
Based on personal health coverage	179 (54.9)
Total governmental support	108 (33.1)
Preferred locations for screening <sup>a</sup>	
Public health center	20 (6.1)
Primary community public hospital	51 (15.6)
General provincial hospital	288 (88.3)
Tertiary or university hospital	106 (32.5)
Private hospital	101 (31)
Private clinic	38 (11.7)

<sup>a</sup> Participants could choose more than one response. DS: Down syndrome, DNA: deoxyribonucleic acid, NIPT: Non-Invasive Prenatal Testing



## Discussion

Our study is a relatively recent study to evaluate the factors influencing pregnant women's decision to accept DS screening, including their knowledge and attitudes, on DS and its screening methods in a developing country such as Thailand. Participants in our study lived in various areas of Thailand, with a variety of levels of education, family incomes and types of health coverage. Almost all participants had no previous history of a child with DS or congenital anomaly. Only one participant was unsure whether or not any of her family members has DS. Our participants had baseline characteristics which were commonly found in other pregnant women. Thus, the results of this study could represent as the Thai data.

Based on the results of this study, the levels of knowledge for both DS and DS screening tended to be intermediate to poor and hence needed to be improved. This was similar to previous studies conducted in university hospitals in Thailand in which the majority of Thai pregnant women had inadequate knowledge on DS screening<sup>(5,15)</sup>. For the participants' attitude, the majority of them in our study had a negative attitude (44.2%). This differs from the previous studies in which the majority of the patients had positive attitudes towards DS and DS screening<sup>(5, 7, 10, 15)</sup>. We believe that by building the pregnant women's knowledge on DS and its screening tests, their attitudes would be improved. This would lead to an overall increase in the rate of DS screening at our institution and thus in Thailand. In addition to arranging a routine academic program using an audiovisual presentation which includes information on DS and DS screening for all pregnant women who make their first visit to our ANC clinic, we plan to provide further genetic counseling methods. Counseling has been shown to be a key role in pregnant women's informed decision and thus is essential to ensure understanding of advantages and limitations of prenatal testing and further actions if there is a positive result<sup>(19-22)</sup>. For instance, a leaflet, a poster or person-to-person counseling by a physician or medical staff may be utilized. The various methods may be compared and the patients' knowledge scores and

attitudes can be re-evaluated<sup>(14, 20)</sup>.

Several studies were conducted at university hospitals in Thailand regarding knowledge and attitudes of Thai pregnant women on DS and its screening. A study from Maharaj Nakorn Chiang Mai Hospital found that most Thai pregnant women had adequate knowledge on DS but not on its screening tests. The majority of the patients had positive attitudes and almost all participants accepted DS maternal serum screening<sup>(15)</sup>. Although most questionnaire items were similar compared with our study, they did not include items evaluating attitudes towards specific DS screening tests. In addition, unlike our study, the categories of response in evaluating attitudes were different; there were only three categories (agree, neutral, disagree)<sup>(15)</sup>. These factors could have led to contrasting results concerning attitudes between studies. Another study conducted by Songklanagarind Hospital depicted that Thai pregnant women had inadequate knowledge in both DS and screening tests<sup>(5)</sup>. Factors that affected their knowledge on DS included levels of education, familial income and types of health coverage. However, the two factors that affected knowledge on DS screening tests were levels of education and types of health coverage. Maternal age was the only significant factor affecting attitudes<sup>(5)</sup>. Most participants in that study had a positive attitude towards DS screening, which again was different from our study. The study focused on evaluating two main aspects of attitude separately: towards DS screening and acceptance of having DS child<sup>(5)</sup>. However, our study evaluated a wider number of aspects including attitudes towards DS, acceptance of having a DS child and different types of DS screening methods; the responses were then analyzed simultaneously to represent the overall attitude of the pregnant women. The results of the latter study were similar to our study in that most patients had intermediate to poor knowledge on DS and its screening tests. The drawback of the previous studies was that they were conducted at the time when prenatal DS screening tests have only been implemented in Thailand for a short while. Many aspects in the social context have obviously evolved over time, including

advancements in visual aids and media used for genetic counseling. We believe these changes could have affected Thai pregnant women's knowledge and attitude levels and thus our current study was conducted also in a university hospital setting.

In our study, based on the chi-square test, the only factor with statistical significance was family income of  $\geq 30,000$  Baht per month. Further multivariate logistic regression analysis showed that Thai pregnant women with family income of  $\geq 30,000$  Baht per month and education level of bachelor degree or higher were more likely to accept DS screening, although these nearly achieved statistical significance. The statistical analyses from our study reflected that income was an important determinant in pregnant women's decision. Although income is a non-modifiable factor, we believe that the government has a role in setting an appropriate screening cost by establishing an effective policy on prenatal DS screening to cover every pregnant woman.

In our study, 91.1% (297/326) of the participants agreed to participate in DS screening with 35.6% (116/326) preferring integrate test and 26.7% (87/326) preferring NIPT. Although NIPT is more costly compared with other screening tests, we believe that many participants still chose NIPT because of its higher detection rate and reduction in false positive rate<sup>(23)</sup>. Most participants wished to evaluate the risk of having a DS fetus and determine the fetal sex. For those who denied to participate in DS screening (28/326, 8.6%), most were worried about the high cost of the price and fear of the venipuncture pain. Therefore, we postulate that psychotherapy and any local anesthetic agent might be offered to individuals with significant degree of fear of venipuncture pain. Another interesting aspect of our study was that most participants preferred general provincial hospital and tertiary or university hospital as screening places. We believe that this is due to patients' confidence in larger medical institutions with a greater number of trained and experienced staffs, including ultrasonologists, and equipments available. The results of our secondary outcomes cannot be compared to other studies because these aspects have never been extensively studied especially in developing countries

like Thailand.

The strengths of our study were its analytic cross-sectional nature and that the included participants may represent all Thai pregnant women based on their varied demographic background. Also, it is one of the first studies in Thailand to evaluate the factors affecting DS screening uptake in a large medical institution such as our university hospital. We believe that the results from this study should raise awareness in our institution and all others in Thailand to promote effective genetic counseling aimed to improve Thai pregnant women's knowledge and attitudes. The government should also carefully consider its universal prenatal DS screening policy to the general Thai population in order to increase access to screening for a greater proportion of Thai pregnant women. Consequently, the overall rate of DS screening should be increased across Thai population. A drawback of our study was the nature of the questionnaire which only asked for the participants' opinion on the preferred screening test if they had agreed to participate. Data on whether or not those participants who agreed to undergo screening really did the test was not collected as this was outside the scope of our study. In addition, there could have been a selection bias because of the variability in baseline maternal demographic characteristics in different clinical settings. Further analysis on the data based on whether or not the pregnant women really undergo screening could be done to evaluate the actual screening rate instead of asking for their opinions. Also, future studies may use a larger sample size to detect more significant factors associated with Thai pregnant women's acceptance towards DS screening. This would build a greater understanding of the significant factors, leading to establishment of effective strategies aimed to increase Thailand's DS screening.

## Conclusion

Thai pregnant women's knowledge on DS and DS screening were mostly intermediate to poor and most of them had negative attitudes. An education level of bachelor degree or higher and family income of  $\geq 30,000$  Baht per month were factors affecting Thai

pregnant women's decision to accept DS screening, although these nearly reached statistical significance.

## Acknowledgment

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## Potential conflicts of interest

The authors declare no conflicts of interest.

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## GYNECOLOGY

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# Incidence and Risk Factors of Surgical Site Infections after Abdominal Hysterectomy for Benign Diseases

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### ABSTRACT

**Objectives:** To study incidence and risk factors of surgical site infection (SSI) after abdominal hysterectomy for benign diseases.

**Materials and Methods:** Retrospective study of 82 patients who underwent abdominal hysterectomies for benign diseases between September 2013 and October 2017 at Warinchumrab General Hospital was performed. SSI was defined using the Centers for Disease Control and Prevention criteria. Independent risk factors of SSI after the abdominal hysterectomy were identified by multivariate regression analysis.

**Results:** Incidences of SSI after abdominal hysterectomy was 9.76% (N = 82). There were 8 superficial incisional SSI, no deep incisional and organ-space SSI. Risk factor associated with superficial incisional SSI was a BMI  $\geq 23.0$  kg/m<sup>2</sup> (odds ratio 1.154 [95% confidence interval 1.045-1.274], p = 0.021).

**Conclusion:** Incidence of SSI after abdominal hysterectomy was 9.76% and the significant risk factor in our study was BMI  $\geq 23.0$  kg/m<sup>2</sup>

**Keywords:** SSI, abdominal hysterectomy, benign disease.

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## อุบัติการณ์และปัจจัยเสี่ยงของการติดเชื้อหลังผ่าตัดมดลูกออกทางหน้าท้อง ในการรักษาเนื้องอกชนิดธรรมดา

ปณณดา อธิบรรณสุข

### บทคัดย่อ

**วัตถุประสงค์:** เพื่อศึกษาอุบัติการณ์และปัจจัยเสี่ยงของการติดเชื้อหลังผ่าตัดมดลูกออกทางหน้าท้อง ในการรักษาเนื้องอกชนิดธรรมดา

**วัสดุและวิธีการ:** การศึกษาวิจัยครั้งนี้ได้ทำการศึกษาวิจัยแบบย้อนหลัง (Retrospective study) ในผู้ป่วยจำนวน 82 คน ที่โรงพยาบาลวารินชำราบ ซึ่งได้รับการวินิจฉัยว่าเป็นโรคเนื้องอกชนิดธรรมดาของมดลูกและได้รับการผ่าตัดมดลูกและปากมดลูกออกทั้งหมดทางหน้าท้อง ได้ทำการศึกษาวิจัยตั้งแต่ เดือนกันยายน 2556 ถึง เดือน ตุลาคม 2560 การติดเชื้อแผลผ่าตัด (Surgical site infection) หมายถึง การติดเชื้อแผลผ่าตัดที่เกิดขึ้นภายใน 30 วัน หลังผ่าตัด [Centers for Disease Control and Prevention criteria] ปัจจัยเสี่ยงอิสระต่างๆ ที่ทำให้เกิดการติดเชื้อแผลผ่าตัดได้นำมาวิเคราะห์โดยใช้การวิเคราะห์การถดถอยพหุคูณ (multivariate regression analysis)

**ผลการศึกษา:** พบว่าผู้ป่วยมีอุบัติการณ์การติดเชื้อหลังผ่าตัดมดลูกออกทางหน้าท้อง 9.76% และพบเฉพาะการติดเชื้อชั้นตื้น (Superficial incisional surgical site infection) เท่านั้น ไม่พบการติดเชื้อชั้นลึก (Deep incisional surgical site infection) และการติดเชื้ออวัยวะ (Organ-space surgical site infection) แต่อย่างไรก็ตาม สำหรับปัจจัยเสี่ยงของการติดเชื้อแผลผ่าตัดในการศึกษาครั้งนี้พบว่า ผู้ป่วยที่มีค่าดัชนีมวลกาย (Body mass index)  $\geq 23.0$  กิโลกรัม/เมตร<sup>2</sup> เป็นปัจจัยเสี่ยงอย่างมีนัยสำคัญทางสถิติ โดยการวิเคราะห์ทางสถิติใช้วิธีการวิเคราะห์การถดถอยพหุคูณ (Odds ratio 1.154 [1.045-1.274],  $p = 0.021$ )

**สรุป:** ในการศึกษาวิจัยครั้งนี้ พบว่าอุบัติการณ์การติดเชื้อแผลผ่าตัด 9.76% และพบว่าดัชนีมวลกายของผู้ป่วยตั้งแต่ หรือมากกว่า 23.00 กิโลกรัม/เมตร<sup>2</sup> เป็นปัจจัยเสี่ยงที่มีนัยสำคัญทางสถิติของผู้ป่วยโรคเนื้องอกชนิดธรรมดาของมดลูกและได้รับการรักษาโดยการผ่าตัดมดลูกและปากมดลูกออกทั้งหมดทางหน้าท้อง

**คำสำคัญ:** การติดเชื้อแผลผ่าตัด, การผ่าตัดมดลูกและปากมดลูกทางหน้าท้อง, เนื้องอกชนิดธรรมดา

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## Introduction

Hysterectomy has become the most common gynecological procedure. Complications of hysterectomy vary based on the route of surgery and surgical techniques. The most common complications of a hysterectomy is infection, 10.5% for abdominal hysterectomy<sup>(1-3)</sup>. The development of surgical site infections (SSI) result in significant patient morbidity. Gynecologic procedures pose a unique challenge in that potential pathogenic microorganisms from skin or vagina and endocervix may migrate to operative sites and can result in vaginal cuff cellulitis, pelvic cellulitis, and pelvic abscess<sup>(4)</sup>.

The purpose of this study was to evaluate the risk factors and incidences of SSIs after abdominal hysterectomy for benign diseases.

## Materials and Methods

The studied patients were those who had undergone abdominal hysterectomy surgery for benign tumors between September 2013 and October 2017 at Warinchamrab General Hospital in Ubonratchathani province, Thailand. The present study was conducted retrospectively by reviewing the medical records of 82 patients, and approved by the Medical Research Ethics Committee of the Warinchumrab General Hospital (REC protocol number 03/2017). Data collection included age, diagnosis, uterine weight, surgical procedure, operative time, presence of co-morbidity, preoperative anemia, American Society of Anesthesiologists (ASA) class, intraoperative blood loss, type of anesthesia, and body mass index (BMI). Exclusion criteria included 1) pregnant women, 2) previous surgical procedures within 30 days prior to hysterectomy, 3) women with diagnosis of preoperative infection prior to hysterectomy, 4) women with the diagnosis of gynecologic cancer.

The Centers for Disease Control and Prevention (CDC) define SSI after gynecologic surgery as an infection occurring within 30 days of an operation occurring one of 3 locations: superficial at the incision site, deep at the incision site, or in other organs or spaces opened or manipulated during an operation<sup>(4)</sup>. It defined as superficial SSI if an infection that involved only skin or subcutaneous tissue of the surgical incision.

All patients in study were prescribed a single 1 gram dose of cefazolin intravenously within an hour before their surgery and preoperative, preparation of the skin with chlorhexidine gluconate to reduce the risk of SSI.

We categorized patients into 2 groups on the basis of 30 days postoperative SSI after hysterectomy, superficial incisional SSI included vaginal cuff cellulitis (group A), and no superficial incisional SSI included vaginal cuff cellulitis (group B).

### Statistical analysis

The group A and group B demographic data were compared using unpaired student t-test. Categorical variables were examined using chi-square analysis and to determine risk factors for SSI. We performed multivariate regression analysis identified risk factors of SSI. Odds ratio was adjust for patient demographics and clinical characteristics. The values were expressed as mean  $\pm$  standard deviation (SD) for parametric distribution, and median and interquartile range for non-parametric distribution. Two tailed p value were used, and  $p < 0.05$  was considered to be statistically significant.

## Results

Incidence of SSI after abdominal hysterectomy for benign diseases were 9.76% ( $n/N = 8/82$ ). In our study, we found superficial incisional SSI included vaginal cuff cellulitis in all 8 patients who had SSI, no patients had deep incisional SSI included pelvic cellulitis or organ-space included adnexal infection and pelvic abscess. Demographic and clinical characteristics of 82 patients are expressed in Table 1. On the basis of SSI, 8 patients with superficial incisional SSI included vaginal cuff cellulitis (group A) and 74 patients without SSI (group B) were compared. The mean age of the patients was  $46.0 \pm 4.0$  years in group A and  $46.4 \pm 5.5$  years in group B. The most common indication of hysterectomy in both groups was myoma uteri, 75.0% in group A and 75.7% in group B, respectively. The median uterine weight of patients in group A was 260 grams (range 140-480) and 340 grams (range 160-603) in group B. The most surgical procedure of patients in group A was total abdominal hysterectomy (TAH) (62.2%) but in group B was TAH with bilateral salpingo-oophorectomy (BSO) (75.0%).



The median operative time was 82.5 min (range 76-88) in group A and 81.5 min (range 70-100) in group B. The most common comorbidity of the patients in group A was diabetes mellitus (37.5%) but in group B was thalassemia (14.9%). The most common type of anesthesia of the patients in both groups was general anesthesia, 87.5% in group A and 74.3% in group B, respectively. The mean BMI of the patients in group A was  $28.2 \pm 3.0$  kg/m<sup>2</sup> and

$25.4 \pm 4.4$  kg/m<sup>2</sup> in group B. The mean of preoperative anemia was hematocrit  $34.9 \pm 8.0\%$  in group A and  $35 \pm 5.6\%$  in group B. The most common classification of ASA in the patients of both groups was class two, 100.0% in group A and 71.6% in group B, respectively. The median intraoperative blood loss in the patients in both groups was 150 ml (range 150-200) in group A and 125 ml (range 50-200) in group B respectively.

**Table 1.** Demographic and clinical characteristics of 30 days post-operative superficial SSI after abdominal hysterectomy (N=82).

Variable	Superficial SSI (Group A, N=8)	No SSI (Group B, N=74)	p value
- Age (years) (mean $\pm$ S.D.)	46 $\pm$ 4.0	46.4 $\pm$ 5.5	0.836
- Diagnosis			0.686
- Myoma uteri	6 (75.0)	56 (75.7)	
- Endometriosis	2 (25.0)	8 (10.8)	
- Myoma uteri and endometriosis	0	8 (10.8)	
- Others	0	2 (2.7)	
- Uterine weight (grams): median (range)	260 (140-480)	340 (160-603)	0.755
- Surgical procedure			0.430
- TAH	6 (75.0)	28 (37.8)	
- TAH with BSO	2 (25.0)	46 (62.2)	
- Operation time (minutes): median (range)	82.5 (76-88)	81.5 (70-100)	0.648
- Comorbidity			0.882
- No Comorbidity	3 (37.5)	38 (51.5)	
- Hypertension	0	5 (6.8)	
- Hypertension and dyslipidemia	1(12.5)	5 (6.8)	
- Diabetes mellitus	3 (37.5)	4 (5.4)	
- Dyslipidemia	0	2 (2.7)	
- Thalassemia	0	11 (14.9)	
- Others	1(12.5)	9 (12.2)	
- Type of anesthesia			0.410
- General	7 (87.5)	55 (74.3)	
- Spinal block	1 (12.5)	19 (25.7)	
- BMI (kg/m <sup>2</sup> ) (mean $\pm$ S.D.)	28.2 $\pm$ 3.0	25.4 $\pm$ 4.4	0.076
- Preoperative GFR (ml/min/1.73 m <sup>2</sup> ) (mean $\pm$ S.D.)	105.4 $\pm$ 13.6	104.0 $\pm$ 11.4	0.754
- Preoperative anemia (% hematocrit) (mean $\pm$ S.D.)	34.9 $\pm$ 7.6	35.0 $\pm$ 5.6	0.955
- ASA (class)			0.384
- Class 1	0	16 (21.6)	
- Class 2	8 (100.0)	53 (71.6)	
- Class 3	0	4 (5.4)	
- Class 4	0	1 (1.4)	
- Intraoperative blood loss (ml): median (range)	150 (150-200)	125 (50-200)	0.942

All values listed as n (%), mean + standard deviation (SD) and median (range)

SSI: surgical site infection, BM: body mass index, GFR: glomerular filtration rate, ASA: American Society of Anesthesiologists, TAH: total abdominal hysterectomy, BSO: bilateral salpingo-oophorectomy

From Table 1, there were no significant difference between group A and group B regarding to age, diagnosis, uterine weight, surgical procedure, operative time, comorbidity, type of anesthesia, BMI, preoperative anemia, ASA class and intraoperative blood loss. We performed multivariate regression analysis to evaluate the risk factors for SSI after the abdominal hysterectomy for benign diseases (Table 2). We found that the BMI

was statistically the significant risk factor associated with SSI with odds ratio (ORs) 1.154, 95% confidence interval (CI) 1.045-1.274,  $p = 0.021$ .

The multivariate regression analysis showed that age, diagnosis, uterine weight, surgical procedure, operative time, comorbidity, type of anesthesia, preoperative anemia, ASA class and intraoperative blood loss had no influence on SSI.

**Table 2.** Factor for superficial SSI after abdominal hysterectomy (multivariate regression analysis).

Variables	Multivariate		p value
	Odds ratio	95% CI	
- Age (years)	0.317	0.037-2.726	0.426
- 31-49			
- 50-55			
- Diagnosis	0.600	0.027-13.567	0.813
- Uterine weight (grams)	2.591	0.292-23.019	0.664
- Surgical procedure	0.203	0.038-1.076	0.061
- TAH			
- TAH with BSO			
- Operative time(mins)	1.189	0.222-6.367	0.838
- 55-74			
- 75-185			
- Comorbidity	1.759	0.392-7.902	0.712
- Type of anesthesia	0.414	0.048-3.583	0.672
- GA			
- SB			
- BMI (kg/m <sup>2</sup> )			
< 23.0	7.286	0.403-131.72	0.101
≥ 23.0	1.154	1.045-1.274	0.021*
- Preoperative anemia	0.745	0.166-3.351	0.730
- ASA Class 2 or higher	1.345	0.068-26.518	0.590
- Intraoperative blood loss (ml)	1.038	0.162-6.639	1.000

\* Statistically significant

TAH: total abdominal hysterectomy, BSO: bilateral salpingo-oophorectomy, GA: general anesthesia, SB: spinal block, BMI: body mass index, ASA: American Society of Anesthesiologists

## Discussion

In our study, we found that incidence of SSI was 9.76% which was similar to the reports by Taru et al<sup>5</sup> and Young et al<sup>(6)</sup> (8.1% and 10.9%, respectively). Our

study showed that the risk factor for SSI was BMI  $\geq 23$  kg/m<sup>2</sup> <sup>(18)</sup>. With regard to the SSI in our study, we found 8 superficial incisional SSI and no deep incisional and organ-space SSI, because all the patients in our

studies received prophylactic antibiotic by way of a single dose of cefazolin 1 gram intravenously before surgery. Prophylactic antibiotics decrease the bacterial inoculum burden on the skin and make the operative site less hospitable to the growth of bacteria. Furthermore, antibiotics concentrate in white blood cells resulting in enhanced phagocytosis of pathogenic bacteria. The antibiotic of choice for prophylaxis should have broad coverage. It should also be inexpensive and easy to administer. Cefazolin meets these criteria. Antibiotics should be administered within an hour of incision<sup>(4)</sup>.

Why high BMI increased SSI, Justin et al<sup>(14)</sup> reported in 2012 that obese women have demonstrated altered immune cell function compared with those of a healthy weight. Due to discrepancies in leucocyte number and subset counts and phagocytic and oxidative burst activity of monocytes, additionally circulating mononuclear cells in obese exhibited a pro-inflammatory state and impaired lymphocyte proliferation to polyclonal stimulation. Type II diabetes, a common complication of obesity is associated with impaired immune cell activity. Individuals with a genetic mutation preventing proper synthesis of the hormone leptin, become morbidly obese and display weakened immune defenses. Interestingly obesity has been shown to enhance thymic aging and reduce T-cell repertoire diversity, thus possibly impacting immune surveillance. The reported findings of immune cell dysfunction suggest that may result in impaired host defense. Indeed, studies have linked obesity with increased risk of infection. Several reports have found obesity to be a significant risk factor for post-operative and surgical site, nosocomial, periodontal and respiratory infections<sup>(14)</sup>.

Andersen et al<sup>(15)</sup> reported in 2016 that obesity was associated with metabolic disturbances that caused tissue stress and dysfunction. Obese individuals are at greater risk for chronic disease and often present with clinical parameters of metabolic syndrome (Mets), insulin resistance and systemic markers of chronic low-grade inflammation. It has been well established that cells of the immune system play an important role in the pathogenesis of obesity and Mets-related chronic diseases, as evidenced by leukocyte activation and dysfunction in metabolic tissue such as adipose tissue,

liver, pancreas, and vasculature. However, recent findings have highlighted the substantial impact that obesity and Mets parameters have on immunity and pathogen defense, including the disruption of lymphoid tissue integrity; alterations in leukocyte development, phenotypes and activity; and the coordination of innate and adaptive immune responses. These changes are associated with an overall negative impact on chronic disease progression, immunity from infection, and vaccine efficacy.

Because SSI in gynecological surgery which represents a significant source of surgical morbidity and mortality and results in significant social and economic cost for patient and health care system<sup>(16)</sup>. Preventing surgical site infection in hysterectomy is essential.

Risk factors associated with SSI are both modifiable and unmodifiable. Unmodifiable risk factors include increasing age, a history of radiation exposure, vascular disease and history of prior SSIs. Modifiable risk factors include obesity, tobacco use, immunosuppressive medications, hypoalbuminemia, route of hysterectomy, hair removal, preoperative infections (such as bacterial vaginosis), surgical scrub skin and vaginal preparation, antimicrobial prophylaxis (inappropriate choice or timing, inadequate dosing or redosing), operative time, blood transfusion, surgical skill and operating room characteristics (ventilation, increase or traffic, and sterilization of surgical equipment)<sup>(17)</sup>.

Although the specific measures vary between studies and a thorough SSI prevention bundle for benign gynecology recently published by the council on patient safety in women's healthcare. Research on SSI bundles indicates that implementation of several evidenced based strategies is likely to have a larger impact than pursuing any single intervention. Interventions clearly supported by the literature include timely administration of appropriately selected prophylactic antibiotics, we suggest a single dose of  $\beta$ -lactam antibiotic, most commonly cefazolin 1 gram intravenously, and based on pharmacokinetic data on obese patients. We recommended increasing the dose of cefazolin to 2 grams in patient BMI  $\geq 23.0$  kg/m<sup>2</sup> for women who undergo an abdominal hysterectomy for

benign diseases to prevent SSI in the future. The use of a chlorhexidine alcohol base for skin preparation, use of suture for skin closure, and maintenance of glycemic control in postoperative procedure will help to decrease the occurrence of SSI in our patients.

## Conclusion

In summary, an incidence of surgical site infection after abdominal hysterectomy in benign diseases in our study was 9.76% and BMI  $\geq 23.0$  kg/m<sup>2</sup> was a significant risk factor for SSI.

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## Potential conflicts of interest

The author declares no conflict of interest.

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## OBSTETRICS

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# Prediction of Successful Outcome of Labor Induction at Term by Transvaginal Sonographic Assessment of Cervical Length

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### ABSTRACT

**Objectives:** To examine transvaginal sonography assessment of cervical length (TVSCL) as a predictor of active phase of labor, successful vaginal delivery after labor induction, and to estimate the most useful cut-off point for cervical length (CL).

**Materials and Methods:** A prospective cohort study was conducted in the Obstetrics and Gynecology Department of Phramongkutklao Hospital. Pre-induction cervical assessment was undertaken in 120 women with singleton pregnancy at 37-42 weeks of gestation who underwent induction of labor. All women were measured for CL using transvaginal sonography followed by pelvic examination for Bishop score (BS) assessment.

**Results:** Successful induction of labor to active phase within 24 hours occurred in 84.1% of the subjects. The best cut-off point of CL for the prediction of successful labor induction to active phase within 24 hours was found to be 3.14 cm or less with a sensitivity of 73.3 %, a specificity of 78.9 %, as well as negative and positive predictive values of 35.7% and 94.9%, respectively. In addition, a 3.14 cm or less cut-off point of CL can be used to predict successful vaginal delivery with a sensitivity of 73.6%, a specificity of 50%, as well as a negative and positive predictive value of 52.3% and 71.8%, respectively.

**Conclusion:** TVSCL was significantly associated with successful induction of labor to active phase within 24 hours and could be used as a predictor for successful induction to vaginal delivery with a 3.14 cm or less cut-off point of CL.

**Keywords:** bishop score, transvaginal sonography cervical length, induction of labor, sensitivity, specificity.

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## การทำนายผลสำเร็จของการชักนำการคลอดในผู้ป่วยตั้งครรภ์ครบกำหนดโดยการวัดความยาวปากมดลูกด้วยอัลตราซาวนด์ทางช่องคลอด

นริศรา สันต์พานิชกิจ, ปรีศนา พานิชกุล

### บทคัดย่อ

**วัตถุประสงค์:** ประเมินการวัดความยาวปากมดลูกด้วยอัลตราซาวนด์ทางช่องคลอดเพื่อทำนายการเข้าสู่ระยะเร่งของปากมดลูก ความสำเร็จในการคลอดทางช่องคลอดหลังการชักนำการคลอด และหาค่าคงที่ของความยาวปากมดลูกที่สามารถทำนายผลสำเร็จของการชักนำการคลอด

**วัสดุและวิธีการ:** เป็นการศึกษาแบบไปข้างหน้าที่มีหญิงตั้งครรภ์เดี่ยว อายุครรภ์ระหว่าง 37-42 สัปดาห์ และมีข้อบ่งชี้ในการนอนโรงพยาบาลพระมงกุฎเกล้าเพื่อชักนำการคลอดเข้าร่วมงานวิจัย 120 คน ผู้เข้าร่วมวิจัยทุกคนจะได้รับการวัดความยาวปากมดลูกทางช่องคลอดตามด้วยการตรวจภายในเพื่อประเมินคะแนนบิชอป ก่อนการชักนำการคลอด

**ผลการศึกษา:** มีหญิงตั้งครรภ์ประสบความสำเร็จในการชักนำการคลอดโดยปากมดลูกสามารถเข้าสู่ระยะเร่งใน 24 ชั่วโมงคิดเป็นร้อยละ 84.1 ของหญิงตั้งครรภ์ที่เข้าร่วมงานวิจัยทั้งหมด และพบว่าเมื่อค่าความยาวของปากมดลูกที่วัดโดยอัลตราซาวนด์ทางช่องคลอดมีค่าน้อยกว่าหรือเท่ากับ 3.14 เซนติเมตร สามารถทำนายความสำเร็จของการชักนำการคลอดจนเข้าสู่ระยะเร่งมีค่าความไวคิดเป็นร้อยละ 73.3 ค่าความจำเพาะคิดเป็นร้อยละ 78.9 ค่าทำนายผลลบคิดเป็นร้อยละ 35.7 ค่าทำนายผลบวกคิดเป็นร้อยละ 94.9 ในส่วนการใช้ความยาวปากมดลูกเพื่อทำนายความสำเร็จในการคลอดทางช่องคลอดมีค่าความไวคิดเป็นร้อยละ 73.6 ค่าความจำเพาะคิดเป็นร้อยละ 50 ค่าทำนายผลลบคิดเป็นร้อยละ 52.3 ค่าทำนายผลบวกคิดเป็นร้อยละ 71.8

**สรุป:** การวัดความยาวของปากมดลูกด้วยวิธีอัลตราซาวนด์ทางช่องคลอดมีความสัมพันธ์กับความสำเร็จในการชักนำการคลอดโดยปากมดลูกสามารถเข้าสู่ระยะเร่งได้ภายใน 24 ชั่วโมง และประสบความสำเร็จในการคลอดทางช่องคลอดอย่างมีนัยสำคัญทางสถิติ โดยที่ความยาวปากมดลูกนั้นมีค่าน้อยกว่าหรือเท่ากับ 3.14 เซนติเมตร

**คำสำคัญ:** คะแนนบิชอป, การวัดความยาวของปากมดลูกด้วยวิธีอัลตราซาวนด์ทางช่องคลอด, การชักนำการคลอด, ค่าความไว, ค่าความจำเพาะ



## Introduction

Induction of labor is a process in which uterine contractions are initiated by medical or surgical means prior to the spontaneous onset of labor that is frequently carried out in approximately 20% of pregnancies<sup>(1)</sup>. Induction of labor is warranted as a therapeutic option when the benefits of expeditious delivery outweigh the risks of continuing the pregnancy. Indications for induction are attributed to a number of factors including health problems and obstetrical complications in pregnancy. The commonest indication for induction is prolonged pregnancy, where several studies have shown that induction compared to expectant management is associated with a substantial reduction in perinatal mortality<sup>(2-4)</sup>. In instances where induction is indicated and the status of the cervix is unfavorable, agents for cervical ripening may be used. The status of the cervix can be determined by the Bishop score (BS) system<sup>(5)</sup>, the sole standard method to predict the outcome of labor induction. The BS system comprises identification of cervical dilation, cervical effacement, cervical consistency, cervical position, and fetal station, where a maximum score of 13 can be obtained<sup>(6)</sup>. The American College of Obstetricians and Gynecologists 2009 defines an unfavorable cervix at  $BS \leq 6$ , and furthermore reports no failures with a score of  $\geq 9$ <sup>(5)</sup>. Be this as it may, this assessment is subjective, allowing for differences to arise in digital assessments of the cervix. These differences are alluded to in several bodies of research and studies, which have demonstrated a poor predictive value for the outcome of induction, especially in women with a low BS, and this contributes to limitations in assessing the change of the internal os when the external os is closed<sup>(7, 8)</sup>.

Transvaginal sonography is a well-known objective technique for assessing the entire length of the cervix and the morphological characteristics of the internal os even when the external os is closed<sup>(9,10)</sup>. A recent systematic review of meta-analysis indicated that transvaginal sonography assessment of cervical length (TVSCL) at or near term has a moderate

capacity to predict the outcome of delivery after induction<sup>(11)</sup>. To date, most studies on the possible role of TVSCL in labor induction have focused specifically on the mode of delivery or the total duration of labor as a primary outcome, e.g. research conducted by Kaoian et al found that TVSCL and BS were useful evaluations prior to labor induction to predict the risk of cesarean delivery<sup>(12)</sup>. However, the mode of delivery and the total duration of labor can be affected by multiple factors other than cervical status, such as parity, body mass index (BMI), fetal weight, and indications of cesarean delivery. To limit the scope of analysis the current analysis will adopt a definition of labor induction as the ability to initiate labor<sup>(5)</sup>. Given the aforementioned limitations and in attempts to provide further and less subjective forms of assessment TVSCL evaluations were performed to probe the degree to which TVSCL and active labor within 24 hours after initiation of labor induction are correlated, as well as to provide an estimate of cut-off points of cervical length (CL) and prediction of successful vaginal delivery after labor induction.

## Materials and Methods

This prospective cohort study was conducted at the Obstetrics and Gynecology Department of Phramongkutklao Hospital between November 2017 and July 2018 upon receiving approval from the Institutional Review Board of the Royal Thai Army Medical Department. In total, pre-induction TVSCL assessment was carried out in 120 women who were attended for delivery. Inclusion criteria for the current analysis comprised singleton pregnant woman, who were at least 18 years old with gestational ages between 37 and 42 weeks, as well as a living fetus with cephalic presentation, absence of labor (defined as the presence of regular and painful uterine contractions), no uterine scar, and no contraindication for vaginal delivery. Women who presented with fetal distress upon initial admission and those who underwent cesarean sections within 24 hours before the onset of active labor were excluded. Eligible women were enrolled into the study after obtaining

written informed consent to participate in the study and baseline characteristics such as age, gestational age (GA), and indication of induction were recorded. TVSCLs in centimeters (cm) were obtained by one of two fellows of maternal fetal medicine who have been extensively trained in transvaginal ultrasonography using a HS60 (Samsung Medison Co. Ltd., Seoul, Korea) machine equipped with a 6 MHz transvaginal probe. Upon obtaining the TVSCL, a BS score was calculated by obstetrics and gynecology residents who were unaware of the result of the sonographic findings, and this was followed by induction of labor as determined by the derived BS score. Clinically, it is difficult to identify the precise time of onset of true labor. Instead, active labor is often recognized by cervical dilatation of 4 cm or greater in the presence of uterine contractions<sup>(13)</sup>.

Preinduction TVSCL was performed according to the Fetal Medicine Foundation protocol<sup>(14)</sup>. After emptying the bladder, subjects were placed in a lithotomy position and a probe was gently placed in the anterior vaginal fornix to ensure a sagittal view of the cervix, identification of the internal os, external os, cervical canal, endocervical mucosa and lessen falsely elongated measurement due to undue pressure. Calipers were used to measure the distance between the internal os and external os. In each evaluation, three measurements were performed, and the shortest distance was taken as the CL.

Induction of labor was performed according to the standard labor induction guidelines of Phramongkutklo Hospital which is based on Royal College of Obstetricians and Gynecologists<sup>(1)</sup> issued in July 2008. If the BS was equal to or less than 6, the induction of labor was started within one hour after the cervical assessment. A 3-milligram (mg) dinoprostone (PGE2) vaginal tablet was inserted, and the time of the application was recorded. The adopted regimens of PGE2 were one dose of vaginal PGE2 followed by a second dose after 6 hours, in the event that labor was not established (up to a maximum of two doses in 24 hours)<sup>(1)</sup>. Oxytocin was administered via intravenous infusion for augmentation of labor

following cervical ripening, BS > 6, in the event that irregular uterine contractions were present, or following amniotomy. Oxytocin was administered as per standard protocols 6 hours after the last PGE2 dose, and if cervical progression did not ensue after 8 hours of oxytocin infusion, the protocol was repeated the following day. Electronic fetal heart rate monitoring was carried out for all women and induction active phase interval, number of doses of PGE2 and mode of delivery were recorded. The primary outcome investigated in this analysis was successful induction, which was defined as the ability to achieve the active phase of labor corresponding to a painful uterine contractions (interval, 2–3 minutes) developed and cervical dilatation of 4 cm or more within 24 hours of initiating induction of labor. Secondary outcomes included producing estimates of the most useful cut-off points of CL and predicting successful vaginal delivery after labor induction.

### **Sample size justification**

Sample size calculations are based on Yang et al's study<sup>(15)</sup> which reported the sensitivity and specificity of transvaginal ultrasound for cervical assessment before induction of labor to predicting successful induction of labor to active phase to be 75% and 83%, respectively. To probe for statistical significance, a type-1 error-value ( $\alpha$ ) of 0.05 was adopted as well as a power-value of 0.8, acceptable error (d) 0.1, and  $Z_{0.025} = 1.96$ . At least one hundred women were required for the sample sized in this study.

### **Statistical analysis**

Data were analyzed using STATA/MP12. Numerical variables were presented in mean  $\pm$  standard deviation (SD) and in median (min-max) while categorical variables were presented as number of cases and percentages. A chi-squared test ( $\chi^2$ ) and Fisher's exact test were used for comparison between the groups to analyze categorical variables, while Mann–Whitney U-test (un-normal distribution) and student's t test (normal distribution) were used for continuous variable analysis, where two-sided p

values were reported throughout. The performance of TVSCL and BS as tests to predict successful induction was evaluated using receiver operating characteristic curves (ROC). The area under the curve (AUC) was then calculated, and the confidence intervals (CIs) for this area were established. Sensitivity, specificity, positive predictive value and negative predictive value at different cut-off points were calculated for both CL and BS. Following this, a Pearson correlation calculation was conducted to analyze the relationship between BS, CL and successful induction time intervals. Statistical significance was defined by p values < 0.05.

## Results

The mean gestation age at induction was 39.2 ± 1.5 weeks and 82 (68.3%) of the 120 women were nulliparous. The indications for labor induction were GA beyond 40 weeks of gestation in 46 women

(38.3%), hypertension in 31 women (25.8%), gestational diabetes mellitus (GDM) in 30 women (25%), oligohydramnios with intrauterine growth restriction (IUGR) in 12 women (10%), and premature rupture of membranes (PROM) in 1 woman (0.8%). Further demographic characteristics of the population are shown in Table 1. Of the total subjects, 101 women (84.1%) had successful induction of labor to active phase within 24 hours, while failure was observed in 19 cases (15.8%). Be this as it may, both groups were similar with regards to mean age, GA, fetal weight and indication of induction. When compared to the women with successful induction of labor to active phase within 24 hours, those for whom labor could not be induced within 24 hours had significantly higher BMIs (27.4 ± 4.7 vs. 22.7 ± 4.2 kg/m<sup>2</sup>, respectively) and a higher proportion of them were among the nulliparous group (18 (22%) vs 1 (2.6%), respectively) (Table 2).

**Table 1.** Demographic characteristics of the study population (n=120).

Characteristics	n	%
Age (years)		
Mean (mean ± SD)	29.5 ± 6.0	
Body mass index (kg/m <sup>2</sup> )		
Mean (mean ± SD)	23.4 ± 4.5	
< 30	111	92.5
30 <sup>+</sup>	9	7.5
Parity		
Nulliparous	82	68.3
Multiparous	38	31.6
Gestational age (weeks)		
Mean (mean ± SD)	39.2 ± 1.4	
Indication of induction		
GDM	30	25.0
HT	31	25.8
Gestational age beyond 40 weeks	46	38.3
Oligohydramnios with IUGR	12	10.0
PROM	1	0.8

SD: standard deviation, GDM: gestational diabetes mellitus, HT: hypertension, IUGR: intrauterine growth restriction, PROM: prelabor rupture of membranes.

**Table 2.** Comparison of demographic characteristics with time of induction to active phase.

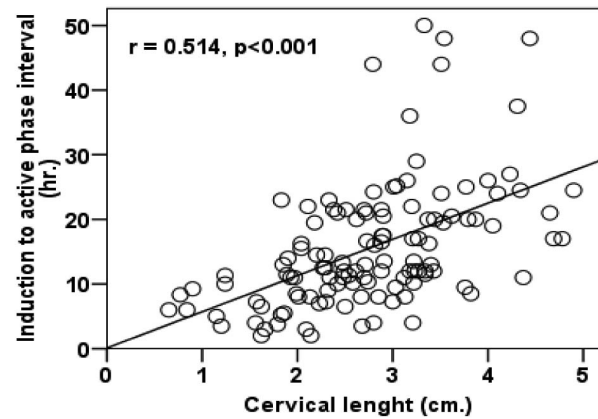
Characteristics	Induction to active phase interval		p value
	< 24 hours (101)	≥ 24 hours (19)	
Maternal age (years) (mean ± SD)	29.3 ± 5.9	30.2 ± 6.7	0.588
GA (weeks) (mean ± SD)	39.3 ± 1.4	38.8 ± 1.2	0.187
Body mass index (kg/m <sup>2</sup> ) (mean ± SD)	22.7 ± 4.1	27.4 ± 4.7	< 0.001
Fetal weight (kg) (mean ± SD)	3.1 ± 0.5	3.1 ± 0.4	0.762
Indication (n (%))			
GA beyond 40 weeks	43 (42.6%)	3 (15.8%)	0.038 *
GDM	23 (22.7%)	7 (36.8%)	0.248*
HT	23 (22.8%)	8 (42.1%)	0.091*
Oligohydramnios with IUGR	11 (10.9%)	1 (5.3%)	0.688*
PROM	1 (1%)	0 (0%)	1*
Parity (n (%))			
nulliparous	64 (63.3%)	18 (94.7%)	0.006*
multiparous	37(36.6%)	1(5.3%)	0.006*

independent t-test, Fisher's exact test\*, significant p<0.05.

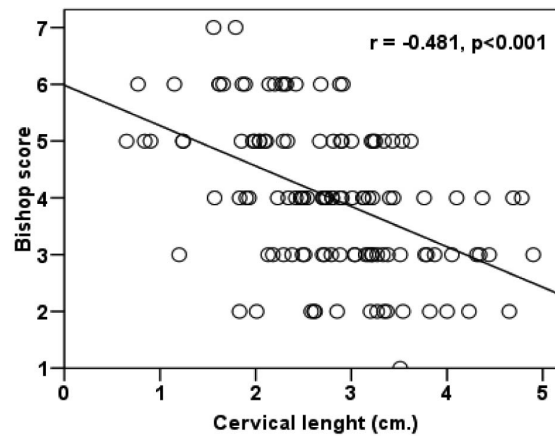
SD: standard deviation, GA: gestation age, GDM: gestational diabetes mellitus, HT: hypertension, IUGR: intrauterine growth restriction, PROM: prelabor rupture of membranes.

The number of parities was found to exert an effect on the duration of the active phase with multiparous women showing shorter duration of labor induction to active phase than for nulliparous women ( $11.6 \pm 5.1$  vs.  $17.5 \pm 10.7$  hours, respectively ( $p < 0.001$ )). Mean CL values in nulliparous and multiparous woman were  $2.8 \pm 0.9$  and  $2.8 \pm 0.9$  cm, respectively ( $p = 0.840$ ) and mean BS in nulliparous and multiparous woman were  $4 \pm 1.4$  and  $4.1 \pm 1.3$  cm, respectively ( $p = 0.618$ ). From this, it can be observed that the number of parities had no noticeable effect on the mean CL and BS. Conversely, BMI and parity provided significant and independent contributions to the prediction of active phase within 24 hours of induction. The mean TVSCL before induction of labor was  $2.8 \pm 0.9$  cm and the mean induction to active phase interval was  $15.6 \pm 9.7$  hours. The association between CL and the induction to active phase interval is shown in Fig. 1. These results indicate that a shorter CL was significantly related to a shorter induction to active phase interval ( $p < 0.001$ ). Furthermore, both cervical

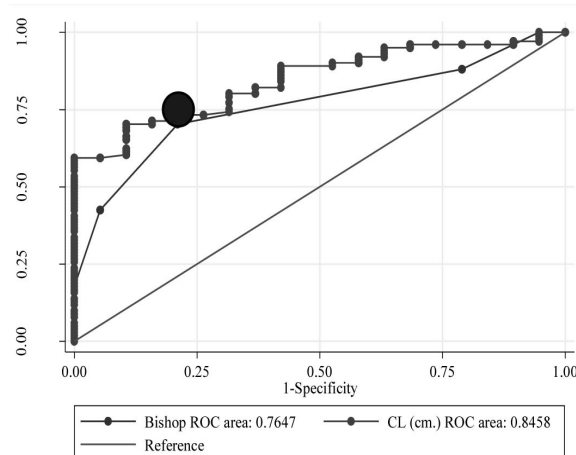
assessment methods were significantly correlated, such that a higher BS scores correlated with lower CL as shown in Fig. 2. ( $r = -0.481$ ,  $p < 0.001$ ). Fig. 3 shows the ROC plots for BS and CL with respect to active phase interval within 24 hours. The values obtained for both BS and CL were consistently above the reference line, which indicated that there was a significant relationship between these variables and prediction of induction of labor. Here, the AUC for CL was 0.846 (95%CI 0.0390-0.770) and the AUC for BS was 0.765 (95%CI 0.671-0.858), however, a p value of 0.115 was found. Both methods (TVSCL and BS) provided a useful prediction of successful induction of labor to active phase within 24 hours. An optimized cut-off point of CL, as determined by the ROC, was found to be 3.14 cm or less with a sensitivity of 73.3%, a specificity of 78.9%, a positive predictive value of 94.9%, and a negative predictive value of 35.7%. This cut off point value could be used in both nulliparous and multiparous groups as the number of parities was not observed to exert an significant influence on the CL.



**Fig. 1.** Correlation between cervical length and Induction to active phase interval (hours).  
Pearson's correlation;  $p < 0.05$  statistical significance.



**Fig. 2.** Correlation between transvaginal sonographic assessment of cervical length and Bishop score.  
Pearson's correlation;  $p < 0.05$  = statistical significance



**Fig. 3.** Receiver-operating characteristic curves for the two methods of assessment.  
Receiver operating characteristic (ROC) curves, Independent T-test, significant  $p < 0.05$

Table 3 contains information concerning the relationship between CL and the success rate of induction of labor to active phase within 24 hours. Here, it can be seen that shorter than median CL achieved significantly higher success rates than those with longer CL values (2.6 cm (0.7-4.8) vs 3.5 cm (2.8-4.9), respectively,  $p < 0.001$ ). It was found that 73.3% of

successful inductions of labor to active phase within 24 hours were predicted adopting a cut-off point of 3.14 cm or less, while only 26.7% of successful inductions presented a CL  $> 3.14$  cm, i.e. CL values below the cut-off point (3.14 cm) were good indicators of successful induction of labor to active phase within 24 hours.

**Table 3.** Predictability of CL for successful induction to active phase.

	Induction to active phase interval		p value
	< 24 hours (101)	$\geq 24$ hours (19)	
CL median (min-max) cm	2.61 (0.65-4.78)	3.51 (2.79-4.9)	$< 0.001$
CL $\leq 3.14$ cm	74 (73.3%)	4 (21.1%)	$< 0.001$
CL $> 3.14$ cm	27 (26.7%)	15 (78.9%)	

Mann-Whitney U test, significant  $p < 0.05$

CL: Cervical length

Investigation into the route of delivery found that 76 women (63.3%) delivered vaginally and 44 women (36.7%) delivered by cesarean section. The indications for cesarean section were fetal distress ( $n = 5$ ), cephalopelvic disproportion ( $n = 26$ ), failed induction ( $n = 12$ ) and preeclampsia with severe feature ( $n = 1$ ). The TVSCL was observed to be significantly shorter in women who delivered vaginally when compared with women who delivered by cesarean section ( $2.6 \pm 0.8$  vs.  $3.0 \pm 1.0$  cm, respectively,  $p = 0.049$ ). Table 4 contains data concerning routes of delivery across CL.

This table indicates that of all vaginal deliveries, 73.7% of women had a TVSCL of 3.14 cm or less, while the same length of CL was observed in only 50% of the women who underwent a cesarean section ( $p = 0.009$ ). Furthermore, a CL cut off point of 3.14 cm or less was found to be a predictor of successful vaginal delivery with a sensitivity of 73.6%, a specificity of 50%, as well as negative and positive predictive values of 52.3% and 71.79%, respectively. Thus, TVSCL was a useful predictor of successful labor induction for vaginal delivery.

**Table 4.** Correlations of cervical length with route of delivery.

	Cesarean section (n = 44) n (%)	Vaginal delivery (n = 76) n (%)	p value
CL (cm)			
$\leq 3.14$	22 (50%)	56 (73.7%)	0.009*
$> 3.14$	22 (50%)	20 (26.3%)	

Chi-squared test, significant  $p < 0.05$

CL: Cervical length

## Discussion

This present demonstrated that successful induction of labor to active phase within 24 hours

occurred in 84.1% of women. In addition, the above results indicated that the pre-induction CL was significantly associated with the induction-to-active



phase interval as well as the success of vaginal delivery. This finding, when considered against previous studies, is both corroborated and contested. Khandelwal et al<sup>(16)</sup> examined 66 women before induction to predict induction of labor to active phase within 6 hours and BS showed more promising statistically significant results than CL. Furthermore, the sensitivity and specificity of BS were found to be higher than TVSCL with sensitivity of 69% and specificity of 79% versus sensitivity of 51% and specificity of 70%, respectively. Park et al<sup>(17)</sup>, conducted a randomized trial which did not demonstrate superiority of one method over the other to predict success in achieving the active phase of labor within 12 hours. However, the present study's findings are corroborated by those of Yang et al<sup>(15)</sup>, who examined 105 women for TVSCL prior to labor induction. Yang et al's results demonstrated that TVSCL was a useful and independent predictor of successful labor induction as well as a predictor of the duration of induction to active phase. Similar to the present, Yang et al's results also indicated that the TVSCL was a better predictor of successful labor induction than the Bishop score. A possible explanation of this could take root in the differences of induction agents used and the ranges of assessment times to achieve active phase after labor induction. Khandelwal et al<sup>(16)</sup> used misoprostol and mechanical devices while Park et al<sup>(17)</sup> used 10-mg dinoprostone vaginal inserts (continuous release) as well as assessment of successful induction within 6 and 12 hours after induction of labor. This differs from the present study which, as stated, made use of 3-mg PGE2 vaginal inserts and assessment at 24 hours after induction of labor.

Perhaps most notable of the results of the present were that 56 women (73.7%) with TVSCL  $\leq$  3.14 cm had successful vaginal delivery while only 22 women (50%) underwent cesarean sections, thus resulting in a significant correlation ( $p = 0.009$ ) (Table 4). Furthermore, a 3.14 cm or less cut-off point of CL was found to predict successful vaginal delivery with a sensitivity of 73.6%, a specificity of 50%, as well as negative and positive predictive values of 52.3% and 71.79%, respectively. This correlation was clear indication that TVSCL was a good predictor of

successful vaginal delivery. These findings were in agreement with those put forth by Pandis et al<sup>(18)</sup>, which similarly demonstrated that CL appears to be a better predictor of successful vaginal delivery within 24 hours than BS with a sensitivity of 87% and a specificity of 71% compared to 58% and 77%, respectively. Furthermore, a systematic review and meta-analysis proposed by Verhoeven et al<sup>(11)</sup> indicated that CL and cervical wedging, as measured sonographically at or near term, had moderate capacity to predict the outcome of vaginal delivery after induction of labor. Daskalakis et al<sup>(19)</sup> consistently showed that transvaginal sonographic measurement of CL was a good predictor of a successful labor induction (vaginal delivery) at term in nulliparous women, while BS was not predictive of the mode of delivery. Although, the outcome of the current study differs from those of Hatfield et al<sup>(20)</sup> which revealed CL did not predict any specific outcome with regards to mode of delivery in their recently published systematic review with meta-analysis, Kaoian et al<sup>(12)</sup> found that TVSCL was more sensitive in predicting risk of cesarean delivery, a finding which was corroborated by the current analysis. Gonen et al<sup>(21)</sup> reported that only the BS and parity were significantly correlated with successful induction and the duration of labor. A possible explanation of these different outcomes may take root in differences in population characteristics, methods of induction of labor, indications of cesarean section and cut-off values. When comparing, the different cut-off points of the CL with previous studies, the present adopted a cut-off point of CL 3.14 cm with sensitivity at 73.3%, and specificity 78.9%. Kaoian et al<sup>(12)</sup> adopted a CL value of 2 cm with sensitivity of 85%, and specificity of 38%. Pandis et al<sup>(18)</sup> used a CL value of 28 mm, sensitivity of 87% and a specificity of 71% while Khandelwal et al<sup>(16)</sup> adopted a CL value less than 25 mm with sensitivity of 51% and specificity of 70%. These differences in CL values support the notion that findings may vary based on populations and corresponding adopted cut-off values.

Parity, BMI, and pre-induction TVSCL provided a significant and independent contribution in the prediction of the outcome of induction of labor. This relationship can be observed given that in multiparous

subjects, the incidence of successful vaginal delivery was approximately 10% higher than in nulliparous subjects. Furthermore, the induction-to-active phase interval in multiparous participants was lower than that found in the nulliparous group, obtaining a p value of less than 0.006. This is important, as it indicates that parity affects the induction-to-active phase interval and successfulness of vaginal delivery, a finding which is corroborated in Pandis et al<sup>(18)</sup> and Gonen et al<sup>(21)</sup>. In addition, when compared to women who had successfully induced labor to the active phase within 24 hours, those for whom labor could not be induced within 24 hours had significantly higher BMIs ( $27.4 \pm 4.7$  vs  $22.7 \pm 4.2$  kg/m<sup>2</sup>, respectively), obtaining a p value of less than 0.001, a finding which is corroborated by the findings of Soghra et al<sup>(22)</sup> and Park et al<sup>(23)</sup>

Ultrasound technology is available in most obstetrics centers, and it is a safe, accurate, and inexpensive form of technology with robust applications in medicine. TVSCL was successfully obtained in all cases with minimal discomfort to the women<sup>(12)</sup> and CL-values appeared to be a more objective and more reproducible than BS values. Furthermore, it has also been shown to have reduced intra- and interobserver variability<sup>(10)</sup>. While CL provides a useful prediction of successful induction of labor to active phase within 24 hours practitioners should receive appropriate training as the technique, when performed at term, is more difficult compared to mid-trimester cervical assessment, especially when the head is engaged and the alignment of the cervix is distorted.

There were several limitations of this study including this present analysis did not exclude other factors that could affect the success of labor induction such as maternal BMI and parity factors in induction of labor as no subgroup analysis of primiparous and multiparous women were conducted. However, the effects of parity on mean CL were considered and it was found that the number of parities did not affect the mean CL. Furthermore, differences of induction protocol may influence the outcome of induction.

Strengths of this current study were various and multifaceted in nature. First, this study was performed

in a tertiary care hospital with a maternofetal medicine fellowship program, where CL was measured by well-trained operators thus decreasing error in measurement. Second, the obstetricians making management decisions were blinded to the CL measurement, thereby decreasing bias in decisions concerning methods of intervention. Third, the definition of successful induction of labor was labor that achieved active phase within 24 hours after induction which differed from other studies that defined successful labor induction as successful delivery. With the broad definition adopted in other studies, several other factors may influence results at various stages of the delivery. Finally, the population of this study included only at-term pregnant women. The population of this study comprised 101 women (84.2%) who achieved the active phase of labor within 24 hours, of which 76 (63.3%) delivered vaginally after induction. From the above, it is important to note that the mode of delivery can be affected by multiple factors other than cervical status, such as parity, BMI, fetal weight, method of induction and indications of cesarean delivery that included cephalopelvic disproportion (82.1%), fetal distress (14.3%), and preeclampsia (3.5%). Of significant importance is the adoption of a unique cut-off point as indicated in the aforementioned statistical analysis, which may differ in other bodies of research.

## Conclusion

TVSCL was significantly associated with successful induction of labor to active phase within 24 hours and could be used as a predictor for successful induction to vaginal delivery with a cut-off point of 3.14 cm or less.

## Acknowledgment

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## Potential conflicts of interest

The authors declare no conflict of interest.

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## OBSTETRICS

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# The Use of the Infant Breastfeeding Assessment Tool among High Risk Mothers for the Prediction of Exclusive Breastfeeding for Six Weeks Postpartum

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### ABSTRACT

**Objectives:** To find the cut-off point, sensitivity and specificity of the infant breastfeeding assessment tool to predict breastfeeding among high risk mother during six weeks postpartum.

**Materials and Methods:** The infant breastfeeding assessment tool was translated to Thai and the validity and reliability was evaluated. Postpartum mothers who delivered at the HRH Princess Maha Chakri Sirindhorn medical center in the Nakhon Nayok province during the period of July 2014 to June 2015 and had high risk for early breastfeeding cessation were included in this study. The mothers and babies were assessed by the infant breastfeeding assessment tool at 16-24 hours postpartum. Following discharge; the exclusive breastfeeding data at the first, second and sixth weeks postpartum was collected by telephone follow-up. The cut-off point, sensitivity and specificity of the infant breastfeeding assessment tool used for exclusive breastfeeding predictions were calculated by the receiver operating characteristic curve.

**Results:** Three hundred and sixty-one high risk mothers for early breastfeeding cessation; teenage mothers, mothers with cesarean deliveries and obese mothers were recruited in this study. The validity of the infant breastfeeding assessment tool was 93.2%. The Cronbach alpha coefficient was 82.7. The cut-off point to predict exclusive breastfeeding at the first, second and sixth weeks postpartum was determined to be 8 points. The sensitivity and specificity of tests for the first, second and sixth week exclusive breastfeeding predictions were 88.9, 88.9, 90.5% and 72.3, 72.0, 74.6%, respectively. The best prediction accuracy was 73.0 percent at the first week postpartum. The relative risk during six-week postpartum period for early breastfeeding cessation between the mothers and babies who had the infant breastfeeding assessment tool scores of less than and greater than 8 points were 1.7-2.1.

**Conclusion:** The infant breastfeeding assessment tool can be used for the prediction of exclusive breastfeeding during the first six weeks postpartum. The accuracy of the test was best at the first week postpartum.

**Keywords:** the infant breastfeeding assessment tool, exclusive breastfeeding, prediction.

## การใช้แบบประเมินการให้นมทารกในมารดากลุ่มเสี่ยง เพื่อทำนายการเลี้ยงลูกด้วยนมแม่ในช่วงหกสัปดาห์หลังคลอด

ภาวีน พัวพรพงษ์, สุทธา หามนตรี, สิริวรรณ ศรีสุวรรณ, สุขวดี เกษสุวรรณ, ศิณัฐชานันท์ วงษ์อินทร์

### บทคัดย่อ

**วัตถุประสงค์:** เพื่อศึกษาหาจุดตัดของแบบประเมินการให้นมทารกในการทำนายการเลี้ยงลูกด้วยนมแม่อย่างเดียวยในช่วงหกสัปดาห์หลังคลอด

**วัสดุและวิธีการ:** ผู้วิจัยได้ทำการแปลแบบประเมินการให้นมทารกเป็นภาษาไทย แล้วทดสอบความตรงโดยใช้ผู้เชี่ยวชาญและนำแบบประเมินไปทดสอบความเชื่อมั่น จากนั้นนำแบบประเมินการให้นมทารกไปประเมินมารดาครรภ์เดียวหลังคลอดช่วง 16-24 ชั่วโมงที่ศูนย์การแพทย์สมเด็จพระเทพรัตนราชสุดาฯ สยามบรมราชกุมารีตั้งแต่ปี 2557 ถึง 2558 จำนวนทั้งสิ้น 862 ราย โดยในจำนวนนี้มีมารดาที่มีความเสี่ยงที่จะหยุดให้นมในระยะแรก ได้แก่ มารดาวัยรุ่น มารดาที่ผ่าตัดคลอด และมารดาที่มีภาวะอ้วนจำนวน 361 ราย และติดตามเรื่องการเลี้ยงลูกด้วยนมแม่หลังคลอดที่สัปดาห์ที่ 1, 2 และ 6 ด้วยการใช้โทรศัพท์เก็บข้อมูลพื้นฐาน ข้อมูลการเลี้ยงลูกด้วยนมแม่อย่างเดียวย และนำมาวิเคราะห์ผลโดยใช้กราฟ receiver operating characteristic

**ผลการศึกษา:** พบว่าความตรงของแบบประเมินร้อยละ 93.8 และความเชื่อมั่นของแบบประเมินจากค่าสัมประสิทธิ์สหสัมพันธ์ร้อยละ 82.7 แบบประเมินการให้นมทารกมีจุดตัดที่ 8 คะแนน สามารถใช้ทำนายการเลี้ยงลูกด้วยนมแม่อย่างเดียวยในช่วงหกสัปดาห์หลังคลอด โดยมีความไวร้อยละ 88.9-90.5 ความจำเพาะ 72.0-74.6 โดยจะมีความถูกต้องในการทำนายสูงที่สุดที่สัปดาห์ที่ 1 (ร้อยละ 73.1) และเมื่อเทียบมารดากลุ่มเสี่ยงที่มีคะแนนจากแบบประเมินการให้นมทารกที่น้อยกว่า 8 จะมีความเสี่ยงในการหยุดการเลี้ยงลูกด้วยนมแม่อย่างเดียวยในช่วงหกสัปดาห์สูง 1.7-2.1 เท่าเมื่อเทียบกับมารดาที่มีคะแนนการประเมินการให้นมทารกมากกว่า 8

**สรุป:** แบบประเมินการให้นมทารกสามารถใช้ทำนายการเลี้ยงลูกด้วยนมแม่อย่างเดียวยในช่วงหกสัปดาห์ได้ โดยมีจุดตัดที่เหมาะสมคือ 8 คะแนน โดยความถูกต้องของการทำนายจะสูงสุดในสัปดาห์ที่ 1 หลังคลอด

**คำสำคัญ:** แบบประเมินการให้นมทารก, การเลี้ยงลูกด้วยนมแม่อย่างเดียวย, การทำนาย



## Introduction

Regarding breastfeeding support, one of the crucial things is breastfeeding assessment. The infant breastfeeding assessment tool is one of the most frequently used and acceptable assessment tools<sup>(1-4)</sup>. This tool is easily used. The inter-rater reliability continues to score high (91%)<sup>(5)</sup>. There are four parameters that include; the readiness to feed, rooting, fixating, and suckling patterns. Each parameter has a range of 0-3 points. The total score can total up to 12 points. The interpretation of scores are; the effectiveness of infant feeding is 'good' if the assessment score totals 10-12 points, 'moderate' at 7-9 points and 'poor' at 0-6 points.

The high risks for mothers with early breastfeeding cessation are; mothers with cesarean deliveries, teenage mothers and obese mothers<sup>(6-11)</sup>. If the health professional could predict early breastfeeding cessation for the high risk mothers, appropriate follow-up with close monitoring and counseling can raise the breastfeeding rates. Assessment tools that could be used as screening tests will help the health professionals in follow-up planning and improvement of exclusive breastfeeding rates. We were interested in studying the use of the infant breastfeeding assessment tool as a screening test to determine the primary outcomes for the cut-off points, sensitivity and specificity for the exclusive breastfeeding rate predictions at the first, second and the sixth weeks postpartum. The comparisons between the exclusive breastfeeding data for high and low risk groups were evaluated for secondary outcomes.

## Materials and Methods

This study is a diagnostic test. The infant breastfeeding assessment tool was translated to Thai. The validity test was evaluated by four breastfeeding specialists following the translation. The reliability test was evaluated from twenty cases from a pilot study. The infant breastfeeding assessment tool was then used for breastfeeding assessment in the singleton postpartum women who delivered without complications. Two nurses, who had passed an infant breastfeeding

assessment tool training program that had included two hours of lecture and two hours of practice, were the infant breastfeeding assessment tool auditors. The nurses assessed the mothers and infants at 16-24 hours postpartum. The demographic data and factors that had effects on exclusive breastfeeding, blood loss and nipple lengths were recorded<sup>(12)</sup>. Following discharge, telephone follow-ups were used for collecting breastfeeding data at six weeks postpartum. The mothers' and infants' data were categorized into high and low risk groups. The high risk group included the mothers delivering by cesarean section, teen and obese mothers. The remaining cases were classified into the low risk group. The data of the high risk group were evaluated for the primary outcomes by the receiver operating characteristic (ROC) curve, the cut-off point, the sensitivity and specificity for the breastfeeding predictions done at the first, second and sixth weeks postpartum. The exclusive breastfeeding data of the low risk group were compared with that of the high risk group for the secondary outcomes.

This study was done in the Nakhon Nayok province which is a rural area in the central part of Thailand. The data was collected during the period from July, 2014 to June, 2015 at the HRH Princess Maha Chakri Sririndhorn Medical Center which has a 'baby friendly' hospital policy. A routine practice in the postpartum ward is breastfeeding education. The one-hour course in breastfeeding includes latching and is taught on the first day postpartum. One nurse teaches a group of 3-5 mothers. The mothers are encouraged to stimulate their infants to feed 8-12 times per day. At the second day postpartum, the mothers and infants are discharged if they had shown no complications. Prior to discharge, the mother's telephone number is confirmed and the breastfeeding-recording notebook is given to the mother with an explanation of the "breastfeeding type" definition, postpartum symptoms and complications which may require further clinical counseling.

Singleton postpartum women who have delivered without complications (i.e. multiple pregnancies, preeclampsia, antepartum hemorrhage and preterm



labor) and who intend to breastfeed for at least six months were recruited. Their infants had birth weights of more than 2,500 grams and were without complications. The mothers suffered no acute postpartum hemorrhages and had no contraindications to breastfeeding. This included any mothers who were HIV positive.

Mothers whose infants were diagnosed with galactosemia were excluded from this study.

Before the study, we had collected data from twenty cases of a previous pilot study and that was done and has analyzed the sensitivity and specificity of the infant breastfeeding assessment tool. The sensitivity and specificity were 0.80 and 0.70, respectively. We set a value of 6% as an acceptable error of sensitivity. The rate of exclusive breastfeeding was 52% and the p value was at 0.05. The calculated a sample size of 328 cases<sup>(13)</sup>. The subjects were summed with an additional 15% for data loss. The total samples collected were 361.

### ***Infant breastfeeding assessment tool***

The infant breastfeeding assessment tool has been translated into a Thai version. The parameters were assessed and these include; readiness to feed, rooting, fixing, and sucking patterns. The criteria of the “readiness to feed” scores; three if the infant starts to feed readily without effort; two if the infant needs mild stimulation to begin feeding; one if infant needs more stimulation to rouse and begin feeding; zero if the infant cannot be aroused. The criteria of ‘rooting’ scores have been set as; three if the infant roots effectively at once, two if the infant needs some coaxing, prompting or encouragement, one if the infant roots poorly even with coaxing, zero if the infant does not attempt to root. The criteria of ‘fixing’ scores are; three if the infant feeds immediately, two if the infant takes 3-10 minutes to start, one when the infant takes over 10 minutes to start, zero if the infant does not feed. The criteria of ‘sucking pattern’ scores have been set as; three if the infant sucks well on both breasts, two if the infant sucks intermittently but needs encouragement, one if the infant sucks weakly or sucks intermittent for short periods, zero if the infant does not suck. The infant breastfeeding

assessment scores have a possible total of 12 points.

The outcomes of this study were to determine the rates of exclusive breastfeeding and breastfeeding. Exclusive breastfeeding is defined as no other food or drink (including water) other than breast milk. This includes milk expressed. The infant is able to receive drops and syrups of vitamins, minerals, medicine and other oral rehydration salt (ORS).

The exclusive breastfeeding rate data at the first, second and sixth weeks postpartum were collected by follow-up via the telephone. The mother was taught to record breastfeedings and any fluids or foods given to the infant in a breastfeeding notebook that was given to the mother prior to discharge. Exclusive breastfeeding results were collected from the mother consistent with the established definitions.

This study has been approved by The Ethics committee of the Srinakharinwirot University, Faculty of Medicine.

### ***Statistical analysis***

Demographic data were reported in means and percentages. We have analyzed the validity by a breastfeeding specialist’s assessment of the infant breastfeeding assessment tool. The reliability was calculated as a Cronbach’s coefficient. A cut-off point and ROC curve have been used to predict the exclusive breastfeeding rates at the first, second and sixth weeks postpartum. The comparison of exclusive breastfeeding rates between both the high and low risk groups were analyzed using the chi-square. The comparison of exclusive breastfeeding rates between the infants who had the infant breastfeeding assessment tool scores, greater and less than the cut-off point of 8, were analyzed by chi-square, relative risk and a 95% confidence interval. A p value of less than 0.05 was considered statistically significant. Statistical analysis was performed using SPSS, IBM Singapore Pte. Ltd (Registration No.1975-01566-C).

## **Results**

The validity and reliability of the infant breastfeeding assessment tool were 93.8% and

82.7%, respectively. The number of postpartum women that had enrolled in our research project totaled 862. There were no mothers whose infants were diagnosed with galactosemia. High risk mothers totaled 361 cases (41.9%). The details of

the demographic data of the high risk group are shown in Table 1. In the high risk group, the percentage of the mothers with cesarean sections, teenage mothers and obese mothers were 83.7, 25.2 and 34.4, respectively.

**Table 1.** The demographic data of the high risk group.

The mother and infant's data	Mean and percentage
The number of cases	361
the teenage mother n (%)	91 (25.2)
the mother with cesarean delivery n (%)	302 (83.7)
the obese mother n (%)	124 (34.4)
Age (year)	25.5 ± 6.5
Para n (%)	
primipara	165 (45.7)
multipara	196 (54.3)
Gestational age (weeks)	38.9 ± 1.1
Mode of delivery n (%)	
vagina delivery	59 (16.3)
cesarean delivery	302 (83.7)
Nipple length (centimeter)	1.0 ± 0.3
Blood loss (millimeter)	622.6 ± 255.4
Body mass index (kg/m <sup>2</sup> )	26.2 ± 12.8
Birth weight (gram)	3,086.0 ± 501.8

The exclusive breastfeeding rates for the high risk group were 74.2, 68.5 and 51.9% at the first, second and sixth weeks postpartum, respectively. When the

exclusive breastfeeding rates of the high risk group were compared with the low risk group, there were statistically significant differences. The details are shown in Table 2.

**Table 2.** The comparison of the exclusive breastfeeding rates between the high and low risk groups at the first, second and sixth week postpartum.

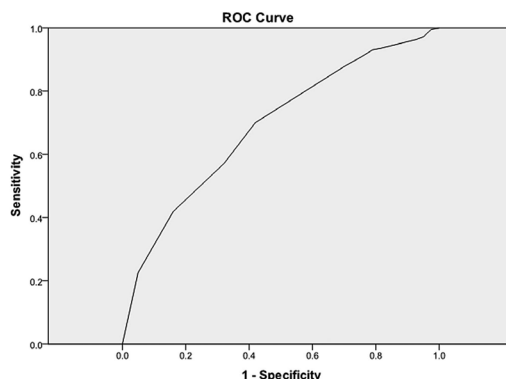
The time to collect data	The number of samples		Exclusive breastfeeding rate		p value
	High risk group	Low risk group	High risk group	Low risk group	
1 <sup>st</sup> week	357	499	265 (74.2)	422 (84.6)	p < 0.001
2 <sup>nd</sup> week	356	497	244 (68.5)	382 (76.9)	p < 0.007
6 <sup>th</sup> week	349	490	181 (51.9)	291 (59.4)	p < 0.03

When the data was analyzed by the ROC curve, the cut-off point of the infant breastfeeding assessment tool's score was 8 points at the first,

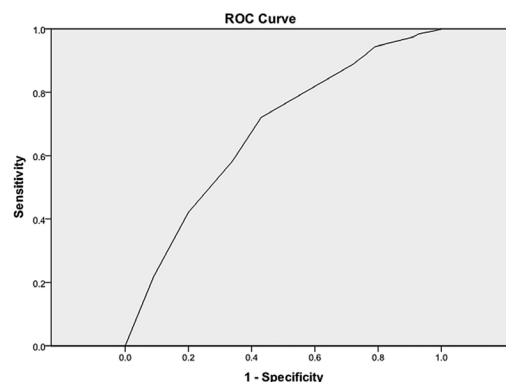
second and sixth weeks postpartum. At the first week postpartum, the accuracy of the test was 73.1 and the sensitive and specificity were 88.9% and

72.3%, respectively. The area under curve was 0.66. At the second week postpartum, the accuracy of the test was 69.7 and the sensitive and specificity were 88.9% and 72.0%, respectively. The area under curve was 0.68. At the sixth week postpartum, the accuracy of the test was 59.3 and the sensitive and specificity were 90.5% and 74.6%, respectively.

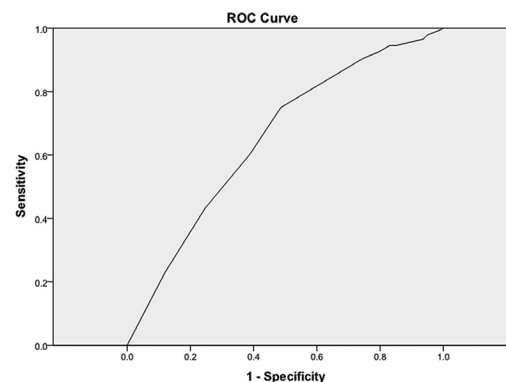
The area under curve was 0.65. The sensitivity and specificity of breastfeeding prediction at six weeks postpartum were 90.7% and 18.8%, respectively. The area under curve was 0.88. The ROC curves of the exclusive breastfeeding predictions at the first, second and sixth weeks are shown in figures 1, 2 and 3.



**Fig. 1.** The ROC curve of the exclusive breastfeeding prediction at the first week postpartum



**Fig. 2.** The ROC curve of the exclusive breastfeeding prediction at the second week postpartum



**Fig. 3.** The ROC curve of the exclusive breastfeeding prediction at the sixth week postpartum

We have categorized the high risk mothers into two groups using the cut-off point of 8 in the infant breastfeeding assessment tool. When exclusive breastfeeding data was compared between the two groups, the mothers who had scored less than 8 had a relative risk of early breastfeeding

cessation at 2.1 times more than the mothers with the score of greater than 8 at the first week postpartum. There were 2.0 and 1.7 times of a relative risk at the second and sixth week postpartum, respectively. The details of relative risks are shown in Table 3.

**Table 3.** The relative risks of early breastfeeding cessation between the mothers who had an infant breastfeeding score more or less than 8 at the first, second and sixth week postpartum.

The time to collect data	The relative risk of early breastfeeding cessation between groups that scored IBFAT less and more than 8	95% confidence interval
1 <sup>st</sup> week	2.1	1.5-3.0
2 <sup>nd</sup> week	2.0	1.5-2.7
6 <sup>th</sup> week	1.7	1.4-2.1

IBFAT= infant breastfeeding assessment tool

## Discussion

From the demographic data of the mothers and infants, the mothers with cesarean deliveries were in the high risk group (83.7%). The data was compatible with the cesarean section rate that had a tendency to rise<sup>(14)</sup>. Cesarean section deliveries had negative effects on exclusive breastfeeding. The comparison of exclusive breastfeeding rates between low and high risk mothers have found that there were statistically significant differences at the first, second and sixth weeks postpartum in this study.

The cut-off point for exclusive breastfeeding predictions at the first, second and sixth weeks postpartum were at 8 points. The sensitivity of the test was high (88.9-90.5%). The best accuracy of the test was found at the first week postpartum (73.1%). The accuracy of the tests decreased over time and it was lowest at the sixth week. The application of the infant breastfeeding assessment tool was its use as a screening tool and it could be used for the prediction of exclusive breastfeeding in the first few weeks. As the few early weeks of postpartum are known as the golden weeks for the breastfeeding support, in a study from Furman et al, the summary

scores of the infant breastfeeding assessment tool had significantly correlated with breast milk intake volume ( $r = 0.651$ ,  $p < 0.001$ )<sup>(1)</sup>. If the scores were low, the mothers and infants may have some problems with low milk intake volumes. Similarly, in the cases where the infant breastfeeding assessment tool scores were less than 8, the mothers have shown 2.1 times for a relative risk of early breastfeeding cessation. It is necessary for the health professional to have close follow-ups, effective breastfeeding counseling and support plans. This may help the mothers in the continuation of exclusive breastfeeding.

In this study, we have chosen to study the infant breastfeeding assessment tool as a screening test for early breastfeeding cessation in high risk mothers (mothers with cesarean deliveries, teenage mothers and obese mothers). The high risk mothers' incidence of early breastfeeding cessation was higher than seen in the low risk mothers. As a result, the screening test among high risk mothers was beneficent and likely to be cost-effective. However, the cost-effectiveness research of this test should be further evaluated.

When the breastfeeding predictions of the

infant breastfeeding assessment scores are compared with LATCH scores, the sensitivity and specificity of the LATCH scores for breastfeeding predictions were 75.0 and 63.2% at the sixth week postpartum as taken from the study of Kumar et al<sup>(15)</sup>. The sensitivity and specificity of LATCH scores were less than that of the sensitivity and specificity of the infant breastfeeding assessment tool. The sensitivity and specificity of infant breastfeeding assessment tool were 90.5 and 74.6, respectively. The positive and significant correlations between the LATCH scores and the infant breastfeeding assessment tool scores were described by a study done by Altuntas et al<sup>(2)</sup>. However, the outcomes and sample characteristics of the studies had shown some differences; the breastfeeding outcome was evaluated in the study of Kumar et al<sup>(15)</sup>, but the exclusive breastfeeding was evaluated in this study. The sample characteristic was of normal postpartum women in the study of Kumar et al, but the sample characteristic in this study regards high risk mothers for early breastfeeding cessation. The use of LATCH scores for exclusive breastfeeding prediction in high risk mothers is likely consistent to the infant breastfeeding assessment scores.

The strength of this study was the explanation of the definition of exclusive breastfeeding, daily-recorded infant feeding advice and the mother's telephone number that had been confirmed prior to the mother's discharge. The percentage of the mother's contact at the sixth week was high (96.7%). However, the factors which identified the high risk group in this study were solely the mothers' factors. The study in the group of infants' factors including preterm and low birth weight should be further examined.

## Conclusion

The infant breastfeeding assessment tool can be used as screening test for exclusive breastfeeding predictions. The cut-off point has been set as 8 points. The sensitivity and specificity of test during six-week postpartum period were 88.9-90.5 and 72.0-74.6,

respectively.

## Acknowledgments

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## Potential conflicts of interest

The authors declare no conflict of interest.

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## GYNECOLOGY

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# Analysis of Adnexal Mass in Women with Previous Hysterectomy - An observational study

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### ABSTRACT

**Objectives:** To characterize the clinicopathological features of adnexal masses arising subsequent to hysterectomy and portion of them requiring re-operation. In addition, average time interval between hysterectomy and diagnosis of adnexal mass was ascertained along with the need of salpingectomy

**Materials and Methods:** This observational study was conducted on the patients who presented with adnexal mass subsequent to hysterectomy. Data regarding characteristics of lesion, clinical presentation, proportion requiring re-operation and histological nature were analyzed.

**Results:** Over the span of 4 years, 115 women with hysterectomy presented with adnexal mass. 93% of them had index hysterectomy abdominally. Out of this 115 patients, 45 (39%) were kept on follow-up in whom mass had resolved subsequently (expectant group) and 70 (61%) required operation for the cure (re-operation group). Median time interval to diagnosis of adnexal mass was longer in re-operation group ( $p < 0.001$ ). Patients in re-operation group were more symptomatic ( $p = 0.011$ ), presented with larger size ( $p < 0.001$ ) and more complex cyst ( $p = 0.0001$ ) with higher number of septa ( $p = 0.007$ ) compared to expectant group. In 74% of patients, mass arose from the ovary and accounted for 72.3% of the benign mass and 100% of malignant mass. In remaining 26%, tube was confirmed as the source of origin. Commonest histological variety was serous cystadenoma.

**Conclusion:** Significant number of adnexal lesion disappeared during follow up. Benign ovarian mass was the predominant lesion in re-operated group. Fallopian tube also contributed prominently in 26%, thus salpingectomy with hysterectomy shall decrease the occurrence of fallopian tube pathology.

**Keywords:** hysterectomy, adnexal mass, adnexal preservation, re-operation.

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## Introduction

Hysterectomy is most frequently performed gynecological surgery. Prevalence of hysterectomy in India is 17/1000 of married women and varies from 2-63/1000 in different states.<sup>(1)</sup> Reoperation following hysterectomy is not uncommon and usually done for adnexal masses which can arise from ovary, tube or surrounding connective tissue. Emergence of subsequent pelvic mass has profound physical and psychological impact on patients especially those requiring re-operation. Complex adnexal mass poses diagnostic as well as surgical challenge to the gynecologist. The incidence of subsequent surgery after hysterectomy varies from 2.8 to 9.2%.<sup>(2)</sup> These subsequent abdominal surgeries are often associated with increased risk of intraoperative complications related to adhesive disease and distorted anatomy.<sup>(3)</sup> Removing ovaries during hysterectomy in young patients has its own long term complications and thus not recommended. Recently, a meta-analysis of three studies of women undergoing hysterectomy for benign indications found women who underwent bilateral salpingectomy concurrently with hysterectomy had a lower risk of developing ovarian cancer when compared with women who did not undergo salpingectomy.<sup>(4)</sup> Many institutions has adopted this practice but still not widely practiced in peripherals. In light of available evidence, this study thus reviewed all the case of adnexal mass appearing in post-hysterectomy women with the primary objective to characterize clinical and histopathological features of post hysterectomy adnexal masses and to determine the proportion requiring reoperation. The secondary objectives were to ascertain time interval between hysterectomy and appearance of adnexal mass along with the need of salpingectomy.

## Materials and Methods

This observational study was conducted after obtaining approval from the institutional ethical committee (AIIMS/Pat/IEC/2019/335) from January 2016 to December 2019 in the Department of Obstetrics and Gynecology at All India Institute of

Medical Sciences (AIIMS) Patna. All the patients presented to gynecology outpatient department during specified time period with pelvic mass and had history of hysterectomy for benign gynecological pathology were included in the study. Patients with history of hysterectomy for malignant gynecological pathology or who did not present during specified time period were excluded from the study.

All demographic characteristics, age at hysterectomy, route and indication of hysterectomy, presenting symptoms and time interval between hysterectomy and appearance of mass were recorded in a checklist. Detailed clinical examination, ultrasound with Doppler study and tumour markers for ovarian cancer were carried out. On the basis of sonographic feature, mass was classified as simple, unilocular or multilocular or complex cyst and solid mass. Patients with simple cyst of size < 7 cm with normal levels of tumour markers were managed expectantly and offered three monthly scan for 18 months. On each visit they were asked about exaggeration or onset of new symptoms. Rest of the patients underwent surgery either laparotomy or laparoscopy. Intraoperative findings, presence of adhesions or any intraoperative complications and histopathology report of removed mass were recorded.

Statistical analyses were performed using SPSS Version 20.0. Wilcoxon rank sum test was used for the comparison of continuous variables of non-normally distributed samples of the two groups. The categorical variables were summarized with rates using chi square test. P value < 0.05 was considered statistically significant.

## Results

Over 4 years of span, 115 women presented with pelvic mass subsequent to hysterectomy who fulfilled the inclusion criteria were included in the study. 68.3% of them had hysterectomy at age < 35 years and 31.8% were in the age group between 35-45 years. Mean age at presentation was 41.3 years. Majority (n = 107) of the patients had index

hysterectomy abdominally and 8 patients had hysterectomy vaginally. Indication of hysterectomy was not known in significant number of cases 42.5% (n = 49). In the remaining patients, pelvic inflammatory

disease (PID) was the most common indication in 28% followed by abnormal uterine bleeding (AUB) in 16%. 2.5% (n = 2) patients had cesarean hysterectomy for postpartum hemorrhage (PPH) (Table 1).

**Table 1.** Age, route and indication of hysterectomy, time interval to appearance of mass.

	Frequency	Percentage
Route of hysterectomy		
Abdominal	107	93.0
Vaginal	8	7.0
Age at hysterectomy		
< 35 years	79	68.8
35-45 years	33	28.8
> 45years	3	2.5
Indication of hysterectomy		
PID	32	28.0
AUB	18	15.6
PPH	2	2.5
Uterine Prolapse	8	7.0
Ovarian cyst	6	5.2
Not known	49	42.5
Time interval to diagnosis of mass		
< 1 year	6	5.0
1-5 years	48	41.3
6-10 years	36	31.3
> 10 years	25	22.5
Management		
Medical	45	39.1
Surgical	70	60.9

PID: pelvic inflammatory disease, AUB: abnormal uterine bleeding, PPH: postpartum hemorrhage.

Among the 115 selected patients, 70 patients underwent surgery for the adnexal mass (re-operation group) and 45 patients were kept on follow-up (expectant group). The adnexal mass resolved subsequently during the follow-up period (mean duration 4.3 months). Table 2 shows the characteristics of adnexal mass in re-operation and expectant group. Number of symptomatic patients were higher in re-operated group (80%) than the expectant group (57.7%) and the difference was statistically significant ( $p = 0.011$ ). Median time interval to diagnosis of mass was

statistically longer in re-operation group (78 months) than the expectant group (8 months) ( $p < 0.001$ ). All borderline and malignant tumors presented after 8 years of index surgery. There was no significant difference in CA125 level in both the groups. Patient in the re-operated group presented with significantly larger size ( $p < 0.001$ ), more complex cyst ( $p < 0.0001$ ) with higher number of septations ( $p = 0.007$ ) as compared to the expectant group. Median size of cyst in re-operated group was 7.9 cm where as in expectant group it was 4.3 cm. In the re-operated group, 30

patients were operated laparoscopically and 40 patients had laparotomy. Dense adhesion was encountered in 21.4% patients (n = 15), 2.8% (n = 2) patients sustained bowel injury and only one (1.4%) had bladder injury. Majority of the mass arising after hysterectomy and requiring re-operation were benign (92.9%), while 5.7% (n = 4) were borderline and only

one was malignant. Most of the masses were ovarian in origin (n = 52) comprising 74.18%. These ovarian masses accounted for 72.3% of benign mass and 100% of borderline and malignant mass overall. Fallopian tube and peritoneum accounted for the rest of the mass 25.8% (n = 18), and all of them were benign (Table 3).

**Table 2.** Characteristics of adnexal mass in re-operation and expectant group.

	Re-operation group (N=70)	Expectant group (n=45)	p value
Symptomatic on presentation	56 (80%)	26 (57.7%)	0.011
Time to diagnosis (months median, minimum-maximum)	78 (8- 360)	8 (3-60)	<.001
Interval to follow up (months)		4.3(2-18)	
Serum CA125 (median, range)	20.3 (4.3-46.4)	7.8 (3.2- 35)	0.189
Sonographic characteristics			
Size (cm, median, minimum-maximum)	7.9 (4.8- 30.4)	4.3 (3.8- 7)	< 0.001
Simple (n,%)	28 (40%)	39 (86%)	< 0.005
Complex (n,%)	42 (60%)	6 (13.3%)	0.0001
Septations (n,%)	47 (67.1%)	18 (40%)	0.007
Abnormal doppler (n,%)	5 (7.1%)	1 (2.2%)	0.466

cm: centimeter

**Table 3.** Histopathological characteristics of removed adnexal mass.

Histology	Frequency	Percentage
<b>Benign</b>	65	92.8
Serous cystadenoma	17	24.3
Mucinous cystadenoma	9	12.8
Endometrioma	14	20
Hydrosalpinx	10	14.3
Cystadenofibroma	3	4.3
Paratubal cyst	8	11.4
Follicular cyst	4	5.7
<b>Borderline</b>	4	5.7
Serous cystadenoma	3	4.3
Mucinous cystadenoma	1	1.4
<b>Malignant</b>		
Serous cystadenocarcinoma	1	1.4

## Discussion

Hysterectomy is generally considered as final treatment of all gynecological problems by the women but this does not hold true if they have to undergo re-operation for gynecological indications. In this review over span of 4 years, 115 patients reported with adnexal mass subsequent to hysterectomy. Exact incidence of adnexal pathology subsequent to hysterectomy could not be calculated as all the patients had hysterectomy outside our institution. Incidence of adnexal mass was higher following abdominal hysterectomy compared to vaginal route (96% vs 4%). This may be due to small peritoneal trauma by vaginal approach or abdominal route is preferred even though criteria for vaginal route are fulfilled. Similar finding has been observed by Holub et al,<sup>(5)</sup> where reoperation rate was 5.6% versus 0.7% in abdominal and vaginal hysterectomy respectively. They suggested that the important factor affecting the reoperation rate were age, primary histologic findings and smaller peritoneal trauma.

Indication of primary surgery was not known in 42.5% (n = 49) of cases due to lack of previous operative note records. This emphasizes the importance of providing detailed operative notes along with histopathological report to the patient at time of discharge. Median time interval from hysterectomy to the diagnosis of mass was longer in re-operated group than the expectant group. All the borderline and malignant tumor appeared after 8 years of index surgery. This is in accordance with the study done on Iranian women by Lalooei et al,<sup>(6)</sup> where all the benign adnexal masses appeared within 10 years of hysterectomy. Loft et al,<sup>(7)</sup> also reported that the protective effect of hysterectomy on the occurrence of ovarian cancer decreased over time in Danish women. Present study had demonstrated that almost 39% of secondary adnexal mass disappeared during follow-up. We decided to follow women up for 18 months as there is evidence in literature that this time period is sufficient for the development of morphological changes which could indicate malignant nature of the lesion.<sup>(8)</sup> Hence we affirmed that all of them did not require operation. The adnexal masses which had been removed were

more symptomatic, larger in size and had features doubtful of malignancy. Majority of mass arose from ovary and were benign though the significant number had also been contributed by tubes. Removal of ovaries before menopause is associated with own sets of risk like cardiovascular, osteopenia etc. The American College of Obstetricians and Gynecologists practice bulletin 2016 also reaffirmed that 'strong consideration should be made for retaining normal ovaries.' Most hysterectomies performed in present study were in younger age group thus retaining healthy ovaries. Retained ovary is associated with the risk of developing pathology. Casiano et al,<sup>(9)</sup> reported the incidence of oophorectomy after hysterectomy up to 9.2%. He proposed that disruption of ovarian blood supply after hysterectomy altered its function resulting in adnexal pathologies. In the present study majority of the mass requiring re-operation were benign (92.9%) and arose from the ovary (74.2%). Commonest histological variety was serous cystadenoma. This is in agreement with the study by Shiber et al.<sup>(10)</sup> They observed that most of the adnexal lesion arising after hysterectomy were benign ovarian mass (80%) and commonest histopathological variety being serous cystadenoma. Though the majority of post-hysterectomy mass were ovarian in origin, significant number 25.8% (n = 18) had been contributed by tubes too. It is now well established fact that tubes serve no purpose after completion of fertility and have potential to induce high grade ovarian serous carcinoma.<sup>(11, 12)</sup> In addition retained tubes can give rise benign lesions such as hydrosalpinx, tubo-ovarian mass, fallopian tube prolapse, mesenchymal cyst of oviduct etc. Morse et al,<sup>(12)</sup> reported that women who underwent hysterectomy had 8% lifetime risk of reoperation for hydrosalpinx. In a study by Falconer et al,<sup>(13)</sup> it was found that salpingectomy along with hysterectomy was associated with reduced risk of ovarian cancer. A 2019 study by Chao et al,<sup>(14)</sup> reviewing 247 women demonstrated the lower incidence of secondary benign pelvic lesion after salpingectomy. Recently Öksüzoğlu et al,<sup>(15)</sup> in 2019 analyzed the characteristics of adnexal lesion appearing after hysterectomy in 137 Turkish women. They reported that



only 51.8% of lesion required surgical management and rest disappeared during follow-up. Among the operated group most of the lesion were benign ovarian mass. Findings of current study is in accordance with this study except the proportion of tubal lesion were higher in our study (25.8% vs 5.6%), this may be due to difference in the study population and also the indication of index surgery between the two groups. Due to unavailability of operative note, we could not study the effect of salpingectomy on occurrence of subsequent adnexal mass. However, it was quite evident from the histology data that 25.8% mass were tubal in origin. Thus author suggest simple procedure of salpingectomy at the time of hysterectomy should be adopted as preventive measure to decrease the incidence of fallopian tube pathology. Second surgery is associated with the attendant complications. We too encountered severe adhesions in 21.4% patients 2 patients sustained bowel injury and bladder injury was seen in one patient. In three cases, laparoscopy was converted to laparotomy due to dense adhesions.

There were few limitations in our study due to inherent retrospective observational nature. First, we could not calculate the incidence of adnexal pathology subsequent to hysterectomy as all index hysterectomy in the studied population was performed outside our institution. Second, due to unavailability of previous operative note, indication of hysterectomy and adnexal status were not known in significant number of cases. Thus, we could not study the effect of salpingectomy on the incidence of adnexal mass arising after hysterectomy.

Despite certain limitations, our findings have implication in managing secondary adnexal masses. Importance of providing detailed operative note and histopathological report to the patient must be emphasized to the treating surgeon. As the incidence of secondary adnexal mass remains significant risk of returning to the operation after hysterectomy should be included in the preoperative counselling of the patients. Prophylactic bilateral salpingectomy should be adopted as it reduces the risk of tubal pathology. Majority of the mass appearing after hysterectomy were benign in

nature, so prophylactic oophorectomy along with hysterectomy is not advised in perimenopausal women.

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## Potential conflicts of interest

The authors declare no conflict of interest.

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## CASE REPORT

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# Successful Conservative Treatment for Large Cervical Ectopic Pregnancy

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### ABSTRACT

A rare case of cervical ectopic pregnancy presented with vaginal bleeding. Pelvic examination revealed large soft bluish mass at the posterior lip of the cervix. Transvaginal ultrasound showed a cervical mass with a gestational sac and 7-mm fetal echo without cardiac motion. Initial serum beta-human chorionic gonadotropin (hCG) was 29,489 mIU/ml. A two-dose regimen of methotrexate was intramuscularly administered. Bilateral uterine artery embolization was performed on day 14 due to heavy bleeding. One week later, sharp curettage at the cervical implantation site was carried out again because of re-massive bleeding. After discharge, serum beta-hCG levels were normal on day 45. Pathological study confirmed the clinical diagnosis of cervical ectopic pregnancy.

**Keywords:** cervical ectopic pregnancy, methotrexate, uterine artery embolization.

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## Introduction

Cervical ectopic pregnancy (CEP) is a rare type of ectopic pregnancy<sup>(1)</sup>. The incidence of CEP is 1 per 10,000 deliveries (less than 0.1% of all ectopic pregnancies)<sup>(2)</sup>. The etiology of CEP remains unknown. Risk factors for CEP include previous ectopic pregnancy, previous cesarean delivery, previous uterine or cervical surgery, in vitro fertilization, history of pelvic inflammatory diseases, smoking, previous pelvic surgery, intrauterine device use, and anatomic anomalies of the genital

tract<sup>(3)</sup>. As CEP can cause catastrophic hemorrhage, early diagnosis and timely management are of the utmost importance. Most of CEP cases are treated by hysterectomy<sup>(2)</sup>.

Methotrexate (MTX), a folinic acid antagonist, is an effective medical treatment for ectopic pregnancy with success rate 90% in properly selected cases, mostly tubal pregnancy<sup>(4-6)</sup>. It can be administered via either systemic or local injection. There are various single-dose (one-dose and two-dose) and multiple-dose

systemic MTX regimens that are prescribed<sup>(4, 5, 7)</sup>. However, there is no standard regimen of systemic MTX for CEP. Uterine artery embolization (UAE) is commonly carried out concurrently in case of severe hemorrhage<sup>(8, 9)</sup>. Curettage at the implantation site and vaginal packing has been reported as a successful conservative treatment for cervical pregnancy with MTX in low-resource settings<sup>(10)</sup>. Herein, we report a case of CEP that was treated with MTX, UAE, and curettage in order to preserve the uterus.

## Case presentation

A 36-year-old woman, parity 2, was referred from a community hospital to our hospital due to bleeding per vagina for 1 day without pelvic pain, nausea, or vomiting. Her underlying disease was

hypertension. She was taking combined oral contraceptive pills irregularly and denied having missed her period. Her vital signs were normal. Her abdomen was soft without any abnormal masses or tenderness on palpation. Pelvic examination revealed an 8-cm, soft, dark bluish mass at the posterior lip of the cervix with minimal bleeding. A urine pregnancy test was positive. Transvaginal ultrasound showed a cervical mass 4.9 x 4.5 cm in diameter with a gestational sac and fetal echo. The uterine cavity was empty. There was a 7-mm fetal pole without cardiac motion that appeared to be at corresponded with 7+ weeks of gestation (Fig. 1). No fluid was detected in the cul-de-sac. The patient's initial serum beta-human chorionic gonadotropin (hCG) was 29,489 mIU/ml. A clinical diagnosis of CEP was made.



**Fig. 1.** Transvaginal ultrasonography revealed an abnormal mass with a gestational sac and fetal echo occupying the posterior lip of cervix.

A two-dose regimen of MTX at 50 mg/m<sup>2</sup> was administered intramuscularly on days 1, 4, 7, and 11. No adverse effects were observed during hospitalization. The patient's serum beta-hCG declined to 5,298 on day 14 after treatment, but she developed heavy vaginal bleeding requiring a transfusion of 4 units of packed red cells. Bilateral UAE was performed by the interventional radiologist and the vaginal bleeding dramatically decreased after the procedure.

One week later, the patient experienced a recurrent episode of massive vaginal bleeding. Pelvic examination revealed a 5-cm soft bluish mass at the

posterior lip of the cervix with bleeding from the mass site. The active cervical bleeding was successfully controlled by sharp curettage at the cervical implantation site followed by vaginal packing within the first 24 hours after the procedure. The patient did not experience any massive vaginal bleeding thereafter.

A weekly serum beta-hCG blood test was administered, which yielded a negative result on day 45 of MTX injection. Pelvic examination on follow-up day 45 revealed a normal cervical contour and proper healing (Fig. 2). Pathological examination of the curettage specimens revealed the presence of chorionic

villi and blood clotting, which confirmed the clinical

diagnosis of CEP in this case.



**Fig. 2.** Per vaginal examination revealed a normal cervical contour after treatment.

## Discussion

We reported a rare case of cervical ectopic pregnancy. The most common presentation is painless vaginal bleeding with abnormal cervical masses or an enlarged cervix. In this case, the patient denied having missed her period, but was taking oral contraceptive pills irregularly.

The diagnosis of CEP has to be made based on physical examination and pelvic ultrasound. Ultrasound diagnostic criteria for CEP include an empty uterus, the gestational sac being located below the level of the internal os, a barrel-shaped cervix, and absence of sliding signs<sup>(3)</sup>. In our case, physical examination revealed a large cervical mass. In addition, transvaginal ultrasound showed a gestational sac with a yolk sac and fetal echo in the mass protruding from posterior lip of the cervix. The uterine cavity was also empty.

Hysterectomy is generally considered a mainstay treatment in cases of uncontrolled severe hemorrhage. Conservative treatment has become increasingly successful in cases of CEP due to early diagnosis being more common, technological advances, and new medications. In cases of early diagnosis, treatment with MTX, which inhibits DNA synthesis and cell reproduction, may be optional<sup>(5,6)</sup>. In this case, a total of four doses of a two-dose regimen of MTX were administered rather than a multiple-dose regimen as in other studies<sup>(10,11)</sup>. A two-dose regimen of 50 mg/m<sup>2</sup> of intramuscular

methotrexate was administered on days 0 and 4. Additional doses of methotrexate were administered on day 7 and/or day 11 if beta-hCG levels did not decrease by 15% during the follow-up period, as has been purposed by Barnhart et al<sup>(4)</sup> to lower the risk of potential side effects of a multiple-dose regimen whilst decreasing serum beta-hCG more rapidly than a single dose regimen.

In a systematic review of MTX treatment of ectopic pregnancy, Yang et al<sup>(11)</sup> reported comparable efficacy between multiple-dose and two-dose regimens but higher side effects in the multiple-dose regimen. In addition, folinic acid (leucovorin) rescue is not required for women treated with the single-dose protocol, even if multiple doses are administered<sup>(4)</sup>.

An intragestational sac or ultrasound-guided intracardiac injection of potassium chloride (KCL), mifepristone, and misoprostal to expulse the cervical gestational sac is another option for CEP treatment<sup>(12)</sup>. A report by Verma et al found that conservative treatment with systemic methotrexate and intragestational KCL sac injection was successful in 19 of 24 (79.2%) cases<sup>(12)</sup>. Interestingly, Osada et al<sup>(13)</sup> reported successful treatment of CEP by ultrasound-guided injection of absolute ethanol into the gestational sac.

UAE can be performed to control a life-threatening uterine hemorrhage in cases of severe postpartum

hemorrhage, morbid placenta adherence, and uterine fibroids<sup>(14)</sup>. In our case, UAE was performed to control massive bleeding from CEP. embolization with absorbable gelatin powder provides temporary obstruction of the blood vessels and allows for the development of collateral circulation. However, collateral flow may begin to develop within hours of the procedure. In our case, massive bleeding re-occurred one week after UAE, which might indicate the collateral flow formation in the vessels. There is no standard recommendation for the most appropriate timing to perform UAE, prophylactic procedure combined with MTX or only in a case that need to do an additional procedure such as uterine curettage or hysteroscopic resection of cervical pregnancy. In our case, MTX was administered and UAE was performed later to prevent further massive bleeding. Unfortunately, curettage was subsequently required in order to control a recurrent episode of massive vaginal bleeding. These may be a large implantation size of cervical pregnancy. In contrast to a report written by Takeda et al, CEP was successfully treated with a combination of bilateral UAE and MTX<sup>(15)</sup>.

## Conclusion

Cervical ectopic pregnancy is a rare clinical entity that may result in hysterectomy if a life-threatening hemorrhage occurs. Our report further demonstrates the benefit of methotrexate treatment in such cases. However, the large size of the cervical mass in this case caused severe bleeding, which required additional interventions including uterine artery embolization and rapid removal of the contraceptive product by sharp curettage at the implantation site to achieve adequate bleeding control.

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## Potential conflicts of interest

The authors declare no conflict of interest.

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