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# Thai Journal of Obstetrics and Gynaecology

ISSN : 0857-6084. The Official Journal of the Royal Thai College of Obstetricians and Gynaecologists

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## **Aim and Scope of the Thai Journal of Obstetrics and Gynaecology (Official journal of the Royal Thai College of Obstetricians and Gynaecologists (RTCOG)**

Thai Journal Obstetrics and Gynaecology (TJOG) is the official journal of The Royal Thai College of Obstetricians and Gynaecologists (RTCOG). This is a double-blind peer-reviewed journal aiming to promote academic knowledge and provide a forum for publication in Obstetrics and Gynecology. 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)

**Language:** Fulltext in English, Abstract both in Thai and English

**Free Access:** online

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

**E-ISSN:** 2673-0871 (Since December 2010)

### **Peer Review Process**

TJOG has double-blind peer-review process. The editorial board consists of professor, associate professor and assistant professor in fields of Obstetrics and Gynaecology, who have experience in conducting and publishing research. At least two reviewers evaluate manuscript. Initial reviews usually accomplish within 4 weeks.

### **Publication Charges**

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### **Subscription**

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### **Sponsor and Source of Support**

RTCOG

### **Journal History**

TJOG is the official journal of RTCOG. This is a double-blind peer-reviewed journal aiming to promote academic knowledge and provide a forum for publication in Obstetrics and Gynecology. 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.

**Direction to contributors.** All papers should be sent to Editor, Thai Journal of Obstetrics and Gynaecology by online submission. The editorial board will decide upon the time of publication and retain the right to modify the style and the length of the contribution. However, major changes will be agreed with the authors.

**Manuscripts.** All manuscripts can be submitted online (<https://tci-thaijo.org/index.php/tjog>) along with a cover letter, author agreement form and the checklist guideline. A cover letter must include name of the corresponding author, full address, telephone number, fax number, and e-mail address, title and category of the submitted manuscript: original article, case report or review articles. Authors for whom English is a second language may choose to have their manuscript professionally edited before submission to improve the English.

The requirements for manuscripts submitted to TJOG conform to the UNIFORM REQUIREMENT FOR MANUSCRIPTS SUBMITTED TO BIOMEDICAL JOURNALS established by the international committee of medical journal editor which published in N Engl J Med 1991;324:424-8 and BMJ 1991;302:338-41.

Manuscripts of original work should be arranged in the conventional order of title page, abstract, keywords, introduction, materials and methods, results, discussion, acknowledgments, references, table and figure legends.

Manuscripts of research article, case report and review article (without author's name) will be reviewed by two reviewers. Editor in chief will make the final decision in case of discrepancy of reviewer's opinion. The editorial board has the right to grammatically correct any content and has all right preserved to consider and to publish any article.

All published manuscripts are properties of TJOG. The content and any opinions in the published papers are the sole responsibility of the authors, not the editorial board.

Title page. The title page should contain the title, which should be concised and informative, the authors' name with the highest academic degree, and address of the authors including the correspondence.

**Abstract.** A structured abstract, with 250 words or less, is submitted as required for regular articles. The abstract should state the Objective, Materials and Methods, Results, and Conclusion, each with a brief adequate presentation. Abstracts for case reports should not exceed 150 words.

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**Introduction.** State clearly the purpose of the study. Summarize the rationale for the study. Give only strictly pertinent references and it is not necessary to include all the background literature.

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#### **Example of references:**

##### **Journal article**

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##### **Book**

Cunningham FG, Leveno KJ, Bloom SL, Hauth JC, Rouse DJ, Spong CY. *Williams Obstetrics*. 23rd ed. New York: McGraw-Hill, 2010: 804-31.

##### **Chapter in a Book**

Phupong V. Management of PPROM AT 32 to 34 weeks. In: Desai SV, Tank P, eds. *Handbok on preterm prelabor rupture of membranes in a low source setting*. New Delhi: Jaypee Brothers Medical Publishers Ltd, 2012: 39-46.

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dpi for gray scale and 300 dpi for colour). Figures should be saved as TIFF or JPEG files. Figures should be completely labelled, taking into account necessary size reduction. Captions should be typed, double - spaced, on a separate sheet.

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The publication ethics is required for publication in TJOG (Thai J Obstet Gynaecol). The publication ethics guidelines are guided by the Committee on Publication Ethics-(COPE).

#### **Editors of Thai Journal of Obstetrics and Gynaecology**

- attempt to meet the demand of readers and authors, improve the quality of the journal, and have processes in place to assure the quality of the material published, seek the opinions of authors, readers, reviewers and editorial board members about the ways to improve the journal's processes and maintain the integrity of the academic record and preclude business needs from intellectual and ethical standards.

- have a duty to act if editors suspect misconduct or if a misconduct is documented, pursue misconduct for the following reasons in published and unpublished work: plagiarism, data fabrication and falsification, when a submitted article has been found to be under revision elsewhere or published elsewhere, or where there is citation manipulation, and are willing to publish corrections, clarifications, retractions and apologies when needed.

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- confirm that the authorship of research publications accurately reflect authors' contributions to the work and reporting, and disclose sources of funding and conflicts of interest.

- present the research conducted in an ethical and responsible manner and comply with all relevant legislation, describe the methods clearly so that the findings can be confirmed by others, present the results clearly, honestly, and without fabrication, falsification or inappropriate data manipulation.

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journal should be published. The editor may be guided by the policies of the journal's editorial board and constrained by such legal requirements regarding libel, copyright infringement and plagiarism. The editor may confer with editorial board or reviewers in making this decision.

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Intellectual property is seriously concerned by TJOG. On submission, all articles are screened using the 'HelioBLAST' (<https://helioblast.heliotext.com>). Any plagiarism is unacceptable. The Editor-in-Chief will be informed. Plagiarism results in rejection. If plagiarism is detected during reviewing process by any means, all the process will be immediately withheld. The Editor-in-Chief will contact the corresponding author and/or all authors for explanation. Rejection of submission will occur once the explanation is unsatisfactory. If plagiarism is detected after publication, the article will be retracted. All the authors' institutions will be contacted to explain the retraction and inform the expected future behaviours. The event of retraction will be officially announced in the Journal.



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## EDITORIAL

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I am pleased to inform the Royal Thai College of Obstetricians and Gynaecologists (RTCOG) members that Thai Journal of Obstetrics and Gynaecology (TJOG) already received the Q4 journal rankings (143/192 journals) with SJR score 0.137 in Obstetrics and Gynaecology category from Scimago Journal & Country Rank 2021. The quality of TJOG has been improved. TJOG has been indexed in many databases: Scopus, TCI, ASEAN Citation Index, DOAJ, EuroPub, and Google Scholar. The journal editorial team would like to thank past RTCOG executive board, past editor in chief, editorial board and staff, reviewers, all members of RTCOG, and all researchers for their kind contribution and support to TJOG.

Editor in Chief and managing staff will attend "Meeting of the project to develop the system and improve the quality of Thai journals in the Scopus database," which is a continuation of the project "TCI-TRF-Scopus Collaboration Project" on August 11, 2022 at Eastin Grand Hotel, Sathorn Road, Bangkok, Thailand.

This fourth issue of TJOG 2022 contains many interesting articles. One special article is "The Thai 2022 Sexually Transmitted Infections Treatment Guideline: Abnormal vaginal discharge".

RTCOG Annual Meeting 2022 will be held during 25-28 October 2022 at Pattaya Exhibition and Convention Hall (PEACH), Royal Cliff Beach Hotel, Chonburi, Thailand. The theme of this meeting is "OB-GYN 2022: Now and Beyond". This meeting will have AOFOG session. All RTCOG members are cordially invited to participate this scientific meeting.

Residents who would like to publish their researches in TJOG should submit their works before September 30, 2022. Our editorial team and constructive reviewers will let them know the results before December 31, 2022.

Wish to see you at RTCOG Annual Meeting 2022 at Pattaya Exhibition and Convention Hall (PEACH), Royal Cliff Beach Hotel, Chonburi, Thailand.

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

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## SPECIAL ARTICLE

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# The Thai 2022 Sexually Transmitted Infections Treatment Guideline: Abnormal vaginal discharge

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## ABSTRACT

Abnormal vaginal discharge is one of the most common presenting symptoms at gynecologic clinics. Sexually transmitted infection (STI) is a subset of all etiologies; but appears to be a major public health concern as it much affects health and economy of the infected people. Improper or delayed management results in greater morbidity and mortality. From the epidemiological surveillance data in Thailand, STI is on the rise; and gonorrhea and chlamydial cervicitis appear to be the main STI causes of abnormal vaginal discharge. In this year, the Division of Autoimmune Deficiency Syndrome (AIDS) and Sexually Transmitted Infections (STIs), Thai Ministry of Public Health, in collaboration with Institute of HIV Research and Innovation (IHRI), Institute of Dermatology, Faculty of Medicine, Chulalongkorn University, and Faculty of Medicine Siriraj Hospital, Mahidol University, has issued the Thai national guideline for diagnosis and treatment of sexually transmitted infections, 2022. As a high proportion of women presenting with abnormal vaginal discharge are non-STI cases, the treatment guideline includes both STI and non-STI causes. And, this article will focus on only the section of the guideline for managing women with abnormal vaginal discharge.

**Keywords:** guideline, sexually transmitted infections, Thai, treatment, vaginal discharge.

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# แนวทางการรักษาโรคติดเชื้อติดต่อทางเพศสัมพันธ์ของไทย พ.ศ.2565: ภาวะระดูขาวผิดปกติ

เจนจิต ฉายะจินดา, กิตติภูมิ ชินธิรัญ, รสพร กิตติเยาว์มาลย์, สุรัสิทธิ์ ชัยทองวงศ์วัฒนา, นิพัฒน์ ธิรตกุลพิศาล

## บทคัดย่อ

ภาวะระดูขาวผิดปกติเป็นอาการนำที่พบบ่อยที่สุดของการหนึ่งในคลินิกวิเคราะห์ ถึงแม้ว่าสาเหตุเพียงส่วนหนึ่งเกิดจากโรคติดต่อทางเพศสัมพันธ์ แต่ถือว่าโรคติดต่อทางเพศสัมพันธ์เป็นปัญหาทางสาธารณสุขที่สำคัญ เนื่องจากส่งผลกระทบในวงกว้างทั้งด้านสุขภาพและเศรษฐกิจ การรักษาที่ช้าหรือไม่เหมาะสมจะส่งผลให้เกิดภาวะแทรกซ้อนตามมาจนอาจถึงแก่ชีวิต จากรายงานเชิงระบบวิทยาในประเทศไทย พบร่างอุบัติการณ์ของโรคติดต่อทางเพศสัมพันธ์มีสูงขึ้น โดยโรคหน่องในเทียมเป็นโรคติดต่อทางเพศสัมพันธ์ที่เป็นปัญหาสำคัญที่ทำให้ผู้หญิงมีภาวะระดูขาวผิดปกติ ในปี พ.ศ.2565 กองโรคเอดส์และโรคติดต่อทางเพศสัมพันธ์ กระทรวงสาธารณสุขร่วมกับ สถาบันเพื่อการวิจัยและนวัตกรรมด้านเօชไอวี สถาบันโรคผิวนังค์ คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย และคณะแพทยศาสตร์ศิริราชพยาบาล มหาวิทยาลัยมหิดล ได้จัดทำแนวทางการวินิจฉัยและการรักษาโรคติดต่อทางเพศสัมพันธ์ เนื่องจากภาวะระดูขาวมีสาเหตุจากทั้งโรคติดต่อทางเพศสัมพันธ์ และไม่ใช่กลุ่มโรคนี้ แนวทางการรักษาจึงได้ครอบคลุมกลุ่มโรคที่ไม่ใช่โรคติดต่อทางเพศสัมพันธ์ด้วย และบทความนี้จะเน้นเฉพาะกลุ่มที่มีอาการระดูขาวผิดปกติเท่านั้น

**คำสำคัญ:** แนวทาง, โรคติดต่อทางเพศสัมพันธ์, ไทย, การรักษา, ระดูขาว

## Introduction

Abnormal vaginal discharge is one of the most common presenting symptoms at gynecologic clinics. Sexually transmitted infection (STI) is a subset of all etiologies; but appears to be a major public health concern as it much affects health and economy of the infected people. Improper or delayed management results in greater morbidity and mortality. According to the estimation by the World Health Organization (WHO) in 2020, there are 374 million new infections from all regions around the world: 156 million are trichomoniasis, 129 millions are chlamydial cervicitis and 82 million are gonococcal infection<sup>(1)</sup>. From the epidemiological surveillance data in Thailand, STI is on the rise, from 28.8 per 100,000 population in 2017 to 33.6 per 100,000 population in 2020<sup>(2)</sup>. In 2021, the most common STIs that caused abnormal vaginal discharge were gonorrhea and chlamydial infection, at 2.4 per 100,000 population and 1.3 per 100,000 population, respectively. The prevalence was highest in people at the age of 15-24 years.

In this year, the Division of Autoimmune Deficiency Syndrome (AIDS) and Sexually Transmitted Infections (STIs), Thai Ministry of Public Health, in collaboration with Institute of HIV Research and Innovation (IHRI), Institute of Dermatology, Faculty of Medicine, Chulalongkorn University, and Faculty of Medicine Siriraj Hospital, Mahidol University, has issued the Thai national guideline for diagnosis and treatment of sexually transmitted infections, 2022. As a high proportion of women presenting with abnormal vaginal discharge are non-STI cases, the treatment guideline includes both STI and non-STI causes. And, this article will focus on only the section of the guideline for managing women with abnormal vaginal discharge.

## Vaginal ecosystem<sup>(3)</sup>

The vagina is a passageway for natural conception, menstruation and birth canal. Also, it is a channel for pathogens to enter the body. Vaginal epithelium protects the body from infection with mucus protein (sialoglycoprotein) coated as a physical defense; provides an immune defense by producing

secretory immunoglobulin A and immunoglobulin G that capture pathogens; and contains immune-related cells<sup>(4)</sup>. Vaginal discharge is another pivotal protective factor of the infection. The normal vaginal discharge consists of secretions from various parts, including cervical gland, fluid from the vaginal wall, fluid from the fallopian tube and endometrial cavity, secretions from the Bartholin's gland and Skene glands, vaginal flora and their metabolic products.

The main bacteria in the vagina of prepuberty women are *E. coli*, *Diphtheroids*, and coagulase-negative *Staphylococcus*. During puberty, *Lactobacilli* spp. are the dominant normal flora bacteria. Estrogen produces more mature squamous cells and increases the accumulation of glycogen in the vaginal epithelium cells. Vaginal enzymes include alpha-amylase breaking down glycogen into maltose, maltotriose, and alpha-dextrins. They are then digested by lactase dehydrogenase of *Lactobacilli* spp. to lactic acid which inhibits the growth of other bacteria. This results in mildly acidic vaginal environment (pH 3.5-4.5) during reproductive period.

Vaginal ecosystem can be frequently disturbed by both intrinsic and extrinsic factors. The intrinsic factors relate to hormonal change, including menopausal period, menstruation, pregnancy and lactation. As such, characters of vaginal discharge vary with age, condition and day of menstrual cycle. Therefore, 'abnormal vaginal discharge' is too complicated to be approached using a 'syndromic approach'. The extrinsic factors cover a wider range of causes, including excessive vaginal cleansing, sugar-rich diet, high level of stress, prolonged use of antibiotics, sedentary lifestyle, hormone use and abnormal bleeding as a side effect etc. These factors should be taken into consideration as an important part for managing women with abnormal vaginal discharge.

## Approach to women with abnormal vaginal discharge

On top of the approach to gynaecologic patients which includes history-taking, physical examination and

pelvic examination; vaginal pH and wet preparation should also be done. History taking to assess the risk of STIs, including the number of sexual partners, new sex partners within prior three months, condom use, and history of STIs in both the woman and her sexual partner(s). Physical examination aims to detect systemic manifestations of STIs such as skin rash and alopecia. Pelvic examination reveals external genital/vaginal/ cervical lesions, urethral discharge and characters of vaginal discharge. Some characters of vaginal discharge may be helpful but not specific such as homogeneous whitish discharge indicating bacterial vaginosis, mucopurulent discharge indicating bacterial infection, yellow or green frothy discharge indicating trichomoniasis and lumpy vaginal discharge (curd-like discharge) indicating fungal vaginitis.

Techniques of pelvic examination should be of concern as the taken specimen will be further tested. A dry speculum should be used so that the pH of vaginal discharge is accurately measured. Collection of abnormal vaginal discharge from the posterior and lateral fornix (high vaginal swab) should be done before Pap testing in order to avoid blood contamination. This specimen will be examined under microscopy (wet preparation). On the contrary, endocervical swab can be done either before or after Pap testing because this specimen will be sent for Gram staining, culture or molecular STI diagnosis.

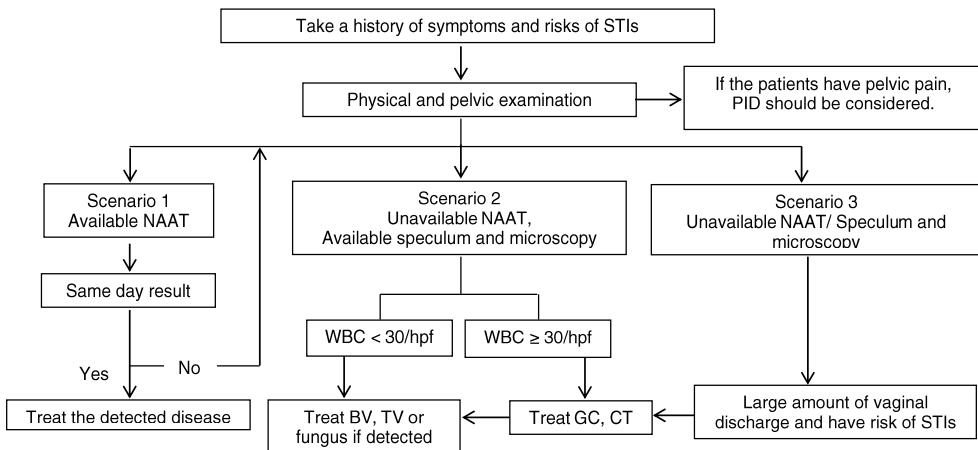
A wet preparation is a test of abnormal vaginal discharge mixing with normal saline solution; dripping on a glass slide; and being examined under a 100x microscope. It should be done within one hour after specimen collection. As the first glance, the ratio of numbers between leukocytes and squamous epithelium and the jerky movement of the organisms (*Trichomonas vaginalis*) should be looked for. Detection of *T. vaginalis* can immediately lead to treatment of trichomoniasis. If number of squamous epithelium is more than that of leukocytes, three conditions are considered, including normal vaginal discharge, bacterial vaginosis and acute vaginal candidiasis. A 10% potassium hydroxide (10% KOH) solution should then be used to break down the cell membranes, but not the cell walls of the fungi,

making the pseudohyphae more noticeable. Moreover, fishy odor, one of the diagnostic criteria for bacterial vaginosis, can be observed (positive whiff test). To detect clue cells, another drop of high vaginal swab will be examined under 400x microscope (high power field; hpf).

If number of leukocytes is more than that of squamous epithelium, the diagnosis can be bacterial vaginitis (gonorrhea, non-gonococcal cervicitis, trichomoniasis, aerobic vaginitis, cytolytic vaginitis) and chronic candidiasis. A drop of 10% KOH solution should also be added to reveal pseudohyphae. Then, another drop of high vaginal swab will be examined under 400x microscope(hpf) to count number of leukocytes. According to the Center for Disease Control and Prevention, the definition of cervicitis is a leukocyte count greater than 10/hpf<sup>(5)</sup> although clinical application is not clear. A previous study showed that 21.8% of high vaginal swab with  $\geq 30$  leukocytes/hpf had *Chlamydia trachomatis*<sup>(6)</sup>.

Apart from wet preparation, vaginal pH and Gram staining are also bed-side diagnostic tools of abnormal vaginal discharge. Vaginal pH  $\geq 4.7$  favors deficient vaginal ecosystem<sup>(7)</sup> which both results in and is resulted from abnormal vaginal discharge. Vaginal pH alone and combining with clinical symptoms demonstrated high diagnostic performance<sup>(7)</sup>. However, contamination of blood, seminal fluid or douching solution deranges the interpretation. Gram staining is useful but appears complicated and time-consuming.

As molecular diagnostic tests of STI pathogens, in an individual test or in a panel form, have currently been widely available, more precise diagnosis and treatment should be the primary goal. Nonetheless, most of the healthcare settings in Thailand where such tests are considered unaffordable, microscopic examination should play the major role. The Thai guideline suggests using  $\geq 30$  leukocytes/hpf as the triage point to starting treatment of gonorrhea and chlamydial cervicitis. In out-reached settings where microscopic examination is not provided, syndromic approach using sexual risk behaviors and naked-eye diagnosis is also acceptable. (Fig. 1)



**Fig. 1.** Algorithm for treating women with abnormal vaginal discharge.

BV: bacterial vaginosis, CT: chlamydial cervicitis, GC: gonorrhea, NAAT: nucleic acid amplification test, PID: pelvic inflammatory disease, STIs: sexually transmitted infections, TV: trichomoniasis, WBC: white blood cell

Remarks: 1. The pH test and wet preparation should be done every time if available.

2. Follow up at 1-2 weeks for assessment of treatment response. If symptoms do not improve, re-evaluation should be done.

Source: Thai 2022 STI treatment guideline

## Recommended treatment regimens by diseases

Non-STI causes of abnormal vaginal discharge

appear more prevalent than STI ones<sup>(8)</sup>.

Characteristics of vaginal discharge were demonstrated in Table 1.

**Table 1.** Characteristics of vaginal discharge by various conditions.

	Normal	Candidiasis	Cytolytic vaginitis	Bacterial vaginosis	Aerobic vaginitis	Gonorrhea	Non-gonococcal infection	Trichomoniasis
Signs and symptoms	Change with day of menstrual cycle, clear or mucoid discharge	Itching, stinging, abrasion, thick, curd-like discharge, discharge, dyspareunia	Itching, marked inflammation, large amount of discharge, dysuria, dysuria, dyspareunia	No inflammation, fishy-odored discharge, homogeneous discharge, whitish discharge	Itching, marked inflammation, large amount of vaginal and urethral discharge, dysuria, dysuria	Large amount of vaginal and urethral discharge, dysuria	Large amount of vaginal and urethral discharge, dysuria (less severe than gonorrhea)	Itching, large amount of vaginal discharge, discharge, yellow or green discharge
pH	≤ 4.5	≤ 4.5	≤ 4.5	> 4.5	> 4.5	> 4.5	> 4.5	> 4.5
wet smear	PMN:EC < 1	PMN:EC < 1	PMN:EC < 1	PMN:EC < 1	PMN:EC > 1	PMN:EC > 1	PMN:EC > 1	PMN:EC > 1
Gram stain	Lactobacilli (gram+ rod)	Pseudohyphae, budding yeast	Lactobacilli (gram+ rod)	Clue cells	Various organisms	Gram negative diplococci	-	Trichomonad

PMN: polymorphonuclear leukocytes, EC: vaginal epithelial cells. Source: Thai 2022 STI treatment guideline

## Vaginal candidiasis

Vaginal candidiasis (VC) is the leading cause of abnormal vaginal discharge<sup>(8,9)</sup>. The most common pathogen is *Candida albicans*, at about

80-90%, followed by *C. glabrata*, *C. tropicalis*, *C. krusei*, etc<sup>(10)</sup>. As *C. albicans* is a normal flora that can live in the vagina. VC is not classified as an STI.

## **Signs and symptoms**

The symptoms of VC are itching inside or outside the vagina and abnormal vaginal discharge such as increased amount or curd-like appearance. In case of severe symptoms, external genital area is involved causing erythema, swelling, painful skin, abrasions, or dyspareunia.

## **Risk factors<sup>(11)</sup>**

Vaginal candidiasis was associated with internal factors in each woman more than the severity of pathogen. Those factors are often related to blood sugar levels, including poorly controlled diabetes, pregnancy, steroid use etc. In addition, long-term use of antibiotics and receiving additional hormones (birth control pills containing estrogen, hormone replacement therapy in menopause) have been associated with vaginal candidiasis. Additional factors related to stress or mood swings, iron deficiency anemia and excessive cleaning of the genitals have also been reported.

## **Diagnosis**

Examination of high vaginal swab under a microscope is the most practical method. For fungal culture, it is reserved for recurrent VC as it can be used to detect drug-resistant strains. Only clinical diagnosis by history or naked-eye diagnosis is not accepted. At present, screening for other STIs among women with VC is not recommended.

## **Treatment**

*C. albicans* responds well to azoles group medication. Oral formulation should be avoided in pregnant and lactating women; and pregnant patients require a longer course of treatment. Vaginal suppositories may reduce the contraceptive effectiveness of condom. Azole cream should be added if there is vulvar involvement but should not be applied deep into the vagina.

Beside medications, advice regarding vaginal hygiene and general healthcare should be underlined. Gentian violet as an adjuvant treatment for women with acute VC significantly helps reduce symptom duration<sup>(10)</sup>. Sexual intercourse should be avoided until all symptoms are subsided. (Table 2, 3)

**Table 2.** Recommended treatment of acute vaginal candidiasis.

Medications*	- Fluconazole 150-200 mg orally single dose - Itraconazole 200 mg orally twice daily for 1 day - Clotrimazole 500 mg vaginal suppository single dose - Clotrimazole 200 mg vaginal suppository daily for 3 days - Clotrimazole 100 mg vaginal suppository daily for 6-7 days - Miconazole 200 mg vaginal suppository daily for 3 days
Abstinence from sex	If having symptoms
Sexual partner treatment	No treatment
Follow-up	Repeat examination only if symptoms persist.

\* Sertaconazole 300 mg ovule is an azole vaginal suppository which shows an acceptable treatment efficacy (unpublished data)<sup>(12)</sup>.

**Table 3.** Recommended treatment of recurrent vaginal candidiasis.

Medications	- Fluconazole 150-200 mg orally every 3 days for 3 doses then Fluconazole 150-200mg orally once weekly for 6 months - Fluconazole 150-200 mg orally every 3 days for 3 doses, followed by Fluconazole 150-200mg orally once weekly for 2 months. At the follow-up visit, fungal culture should be done. If negative, fluconazole 150-200mg orally every 2 weeks for another 2 months. At the follow-up visit, fungal culture should be done. If negative, fluconazole 150-200 mg orally every 4 weeks for another 4 months. At the follow-up visit, fungal culture should be done. If negative, the medication can be discontinued.* *If there is a breakthrough symptom, re-evaluation should be done; and fluconazole at the previous dose should be continued.
Abstinence from sex	If having symptoms
Sexual partner treatment	No treatment
Follow-up	Repeat examination only if symptoms persist.

No improvement of symptoms may be caused by azole resistance or non-albicans *Candida* pathogens. Alternative treatments are nystatin 100,000 units vaginal suppositories for 12-14 nights or Amphotericin B vaginal suppositories 50 mg vaginal suppositories for 14 nights<sup>(11)</sup>. A study in Thailand demonstrates that a course of 6 dequalinium chloride 10 mg vaginal tablets has an acceptable efficacy<sup>(13)</sup>.

## Bacterial vaginosis (BV)

BV is not considered as an STI because it is caused by an imbalance of bacterial community in vagina. There is an increase of anaerobic bacteria replacing *Lactobacilli* spp.

### Signs and symptoms

BV is mostly asymptomatic. Those who have symptoms often present with whitish or grayish vaginal discharge or with fishy-odor discharge. The smell becomes striking during sexual intercourse and around menstrual period.

### Risk factors

Disturbance of vaginal ecosystem includes vaginal douching, excessive genital cleansing,

prolonged vaginal bleeding or following any kinds of vaginal infection.

### Diagnosis

The most commonly used bedside diagnostic tool of BV is Amsel criteria<sup>(14)</sup>. Diagnosing BV by Amsel criteria requires the presence of 3 out of 4 criteria; homogeneous creamy grayish-white discharge, vaginal pH is  $> 4.5$ , fishy-odor discharge either before or after adding 10% KOH (whiff test), and presence of clue cells. The limited use of Amsel criteria is when there is contamination of blood, seminal fluid or amniotic fluid. Another diagnostic method of BV which has high diagnostic accuracy is the detection of  $\geq 20\%$  clue cells in either wet preparation or Gram staining (sensitivity 87.1% and specificity 55.8%)<sup>(15)</sup>.

### Treatment

Antibiotic treatment together with risk behavior modification is recommended. As metronidazole is the main antibiotics, patients should be advised to avoid alcohol consumption until  $\geq 24$  hours after last metronidazole intake or for  $\geq 72$  hours after last tinidazole intake to avoid disulfiram-like reaction. Common side effects of the medications include nausea, vomiting, and metallic taste. (Table 4)

**Table 4.** Recommended treatment of bacterial vaginosis.

Medications	<ul style="list-style-type: none"> <li>- Metronidazole 400-500 mg orally twice daily for 7 days</li> <li>- Metronidazole 2 g orally single dose</li> <li>- Metronidazole 750 mg vaginal suppository daily for 7 days</li> <li>- Tinidazole 2 g orally single dose</li> <li>- Clindamycin 300 mg orally twice daily for 7 days</li> </ul>
Abstinence from sex	If having symptoms
Sexual partner treatment	No treatment
Follow-up	Repeat examination only if symptoms persist.

## Vaginal trichomoniasis

Vaginal trichomoniasis is an STI caused by *Trichomonas vaginalis* which has an oval shape and is sized slightly larger than a leukocyte. It has a jerky movement due to having five flagella.

### Signs and symptoms

Vaginal trichomoniasis can be asymptomatic. Patients with symptoms often present with yellow or green frothy vaginal discharge and itching in the vagina. Some may have fishy-odor discharge and dysuria. The pelvic

examination may reveal inflamed vaginal mucosa and friable cervix with bleeding beneath the mucosa (strawberry cervix).

### Risk factors

Vaginal trichomoniasis is a disease that is transmitted only from person to person through sexual intercourse. Risk factors are therefore related to unprotected sex with people with the disease.

### Diagnosis

The simplest bed-side diagnostic tool is wet

preparation. However, the sensitivity is only 40-70% and its accuracy is greatly reduced if examination is performed later than an hour of specimen collection<sup>(16)</sup>. Nucleic acid amplification test (NAAT) is an alternative option<sup>(17)</sup>.

### Treatment

Symptoms of TV can be non-specific and mimicks other STIs, especially VC. Moreover, the coinfection is common. Prescribing metronidazole with other medication, a clear advice regarding side effects and how to properly consume is necessary. (Table 5)

**Table 5.** Recommended treatment of trichomoniasis.

Medications	Recommended regimen
	<ul style="list-style-type: none"> <li>- Metronidazole 2 g orally single dose</li> <li>- Metronidazole 400-500 mg orally twice daily for 5-7 days</li> </ul>
	Alternative regimen
	<ul style="list-style-type: none"> <li>- Tinidazole 2 g orally single dose</li> </ul>
	Follow-up at 1-2 weeks:
	<p>If symptoms persist and trichomonad is detected under microscopy.</p> <ul style="list-style-type: none"> <li>- Metronidazole 400 - 500 mg orally twice a day for 7 days if the first regimen is the single dose.</li> </ul>
	Follow-up at 1-2 weeks:
	<p>If symptoms persist and trichomonad is detected under microscopy.</p> <ul style="list-style-type: none"> <li>- Metronidazole 2 g orally once daily for 5-7 days or</li> <li>- Metronidazole 800 mg orally 3 times a day for 7 days</li> </ul>
Abstinence from sex	Until sexual partner(s) are treated
Sexual partner treatment	Expedited treatment with the same regimen
Follow-up	1-2 weeks and 3 months after the date of treatment

### Aerobic vaginitis (AV)<sup>(18, 19)</sup>

It is not an STI but a form of vaginal dysbiosis. The decrease of *Lactobacilli* spp. is caused by an overgrowth of aerobic vaginal flora, including *E. coli*, *Enterococci* spp., *Staphylococcus aureus*, gr. B *Streptococcus*<sup>(19)</sup>. AV has also been found to be associated with STIs by increasing the STIs, i.e. *C. trachomatis*, *N. gonorrhoeae*, *T. vaginalis*, and it was found to be associated with infections of other bacteria in the pelvic cavity, preterm labor, and premature rupture of membranes.

### Signs and symptoms

Severe inflammation and large amount of yellow vaginal discharge are common. The most common history is that symptoms persist for a long time despite multiple medical visits.

### Diagnosis<sup>(20)</sup>

Diagnosis is usually based on Gram staining and microscopic examination by using the proportion of *Lactobacilli* spp., high white blood cell count, and normal flora organisms to aggregate the scores into AV scores which include *Lactobacillus* grade, white blood cell count, toxic leucocyte ratio, and background flora. Interpretation: Normal score = 0-4, Moderate

AV score = 5-6, Severe AV score = 6-10.

### Treatment

The goal of treatment is to correct three

conditions: atrophy, inflammation and abnormal flora. Based on the authors' experience, a course of treatment is usually longer than 7 days. (Table 6)

**Table 6.** Recommended treatment of aerobic vaginitis.

Medications	Topical estrogen is to resolve atrophy. Topical corticosteroid is to relieve inflammation. For antibiotics, including the use of lactobacilli suppository, there is no consensus on which medication and in what form to use. Amoxicillin/Clavulanic acid 1 g orally twice a day or Moxifloxacin 400 mg orally once a day for 7 days has been proposed.
Abstinence from sex	If having symptoms
Sexual partner treatment	No treatment
Follow-up	Repeat examination only if symptoms persist.

### Cytolytic vaginitis<sup>(21)</sup>

Cytolytic vaginitis is usually caused by an increase in the number of *Lactobacilli* spp. causing irritation; and excessive production of lactic acid and hydrogen peroxide that damages the vaginal epithelium.

#### Signs and symptoms

Severe inflammation and large amount of yellow vaginal discharge are common. The most common history is that symptoms persist for a long time despite multiple medical visits.

#### Diagnosis

Wet preparation or Gram staining reveals many gram-positive rod bacteria compatible with *Lactobacilli* spp. together with a large number of epithelial cells. If the patients have cytolytic vaginitis for a long time, there will be an increase in leukocytes.

### Treatment

The goal of treatment is to alkalinise intravaginal condition. Douching with sodium bicarbonate solution as being recommended seems impractical in Thai women. And, some women need a longer course of treatment. (Table 7)

**Table 7.** Recommended treatment of cytolytic vaginitis.

Medications	Vaginal douching with 1 to 2 tablespoons of sodium bicarbonate (NaHCO <sub>3</sub> ) or baking soda mixed with 1 -1.5 litre of warm water. Vaginal douching with a slightly longer douching time is effective without the use of antibiotics. It has been suggested to do douching twice a week, every 2 weeks. Symptoms should improve in about 2-3 weeks after treatment has started.
Abstinence from sex	* Based on the authors' experience, sodium bicarbonate 300 mg tablet (Sodamint <sup>®</sup> ) being applied intravaginally 2-3 times a day for two weeks shows good clinical and microscopic outcomes.
Sexual partner treatment	If having symptoms
Follow-up	No treatment

### Gonococcal infection

The pathogen is *Neisseria gonorrhoeae* and the

trophic cell is columnar cell which is the lining of urethra, endocervix, fallopian tubes, and conjunctiva. This

organism can enter bloodstream to other organs such as joints, meninges, heart etc.

### **Signs and symptoms**

The symptoms are abnormal vaginal and/or urethral discharge and dysuria.

### **Diagnosis**

The wet preparation test revealed a large number

of white blood cells. Gram staining revealed intracellular gram-negative diplococci. More sensitive diagnostic method is nucleic acid amplification test (NAAT). Culture should be done to determine drug resistance.

### **Treatment**

The drug resistance of *N. gonorrhoea* has been a global concern resulting in an increasing dose of antibiotic regimens. (Table 8)

**Table 8.** Recommended treatment of gonococcal infection.

Medications	Recommended regimen
	- Ceftriaxone 500 mg intramuscular injection single dose <sup>(5)*</sup>
Abstinence from sex	Alternative regimen
Sexual partner treatment	- Cefixime 800 mg orally single dose*
	- Gentamicin 240 mg intramuscular injection single dose PLUS Azithromycin 2 g orally single dose
	* Treatment of <i>C. trachomatis</i> infection should be added if only it cannot be excluded. Until 7 days after treatment and until sexual partner has completed treatment.
	Sexual partners who have had sex within 60 days before the patient had symptoms are recommended to receive evaluation and treatment as the index patient. However, if being unable to come for evaluation, expedited partner therapy should be done.
Follow-up	7 days after the day of treatment

### **Test of cure (TOC)<sup>(22)</sup>**

The patients who require TOC are those who still have symptoms or extragenital infection; or have been treated with non-ceftriaxone medication. TOC will help to detect treatment failure, drug resistance, drug compliance and side effects. Moreover, education regarding risky sexual behaviors that cause re-infection, monitoring of sexual partners, and promoting health can also be done.

### **Non-gonococcal infection**

Most cases are caused by *C. trachomatis*, followed by *Mycoplasma genitalium*. Other organisms being reported include *Mycoplasma hominis*, *Ureaplasma urealyticum*, *Ureaplasma parvum*, and others<sup>(23)</sup>. Owing to the minimal symptoms, the infections can continually spread and re-infection

appears common.

### **Signs and symptoms**

Signs and symptoms are similar to gonorrhea but are less severe.

### **Diagnosis**

The wet preparation test reveals a large number of white blood cells. Gram staining and bacterial culture are negative. NAAT is the main diagnostic tool to identify non-gonococcal pathogens.

### **Treatment**

Data are limited for the treatment of some pathogens. This guideline includes the recommended treatment of *C. trachomatis* and *M. genitalium*. (Table 9)

**Table 9.** Recommended treatment of non-gonococcal infection.***Chlamydia trachomatis treatment*<sup>(24)</sup>**

Medications	<ul style="list-style-type: none"> <li>- Doxycycline 100 mg orally twice a day after meal for 7 days</li> <li>- Azithromycin 1 g orally single dose</li> <li>- Erythromycin stearate 500 mg orally 4 times a day after meal for 14 days</li> <li>- Amoxicillin 500 mg orally 3 times a day after meal for 7 days</li> </ul>
Abstinence from sex	Until 7 days after treatment and until the sexual partner has completed treatment.
Sexual partner treatment	Sexual partners who have had sex within 60 days before the patient had symptoms are recommended to receive evaluation and treatment as the index patient. However, if being unable to come for evaluation, expedited partner therapy should be done.
Follow-up	2 weeks after the date of treatment

***Mycoplasma genitalium treatment*<sup>(25)</sup>**

Medications	<ul style="list-style-type: none"> <li>- Doxycycline 100 mg orally twice a day for 7 days, followed by Azithromycin 1 g orally initial dose, followed by 500 mg orally once daily for 3 additional days</li> <li>If symptoms persist,</li> <li>- Moxifloxacin 400 mg orally once a day for 10 days</li> </ul>
Abstinence from sex	Until 7 days after treatment and until the sexual partner has completed treatment.
Sexual partner treatment	Treat only the current sex partner
Follow-up	2 weeks after the date of treatment

**Test of Cure (TOC)<sup>(24)</sup>**

It is not recommended for all patients as dead organisms can be detected for up to 5 weeks after treatment. TOC should be done for those with incomplete treatment or persistence of symptoms. TOC at 3-6 months after complete treatment is suggested, especially those being in the age group of < 25 years.

## Conclusion

Abnormal vaginal discharge is a common presenting symptom at all gynaecologic clinics. The etiologies can be STIs or non-STIs. According to the Thai 2022 STI treatment guideline, clinical-based and basic laboratory-based approach is designed to fit all healthcare settings. However, if treatment response does not meet care-givers' expectation, consultation to specialists is recommended.

## Potential conflicts of interest

The authors declare no conflicts of interest.

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## OBSTETRICS

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# Comparative Performance of Ultrasonographic Fetal Biometry and Three Clinical Equations in the Intrapartum Period for Estimating Fetal Weight in Thai Singleton Pregnant Women Giving Birth at a Referral Tertiary Hospital

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## ABSTRACT

**Objectives:** To compare the accuracy of fetal weight estimation by ultrasonography and three clinical equations and also to examine the ability of these estimation methods to predict low birth weight and macrosomia in Thai pregnant women giving birth at a referral tertiary hospital in northeastern Thailand.

**Materials and Methods:** Two hundred singleton pregnant women giving birth at Sanpasitthiprasong Hospital during September 2018 – March 2019 were recruited. Fetal weight was estimated by trans-abdominal ultrasound and three existing clinical equations: Dare's, Johnson's and Buchmann's methods. Proportions of within 10% accuracy compared to actual birth weight were computed and measures of ability to predict low, normal birth weight and macrosomia (sensitivity/specificity, positive/negative predictive values and area under the receiver operating characteristics (AUR)) were compared using McNemar's test and nonparametric method.

**Results:** The mean actual birth weight was  $3,069.9 \pm 464.8$  grams. Overall, ultrasonography resulted in a higher proportion of within-10% accuracy than Dare's, Johnson's and Buchmann's methods (70.5%, 38.5%, 24.5% and 58.5%, respectively,  $p < 0.001$ ). Similar findings were observed for normal birth weight and for both term and preterm neonates. Ultrasonography had the best ability to predict low birth weight with sensitivity, specificity and AUR of 75% (95% confidence interval (CI) 51-91%), 94% (95%CI 89-97%) and 0.84 (95%CI 0.75-0.94), while Dare's and Johnson's methods better predicted macrosomia than the other two methods ( $p = 0.002$ ).

**Conclusion:** Intrapartum ultrasonography had the highest accuracy in estimating actual birth weight, overall and particularly best in low birth weight. However, Dare's and Johnson's clinical equations appeared to predict macrosomia well and might probably be useful when large fetus is suspected in clinical practice.

**Keywords:** estimated fetal birth weight, ultrasonography, clinical equations, accuracy, predictive ability.

## การศึกษาเปรียบเทียบความสามารถในการคำนวณน้ำหนักทารกในครรภ์ระหว่างการใช้อัลตราซาวด์และสมการทางคลินิก 3 สมการ ในระยะการคลอดในกลุ่มสตรีตั้งครรภ์ชาวไทยที่คลอดบุตรในโรงพยาบาลติดภูมิ

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### บทคัดย่อ

**วัตถุประสงค์:** เพื่อเปรียบเทียบความถูกต้องในการคำนวณน้ำหนักทารกในครรภ์ระหว่างการใช้อัลตราซาวด์ และสมการทางคลินิก 3 สมการ และเพื่อเปรียบเทียบความสามารถในการคำนวณน้ำหนักทารกแรกเกิดที่มีน้ำหนักตัวน้อยและตัวโต ในกลุ่มสตรีตั้งครรภ์ชาวไทยที่คลอดบุตรในโรงพยาบาลติดภูมิทางภาคตะวันออกเฉียงเหนือของประเทศไทย

**วัสดุและวิธีการ:** สตรีตั้งครรภ์ชาวไทยจำนวน 200 คน ที่คลอดบุตร ณ โรงพยาบาลสหพัฒน์ประเสริฐ ระหว่างเดือนกันยายน พ.ศ. 2561 ถึง มีนาคม พ.ศ. 2562 จะได้รับการประเมินน้ำหนักทารกในครรภ์โดยการคำนวณน้ำหนักทารกแรกเกิด 3 สมการ (Dare's, Johnson's and Buchmann's equations) โดยทำการเปรียบเทียบค่าความแม่นยำภายในร้อยละ 10 (Within 10% accuracy) ของแต่ละวิธี เมื่อเปรียบเทียบกับน้ำหนักแรกเกิดจริง และเปรียบเทียบค่าความสามารถในการคำนวณน้ำหนักทารกน้อย น้ำหนักปกติ และน้ำหนักเกินเกณฑ์ (sensitivity/specificity, positive/negative predictive values and area under the receiver operating characteristics (AUR)) โดยใช้สถิติ McNemar's test และ non-parametric method

**ผลการศึกษา:** ค่าเฉลี่ยของน้ำหนักทารกแรกเกิด  $\pm$  ค่าเบี่ยงเบนมาตรฐานเท่ากับ  $3,069.93 \pm 464.84$  กรัม จากการศึกษาโดยรวม ค่าความแม่นยำภายในร้อยละ 10 ของการประมาณค่าโดยใช้อัลตราซาวด์ สูงกว่าวิธีของ Dare's, Johnson's และ Buchmann's (ความถูกต้องร้อยละ 70.5, 38.5, 24.5 และ 58.5 ตามลำดับ,  $p < 0.001$ ) และผลการศึกษาเกี่ยวกับกลุ่มที่น้ำหนักทารกน้อย น้ำหนักตัวปกติ และน้ำหนักเกินเกณฑ์ (น้ำหนักตัวน้อยกว่า 2,500 กรัม) ได้ดีที่สุด โดยมีค่า sensitivity ที่ร้อยละ 75 (95% confidence interval 51-91%) ค่า specificity ร้อยละ 94 (89-97%) และพื้นที่ใต้โค้ง AUR 0.84 (0.75-0.94) แต่วิธีของ Dare's และ Johnson's มีความสามารถในการคำนวณน้ำหนักทารกตัวโต (น้ำหนักแรกเกิดมากกว่า 4,000 กรัม) ที่สูงกว่าวิธีอื่น ( $p = 0.002$ )

**สรุป:** การอัลตราซาวด์ในระยะคลอดมีความถูกต้องในการประมาณการน้ำหนักทารกแรกเกิดสูงที่สุด และสามารถคำนวณน้ำหนักทารกน้อยได้ดีที่สุดเมื่อเทียบกับสมการทางคลินิกอื่น อย่างไรก็ตามสมการทางคลินิกของ Dare's และ Johnson's มีความสามารถในการคำนวณน้ำหนักเกินเกณฑ์ได้ดีที่สุดและอาจนำมาใช้ในเวชปฏิบัติเมื่อสงสัยการมีทารกตัวโต

**คำสำคัญ:** การประมาณการค่าน้ำหนักทารก, อัลตราซาวด์, สมการทางคลินิก, ความถูกต้อง, ความสามารถในการคำนวณ

## Introduction

Assessment of fetal size is critical for decision making in routes and methods of delivery. Accurate estimation of fetal weight could help reduce the incidence of maternal and neonatal injury during labor and rate of inappropriate cesarean section<sup>(1, 2)</sup>. Additionally, fetal birth weight estimation may also be beneficial in predicting perinatal morbidity and mortality particularly in those with birth weight of the lower than the 10th percentile<sup>(3-5)</sup>.

Assessing the size of the fetus can be accomplished in a number of ways: mother self-assessment based on prior pregnancy, estimation equations based on height of fundus and abdominal girth and ultrasonography, all of which are essentially assessor-dependent<sup>(6)</sup>. Equations based on ultrasonographic findings have been increasingly used, but some studies reported that these ultrasonography-based equations resulted in a systematic underestimation of fetal weight especially if the ultrasonography was performed during intrapartum period<sup>(7, 8)</sup>. Previous studies have showed inconsistent results concerning clinical equations that best predicted fetal birth weight. Some studies found that intrapartum ultrasonography better predicted fetal weight than other clinical equations<sup>(9-11)</sup>, while other studies showed that Dare's equation and ultrasonography predicted fetal weight better than Johnson's equation in term normal weight fetus<sup>(12)</sup> and large fetus<sup>(6)</sup>. Furthermore, a few studies compared the predictive performance of several clinical equations<sup>(9-11, 13, 14)</sup>, and most of the previous studies were performed in term low risk pregnancy<sup>(6, 10, 13)</sup>. Evidence on high risk group is limited<sup>(14)</sup>. Therefore, the present study primarily aimed to compare the performance of four methods to estimate fetal weight in low and high risk pregnancy: three existing standard clinical equations and ultrasonography-based estimation. The secondary objective was to examine the ability of these estimation methods to predict low birth weight and macrosomia in Thai pregnant women giving births at a referral tertiary hospital in northeastern Thailand.

## Materials and Methods

In this observational analytical study, 200 singleton pregnant women with a gestational age of 28-42 weeks and cephalic presentation who gave births at the Department of Obstetrics and Gynecology, Sanpasithiprasong Regional Hospital between September 2018 and March 2019 were recruited. The present study focused on pregnancy with all range of risk (i.e. low risk: term low risk pregnancy, pre-pregnancy body mass index (BMI) > 30 kg/m<sup>2</sup>, teenage pregnancy, low birth weight, and macrosomia) and those whose physical examination and ultrasonography were performed in the intrapartum period and within 24 hours before delivery. Pregnant women who presented in both latent and active phase of 1st stage of labor with either intact or ruptured membranes were included. We excluded mothers who have conditions that required specific treatment and possibly prevented them from participating in the study. Those with fetal malformation, oligohydramnios, polyhydramnios and other maternal conditions which could affect fundal height and fetal growth; namely, pregnancy induced hypertension, gestational and overt diabetes, and uterine/ovarian tumors were excluded. Oligohydramnios and polyhydramnios were based on antenatal care history and ultrasonographic finding at recruitment. Sample sizes determination was based on a research question "whether there was a difference in the within-10% accuracy between different tools (whether the proportion was different for at least one group)" According to previous literature reporting the within-10% accuracy of 53.5%<sup>(15)</sup> and 82%<sup>(16)</sup> for Dare's and Hadlock's equations, a sample size of 172 was required at 95% confidence level and 90% power using the following formula. The sample size was increased to 200 to account for 15% missing data/loss to follow-up.

$$n = \left[ \frac{z_{1-\alpha/2} \sqrt{p_{01} + p_{10}} + z_{1-\beta} \sqrt{p_{01} + p_{10} - (p_{01} - p_{10})^2}}{\Delta} \right]^2$$

All pregnant women meeting the above inclusion/exclusion criteria gave written informed consent. This study was approved by the Sanpasitthiprasong Regional Hospital Ethic Committee (055/2561).

Data collection was performed during the intrapartum period. After giving informed consent, participants were questioned about personal and medical history as well as obstetric history including gravid and parity, gestational age (GA) and due date. Data on antenatal care including pre-pregnancy BMI were obtained using medical and antenatal care record reviews by the investigators, NP and PP. BMI was categorized according to the World Health Organization (WHO) Expert Consultation's recommendation on appropriate BMI for Asian populations<sup>(17)</sup>. Weight gain during pregnancy was defined based on pre-pregnancy BMI group<sup>(18)</sup>. Symphysis-height of fundus (SFH) and abdominal girth (AG) were assessed by 2<sup>nd</sup> year residents using non-stretch tape. The height of uterine fundus was measured from the pubic symphysis to the top of the uterus measure after emptying bladder. Following the widely-used method<sup>(19, 20)</sup>, AG was measured at the level of the umbilicus. Per vaginal examination was carried out by 2<sup>nd</sup> year obstetric and gynecological (OBGYN) residents and the station of fetal head assessed with reference to ischial spine. After that, ultrasonography was performed by the same residents using Samsung Sonoage R5 following standard protocols. Biparietal diameter (BPD) was measured at the level where both thalami and cavum septum pellucidum were visualized. BPD was measured from inner to outer table of the skull bones. Head circumference was measured in the same plane. Abdominal circumference was measured at the level of bifurcation of the hepatic vein into right and left branches. Femoral length was measured with the femur excluding the femoral head and the epiphysis along the vertical axis seen transversely<sup>(21)</sup>. Ultrasonographic findings at recruitment were also used to exclude women with certain abnormalities described in the above exclusion criteria. For each

pregnant woman, all measurements and ultrasonography were performed by one of the 2<sup>nd</sup> year residents who were trained specifically for this study and every measurement performed in the present study was verified by Maternal Fetal Medicine (MFM) specialist. In case that there was discordance of the measurements between the resident and MFM specialist, results by the MFM specialist were used. After that, the weight of baby was estimated by four different methods: ultrasonography-based Hadlock IV, Dare's, Johnson's, and Buchmann's clinical equations with detailed equations as shown below.

Hadlock IV(21):  $\text{Log10 (EFW)} = 1.3596 - 0.00386 \cdot \text{AC} \cdot \text{FL} + 0.0064 \cdot \text{HC} + 0.00061 \cdot \text{BPD} \cdot \text{AC} + 0.0424 \cdot \text{AC} + 0.174 \cdot \text{FL}$

Dare's<sup>(19)</sup>:  $\text{EFW} = \text{SFH} \text{ (cm)} \cdot \text{AG} \text{ (cm)}$

Johnson's<sup>(22)</sup>:  $\text{EFW} = 155 \cdot (\text{fundal height (cm)} - x)$   
where  $x = 11$  at plus station;  $= 12$  at zero station;  
 $= 13$  at minus station

Buchmann's<sup>(23)</sup>:  $\text{EFW} = (\text{SFH (cm)} - 5) \cdot 100$

EFW: estimated fetal weight (grams), AC: abdominal circumference (cm), FL: fetal length (cm), HC: head circumference (cm), BPD: biparietal diameter (cm), SFH: Symphysis-height of fundus (cm), AG: abdominal girth (cm)

Actual birth weight of the newborns in grams was measured by registered nurses using Seca 334 Equip Health Care and recorded in a case record form. Low birth weight and macrosomia were defined as actual birth weight of  $< 2,500$  and  $\geq 4,000$  grams, respectively.

## Statistical analyses

All statistical analyses were performed using Stata software version 14.2 (StataCorp LLC, Texas). Data on mother characteristics including personal and obstetric history, physical examination results,

and actual birth weight of the newborn were described using number (percentage), mean (standard deviation (SD)), median (interquartile range (IQR)) for categorical, normally - and non-normally distributed continuous variables respectively. Mean birth weight computed by each estimation equation was compared with actual birth weight using the pair t test. Mean absolute error was computed as the average of the absolute difference between actual and estimated fetal birth weight by each estimation method. Mean absolute error percentage was computed as the mean of the product of dividing absolute difference between actual and estimated birth weight by actual birth weight and multiplying by 100. Accuracy within 10% of actual birth weight was computed and compared between two methods using McNemar's test and across four methods using Cochran's Q test. This was performed for all participants and stratified by levels of actual birth weight (< 2,500, 2,500-3,999 and  $\geq$  4,000 grams) and gestational age at birth (< 37, and  $\geq$  37 weeks). Ability of the four equations to predict low birth weight and macrosomia was examined and sensitivity, specificity, positive predictive value, negative predictive value, and the area under the receiver operating characteristics curves (AUR) were computed. Comparison in these predictive ability measures was carried out using McNemar's test and non-parametric methods<sup>(24)</sup>. A p value of  $< 0.05$  was considered statistically significant.

## Results

Characteristic of mothers and actual birth weight of the newborns are shown in Table 1. The mean  $\pm$  SD age of mothers was  $26.1 \pm 6.3$  years, with two-thirds aged between 20 - 34 years. The average pre-pregnancy BMI was  $22.0 \pm 4.5$  kg/m<sup>2</sup>, with approximately one-third being over-weight or obese. Most of the pregnant women had never given birth before (55.5%) and the median (IQR) of gestational age was 38 (38-39) weeks. An average actual fetal birth weight  $\pm$  SD was  $3,069.9 \pm 464.8$  grams and 87

percent weighed within normal birth weight category. Considering high risk groups, 16.5 percent of all participants were teenage pregnancy (age  $< 20$  years old), 18 percent were obese according to pre-pregnancy BMI, 8.5 percent presented with preterm pregnancy and 13 percent were either low birth weight or macrosomia.

Table 2 shows the actual birth weight of newborns and fetal birth weight estimated using four different methods in all participants and by actual birth weight category. The mean  $\pm$  SD actual birth weight of newborns was  $3,069.9 \pm 464.8$  grams. Overall, the four methods gave different mean  $\pm$  SD estimation of fetal birth weight, ranging from  $2,976.5 \pm 447.7$  to  $3,682.4 \pm 499.6$  grams. The fetal birth weight estimated by the Buchmann's method was comparable with the average actual birth weight, while those of other three estimation methods were different from the actual values. Considering absolute differences between actual and estimated fetal birth weight, the smallest absolute difference was observed for ultrasound method, while the largest observed for the Johnson's method (absolute difference  $\pm$  SD of  $238.3 \pm 213.4$  and  $654.1 \pm 418.8$  grams, respectively). However, there was no discrepancy in the absolute difference between the actual birth weight and estimated birth weight obtained from each of the four clinical equations. Ultrasonography had the lowest mean absolute error percentage, followed by Buchmann's method, while highest mean absolute error percentage was observed for Johnson's method. When considering within 10% difference from the actual birth weight, the proportion of having within 10% accuracy differed across four different estimation methods ( $p < 0.001$ ), with the highest proportion of within-10% accuracy observed for ultrasonography. Similar results were observed for those with low and normal actual birth weight. However, in infants with actual birth weight of  $\geq 4,000$  grams, the Johnson's and Dare's clinical equations gave more accurate estimations than the Buchman's and ultrasonography methods as indicated by both mean absolute error percentage and within-10% accuracy.

**Table 1.** Characteristics of participating pregnant women and actual birth weight of the newborns (n = 200).

Characteristics	
Maternal age (years)	26.1 ± 6.3
Maternal age group	
< 20 years	33 (16.5%)
20 - 34 years	143 (71.5%)
≥ 35 years	24 (12%)
Pre-pregnancy BMI (kg/m <sup>2</sup> )	22.0 ± 4.5
Pre-pregnancy BMI group	
< 18.5 kg/m <sup>2</sup>	38 (19%)
18.5 - 22.9 kg/m <sup>2</sup>	103 (51.5%)
23 - 24.9 kg/m <sup>2</sup>	23 (11.5%)
25 - 29.9 kg/m <sup>2</sup>	22 (11%)
> 30 kg/m <sup>2</sup>	14 (7%)
Weight gain (kg)	13.2 ± 5.8
Weight gain category	
Low weight gain	71 (35.5%)
Normal weight gain	61 (30.5%)
Excessive weight gain	68 (34.0%)
Gravida	2 (1-2)
Parity	0 (0-1)
Gestational age (weeks)	38 (38-39)
Gestational age group	
Preterm	17 (8.5%)
Term	183 (91.5%)
Symphysis - fundal Height (cm)	35.4 ± 3.2
Abdominal girth(cm)	139 ± 69.5
Membranes intact	143 (71.5%)
Actual fetal birth weight (grams)	3069.9 ± 464.8
Category of actual birth weight	
< 2,500 grams	20 (10%)
2,500 - 3,499 grams	174 (87%)
≥ 3,500 grams	6 (3%)

Data are presented as mean ± standard deviation, n (%) or median (interquartile range). BMI: body mass index and BMI was categorized according to the WHO Expert Consultation's recommendation on Asian Pacific criteria<sup>(10)</sup>

**Table 2.** Accuracy of fetal birth weight estimated by four different methods, overall and by fetal birth weight category.

	Ultrasound	Dare's	Johnson's	Buchmann's	p value
<b>Overall (n = 200): mean ± SD, actual FBW 3,069.9 ± 464.8 gm</b>					
Mean ± SD of estimated FBW	2,976.5 ± 447.7*	3,451.6 ± 578.8*	3,682.4 ± 499.4*	3,032.7 ± 310.5	
Mean absolute error ± SD	238.3 ± 213.4	489.7 ± 405.6	654.1 ± 418.8	320.3 ± 239.3	
Mean absolute error percentage ± SD	7.1 ± 6.5	16.3 ± 14.9	22.3 ± 16.3	10.2 ± 8.6	
Accuracy within 10% of actual birth weight, n (%)	141 (70.5)**	77 (38.5)	49 (24.5)	117 (58.5)	< 0.001
<b>&lt; 2500 gm (n = 20): mean actual FBW 2,233.9 ± 140.4 gm</b>					
Mean ± SD of estimated FBW	2,276.5 ± 295.0	3,058.0 ± 450.9*	3,309.3 ± 390.4*	2,780.0 ± 246.2*	< 0.001
Mean absolute error ± SD	152.8 ± 130.0	824.0 ± 432.5	1,075.4 ± 356.1	546.1 ± 242.1	< 0.001
Mean absolute error percentage ± SD	6.4 ± 5.7	36.9 ± 20.0	48.1 ± 17.1	24.5 ± 12.2	
Accuracy within 10% of actual birth weight, n (%)	14 (70.0)	2 (10.0)	0 (0)	3 (15.0)	< 0.001
<b>2500-3999 gm (n = 174): mean actual FBW 3,129.9 ± 346.4 gm</b>					
Mean ± SD of estimated FBW	3,037.5 ± 383.4*	3,471.2 ± 568.6*	3,706.2 ± 490.6*	3,050.3 ± 303.2*	< 0.001
Mean absolute error ± SD	236.4 ± 208.6	462.1 ± 389.0	621.5 ± 397.6	279.6 ± 212.4	< 0.001
Mean absolute error percentage ± SD	7.0 ± 6.5	14.4 ± 12.4	20.0 ± 13.4	8.3 ± 6.3	0.027
Accuracy within 10% of actual birth weight, n (%)	125 (71.8)	69 (39.7)	44 (25.3)	114 (65.5)	< 0.001
<b>≥ 4000 gm (n = 6): mean actual FBW 4,116.7 ± 129.99 gm</b>					
Mean ± SD of estimated FBW	3,538.5 ± 304.3*	4,197.3 ± 275.6	4,236.7 ± 288.6	3,366.7 ± 163.3*	< 0.001
Mean absolute error ± SD	578.2 ± 275.0	175.0 ± 94.6	195.0 ± 172.0	750 ± 115.9	< 0.001
Mean absolute error percentage ± SD	13.5 ± 6.9	3.7 ± 2.3	4.3 ± 3.9	17.7 ± 2.8	0.484
Accuracy within 10% of actual birth weight, n (%)	0 (0)	4 (66.7)	5 (83.3)	0 (0)	< 0.001

p value for comparison in within 10% accuracy for four estimation methods using Cochran's Q test. FBW: fetal birth weight, SD: standard deviation. \*statistically significant difference between actual birth weight and estimated values from each methods using paired t test (p < 0.05)

\*\*statistically significant difference in proportion between the best and second-best estimation methods using McNemar's test (p < 0.05)

Table 3 shows the actual fetal birth weight and birth weight estimated using four different methods by category of gestational age at birth. Among the four estimation methods, ultrasonography showed the smallest mean absolute error and mean absolute error percentage and highest proportion of within-10% accuracy. This was similar for both preterm and term infants.

Ability of four estimation methods to predict low, and normal birth weight and macrosomia based on actual birth weight is shown in Table 4. Ultrasonography had the best performance to predict low birth weight, with the sensitivity, specificity and AUR of 75.0 (95% confidence interval 50.9-91.3), 93.9 (89.3-96.9) and

0.84 (0.75-0.94), respectively. Similar findings were observed for prediction of normal fetal birth weight, with ultrasonography showing the highest AUR of 0.76. In the contrary, Dare's and Johnson's equations were better than Buchmann's method at predicting macrosomia (actual birth weight of  $\geq 4,000$  grams), with the sensitivity, specificity and AUR of 66.7%, 84.5% and 0.76 and 83.3%, 75.3% and 0.79 for Dare's and Johnson's equations, respectively. As ultrasonography did not predict anyone to have birth weight of  $> 4,000$  grams, AUR for ultrasonography could not be computed. In other words, ultrasonography had no ability to discriminate between those with and without macrosomia.

**Table 3.** Accuracy of fetal birth weight estimated using four different methods by gestational age at birth.

Gestational age	Ultrasonography	Dare	Johnson	Buchmann	p value
<b>Preterm (n = 17): mean <math>\pm</math> SD, actual FBW of 2,486.5 <math>\pm</math> 373.3 grams</b>					
Mean $\pm$ SD of estimated FBW	2,316 $\pm$ 340.0	3,096.6 $\pm$ 337.7*	3,382.6 $\pm$ 465.8*	2,823.5 $\pm$ 281.8*	< 0.001
Mean absolute error $\pm$ SD	284.8 $\pm$ 277.6	732.6 $\pm$ 348.1	1,035.6 $\pm$ 321.6	484.7 $\pm$ 338.7	< 0.001
Mean absolute error percentage $\pm$ SD	10.2 $\pm$ 8.7	30.5 $\pm$ 16.8	42.7 $\pm$ 17.6	19.9 $\pm$ 15.1	< 0.001
Accuracy within 10% of actual birth weight, n (%)	11 (64.7)	3 (17.6)	0 (0)	4 (23.5)	< 0.001
<b>Term (n = 183): mean <math>\pm</math> SD, actual FBW of 3,124.13 <math>\pm</math> 435.04 grams</b>					
Mean $\pm$ SD of estimated FBW	3,037.8 $\pm$ 405.6*	3,484.6 $\pm$ 586.0*	3,710.3 $\pm$ 494.6*	3,052.2 $\pm$ 306.6*	< 0.001
Mean absolute error $\pm$ SD	224.0 $\pm$ 206.9	467.2 $\pm$ 404.0	618.6 $\pm$ 409.7	305.0 $\pm$ 223.1	< 0.001
Mean absolute error percentage $\pm$ SD	6.8 $\pm$ 6.2	15 $\pm$ 14.1	20.4 $\pm$ 14.9	9.3 $\pm$ 7.1	< 0.001
Accuracy within 10% of actual birth weight, n (%)	130 (71.0)	74 (40.4)	49 (26.8)	113 (61.8)	< 0.001

p value for comparison in within 10% accuracy for four estimation methods using Cochran Q test. FBW fetal birth weight, SD standard deviation

\*statistically significant difference between actual birth weight and estimated values from each method using paired t test ( $p < 0.05$ )

\*\*statistically significant difference in proportion between the best and second-best estimation methods using McNemar's test ( $p < 0.05$ )

**Table 4.** Ability of four fetal birth weight estimation methods to predict low, normal and high actual birth weight (n = 200).

	Ultrasonography	Dare's	Johnson's	Buchmann's	p value
<b>Prediction of low birth weight</b>					
Sensitivity	75.00 (50.90-91.34)	5.00 (0.13-24.87)	0 (0-16.84)	10.00 (1.23-31.70)	
Specificity	93.89 (89.33-96.91)	97.78 (94.41-99.39)	98.89 (96.04-99.87)	98.89 (96.04-99.87)	
Positive predictive value	57.69 (42.17-71.83)	20.00 (2.85-68.04)	0	50.00 (12.96-87.04)	
Negative predictive value	97.13 (94.05-98.64)	90.26 (89.31-91.12)	89.90 (89.76-90.04)	90.82 (89.52-91.97)	
AUR	0.84 (0.75-0.94)	0.51 (0.46-0.56)	0.49 (0.49-0.50)	0.54 (0.48-0.61)	< 0.001
<b>Prediction of normal birth weight</b>					
Sensitivity	93.68 (88.97-96.80)	81.03 (74.41-86.57)	71.26 (63.93-77.86)	97.70 (94.22-99.37)	
Specificity	57.69 (36.92-76.65)	23.08 (8.97-43.65)	19.23 (6.55-39.35)	7.69 (0.95-24.13)	
Positive predictive value	93.68 (90.42-95.88)	87.58 (84.95-89.80)	85.52 (82.72-87.93)	87.63 (86.35-88.81)	
Negative predictive value	57.69 (41.34-72.51)	15.38 (7.79-28.12)	9.09 (4.21-18.53)	33.33 (8.79-72.18)	
AUR	0.76 (0.66-0.86)	0.52 (0.43-0.61)	0.45 (0.37-0.54)	0.53 (0.47-0.58)	< 0.001
<b>Prediction of macrosomia</b>					
Sensitivity	0 (0.00-45.93)	66.67 (22.28-95.67)	83.33 (35.88-99.58)	0 (0.00-45.93)	
Specificity	100.00 (98.12-100.00)	84.54 (78.67-89.32)	75.26 (68.57-81.16)	98.97 (96.33-99.87)	
Positive predictive value	-	11.76 (6.48-20.42)	9.43 (6.32-13.85)	-	
Negative predictive value	97.00 (97.00-97.00)	98.80 (96.35-99.61)	99.32 (96.06-99.89)	96.97 (96.93-97.01)	
AUR	NA*	0.76 (0.55-0.96)	0.79 (0.63-0.96)	0.49 (0.49-0.50)	0.002

Data in the brackets are 95% confidence interval of its predictive measure

p value for comparison of area under the receiver operating characteristic curve (AUR) across four estimation methods.

\*Ultrasonography did not predict anyone to have birth weight of  $> 4,000$  grams, so AUR for ultrasonography could not be computed.

## Discussion

In this observational comparative study in contemporary Thai women and their neonates including both low and high-risk pregnancy, the accuracy and predictive ability of four different estimation methods were compared against actual birth weight. In our study had more pre-pregnancy BMI over 23 but it was not affected to measure SFH and AG for estimated fetal birth weight<sup>(20)</sup>. Overall, ultrasonography-based Hadlock IV method resulted in the highest proportion of within 10% accuracy among all four methods. Similar results were observed for both low and normal birth weight and both term and preterm neonates, except for those with actual birth weight of more than 4,000 gram in which Dare's and Johnson's clinical equations showed the highest within 10% accuracy.

Ultrasonography-based Hadlock equation has been widely used and this equation showed reasonably high within-10% accuracy. Previous studies in low risk pregnancy showed that the within-10% accuracy of Hadlock equation ranged between 65% to 96%<sup>(6, 10, 16, 25, 26)</sup>. This was consistent with our study, although our estimates of within-10% accuracy sit at the lower end of the range. The reason for this may be the difference in study populations. While previous studies mostly investigated low risk term pregnancy, our study also included high risk pregnancy, (i.e. with 8.5% of preterm and 13% of low birth weight/macrosomia). A subgroup analysis in our study showed that ultrasonography had low accuracy in infants weighted  $\geq 4,000$  grams. This may be explained by likely inadequate ultrasonography view to measure AC in large fetus, standardization of measurements and a small sample size in this subgroup. This further suggests that cautious should be taken when using ultrasonography-based Hadlock equation to estimate fetal weight in large fetus.

Clinical equations may be alternative to ultrasonography as many studies showed that they provided comparable accuracy and predictive ability to ultrasonography-based equations in low risk term pregnancy<sup>(6, 12, 15, 16, 27)</sup>. Similarly, our study found that Buchmann's method and ultrasonography showed

similar within-10% accuracy particularly in normal weight and term neonates. Our subgroup analysis suggested that the most accurate fetal weight estimation method may differ in groups with different actual birth weight and gestational age. Therefore, choice of equations used to estimate fetal birth weight shall be made with caution. Of note, a randomized control trial revealed that estimates based on clinical equations were significantly more likely to be within 10% of actual weight than those derived from ultrasonographic estimates and both clinical and ultrasonographic methods showed a similar ability to discriminate normally and abnormally grown fetuses<sup>(13)</sup>. Take the results of these studies together, clinical equations are adequately accurate in estimating fetal birth weight and likely to be useful in resource-constrained settings where ultrasonography may not be available.

Various measures of predictive ability have an important role in detecting for high risk group in clinical practice. A small number of previous studies examined ability of various estimation methods to predict these high risk conditions and suggested that the positive predictive values of different methods varied greatly across estimation tools, for example, positive predictive value of 55% for Johnson's clinical equation<sup>(6)</sup>, 70% for Dare's equation<sup>(6)</sup> and 70% for ultrasonography<sup>(6)</sup> for predicting low birth weight. While these previous studies mostly focused on term low risk pregnancy, our study provided an opportunity to explore the predictive ability in high risk pregnancy. Additionally, our study showed that Dare's and Johnson's methods in particular had the greater predictive values for macrosomia than ultrasonography and they may be useful in case that large fetus is suspected.

However, only few studies examined a comprehensive set of predictive ability measures including sensitivity/specificity, positive/negative predictive values and AUR. Sensitivity/specificity, and positive/negative predictive values are among the most widely accepted measures; however, these measures are trade-off to each other. That is, estimation methods with high sensitivity essentially had low specificity. This underlines the need for measures of predictive ability

that account for both sensitivity and specificity, such as AUR and Net Reclassification Improvement. To our knowledge, our study was among the first that reported AUR for prediction of low birth weight and macrosomia. AUR is a measure of discriminatory ability which is a combined measure of sensitivity and specificity<sup>(24)</sup>. This measure would help distinguish between those who have and do not have a condition of interest, which may be very useful in clinical practice.

The present study was among the first few studies that compared the performance of multiple methods, both clinical equations and ultrasonography-based, to predict actual fetal birth weight in low, and high risk pregnancy groups, using standard measures of predictive ability. However, our study had a number of limitations. First, although this study was among the largest studies to date, the number of newborns in low birth weight and macrosomia categories as well as preterm pregnancy was relatively small and may have impacted the predictive performance of the estimation methods considered in this study. Larger studies in these high risk groups may be needed. Second, ultrasonography, which is an operator-dependent procedure, was undertaken by 2<sup>nd</sup> year OBGYN that increased maternal pre-pregnancy BMI did not affect to the accuracy of SFH and AG measurements and estimated fetal birth weight<sup>(20)</sup>. Therefore, the measurement biases and their impact on Hadlock's estimation method may be limited. A previous study suggested that fetal birth weight estimated from ultrasonography performed residents correlated well with the actual birth weight, albeit with low sensitivity to detect macrosomia<sup>(15)</sup>. Furthermore, due to physical examination and subsequent ultrasonography of each participant were performed by the same physician, there was possibility that data obtained from physical examination might influence ultrasonography measurements and estimated fetal birth weight. However, this influence was likely to be limited because parameters from physical examination were only collected and computation of fetal birth weight based on these parameters was done after performing ultrasonography. Therefore, at the time ultrasonography

was being performed, no information on fetal birth weight estimated from clinical equations was known to the physicians. Besides, due to unavailability of data from previous literature, we were not able to calculate sample size to address a research question "to examine the ability of these estimation methods to predict low birth weight and macrosomia in Thai pregnant women". Therefore, it is possible that a study may be underpowered to detect the difference between multiple tools in the ability to predict low birth weight/macrosomia. Additionally, all the clinical equations included in this study were developed in western populations; recalibration of these tools may be needed before use in this Thai population. Alternatively, a population-specific clinical equation should be developed and this may be useful in district community hospitals where OBGYN specialists are not always available.

## Conclusions

Among four existing clinical equations, ultrasonography-based estimation equation performed the best at predicting actual fetal birth weight regarding within-10% accuracy, sensitivity/specificity and discriminatory ability to predict low and normal birth weight. Dare's and Johnson's equations performed better than Buchmann's method and ultrasonography at predicting macrosomia and may therefore be probably useful when large fetus is suspected in clinical practice.

## Potential conflicts of interest

The authors declare no conflicts of interest.

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## OBSTETRICS

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# Knowledge, Attitudes, and Intention to Receive Pertussis Vaccine in Pregnant Women Attending the Antenatal Care Clinic, King Chulalongkorn Memorial Hospital

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## ABSTRACT

**Objectives:** Although pertussis vaccination in pregnancy to protect young infants is recommended, the vaccine coverage among Thai pregnant women remains suboptimal. This study aimed to determine the proportion of women intending to receive the pertussis vaccine during the current pregnancy.

**Materials and Methods:** A cross-sectional descriptive study was conducted in Thai pregnant women attending the antenatal care clinic at King Chulalongkorn Memorial Hospital from March to August 2020. A self-administered questionnaire was used to obtain information from participants regarding knowledge, attitudes, and intention to receive pertussis vaccine during pregnancy. Logistic regression analysis was used to determine factors associated with maternal intention.

**Results:** A total of 387 pregnant women completed the questionnaire. The mean score of knowledge about pertussis and the vaccine was  $11.8 \pm 2.1$  out of 20. Most of the participants had favorable attitudes on pertussis vaccination during pregnancy period. Intention to receive pertussis vaccination during pregnancy was reported in 45.5% (95% confidence interval 40.5% to 50.4%) of women. This proportion would be improved to be 81.9% if their doctors had recommended the vaccine and reassured them about fetal safety. The important influencers on the decision to vaccinate during pregnancy included their doctors (51.0%) and husbands (20.3%). Intention to receive pertussis vaccination during pregnancy would have increased if the participants had known the disease (adjusted odds ratio (OR) 1.74, 95% confidence interval (CI) 1.08 to 2.79) and believed that pertussis vaccination during pregnancy was safe (adjusted OR 2.03, 95% CI 1.20 to 3.43).

**Conclusion:** Almost half of the pregnant women intended to receive the pertussis vaccine during pregnancy. To improve vaccination coverage among pregnant women, the disease and safety of pertussis vaccine should be emphasized.

**Keywords:** pertussis, vaccine, intention to receive vaccine, pregnant women.

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# ความรู้ ทัศนคติ และความประسังค์ต่อการได้รับวัคซีนไอกรนของหญิงตั้งครรภ์ที่มาคลินิกฝากครรภ์โรงพยาบาลจุฬาลงกรณ์

อธิศ รัตตนาแสงสรวง, วิรากรณ์ ธีระกุล, สุรัสิทธิ์ ชัยทองวงศ์วัฒนา

## บทคัดย่อ

**วัตถุประสงค์:** แม้จะมีคำแนะนำของการให้วัคซีนไอกรนแก่หญิงตั้งครรภ์เพื่อการป้องกันตัว แต่ความครอบคลุมของการได้รับวัคซีนในหญิงตั้งครรภ์ไทยยังไม่เพียงพอ การศึกษานี้มีวัตถุประสงค์เพื่อสำรวจอัตราของหญิงตั้งครรภ์ที่มีความประสังค์ในการรับวัคซีนไอกรนในขณะตั้งครรภ์

**วัสดุและวิธีการ:** การศึกษาเชิงพรรณนาในหญิงตั้งครรภ์ที่มาคลินิกฝากครรภ์ โรงพยาบาลจุฬาลงกรณ์ ตั้งแต่เดือนมีนาคมถึงเดือนสิงหาคม พ.ศ.2563 โดยใช้การตอบแบบสอบถามด้วยตนเองเพื่อรับรวมข้อมูลเกี่ยวกับความรู้ ทัศนคติ และความประสังค์ต่อการได้รับวัคซีนไอกรนขณะตั้งครรภ์ และวิเคราะห์หาปัจจัยที่สัมพันธ์กับความประสังค์ดังกล่าวของหญิงตั้งครรภ์ ด้วยการวิเคราะห์ทดสอบโดยโลจิสติกส์

**ผลการศึกษา:** หญิงตั้งครรภ์ที่ตอบแบบสอบถามครบรวมทั้งสิ้น 387 ราย มีคะแนนเฉลี่ยของความรู้เกี่ยวกับโรคไอกรนและวัคซีนเท่ากับ  $11.8 \pm 2.1$  จากคะแนนเต็ม 20 อาสาสมัครส่วนใหญ่มีทัศนคติที่ดีต่อการได้รับวัคซีนไอกรนขณะตั้งครรภ์ และร้อยละ 45.5 (ความเชื่อมั่นร้อยละ 95 เท่ากับ 40.5 - 50.4) มีความประสังค์ในการรับวัคซีนไอกรนขณะตั้งครรภ์โดยสัดส่วนดังกล่าวจะเพิ่มขึ้นเป็นร้อยละ 81.9 หากแพทเที่ยวให้คำแนะนำในการฉีดวัคซีนและยืนยันเรื่องความปลอดภัยต่อทารกในครรภ์ ทั้งนี้บุคคลที่มีความสำคัญต่อการตัดสินใจในการรับวัคซีนมากที่สุด ได้แก่ แพทย์ (ร้อยละ 51) และสามี (ร้อยละ 20.3) ปัจจัยที่มีความสัมพันธ์ในการเพิ่มความประสังค์ในการรับวัคซีน ได้แก่ รู้จักโรคไอกรน (adjusted odds ratio (OR) 1.74, ความเชื่อมั่นร้อยละ 95 เท่ากับ 1.08 - 2.79) และ ความเชื่อว่าการได้รับวัคซีนไอกรนขณะตั้งครรภ์มีความปลอดภัย (adjusted OR 2.03, ความเชื่อมั่นร้อยละ 95 เท่ากับ 1.20 - 3.43)

**สรุป:** เกือบครึ่งหนึ่งของหญิงตั้งครรภ์มีความประสังค์ในการรับวัคซีนไอกรนขณะตั้งครรภ์ การเพิ่มความครอบคลุมของการได้รับวัคซีนในหญิงตั้งครรภ์ อาจทำได้โดยการให้ความรู้เกี่ยวกับโรคไอกรนและความปลอดภัยของวัคซีน

**คำสำคัญ:** โรคไอกรน, วัคซีน, ความประสังค์ในการรับวัคซีน, หญิงตั้งครรภ์

## Introduction

Pertussis, or whooping cough, is one of the serious respiratory diseases that cause morbidities or even life-threatening complications in infants<sup>(1,2)</sup>. But since 1950, cases of pertussis have been gradually decreased after the implementation of DTP (diphtheria toxoid, tetanus toxoid, and whole-cell pertussis vaccine) to infants by Expanded Programme of Immunization (EPI). However, a resurgence of pertussis was noted in the United States of America and some European countries in the early 20<sup>th</sup> century<sup>(3,4)</sup>. There are many causes to describe this reemergence such as the advancing technology of disease diagnosis, the increased disease awareness, and more rapidly waning of immunity that induced by acellular pertussis vaccines<sup>(5)</sup>.

After DTP or DTaP (diphtheria toxoid, tetanus toxoid and acellular pertussis vaccine) vaccines have been given to young infants, the immunity for pertussis will take effect at the age of 6 months to the first year, which opens a wide window of significant vulnerability<sup>(6)</sup>. Nevertheless, there are several pertussis strategic preventions for infants such as the cocooning vaccination, or newborns' early vaccination. The Center for Disease Control and Prevention (CDC) has initiated a pertussis prevention guideline for infants since 2005. They somehow concluded in 2012 that the pregnancy-period immunization is the most efficient approach to prevent pertussis in infants<sup>(7)</sup>. The process starts with pertussis vaccination of pregnant women. Mothers then will develop anti-pertussis antibodies that will be transferred to fetuses through the placenta. As such, newborn babies will be protected by preborn pertussis immunity before they get the DTP or DTaP vaccines<sup>(7)</sup>.

Although vaccination against pertussis during pregnancy has been recommended in many countries, immunization coverage is still low. One of the factors increasing maternal immunization is the advice or recommendation by doctors or health care providers. The study in Canada<sup>(8)</sup> found that 89% of the pregnant women would receive Tdap vaccination if the vaccine were recommended by their physician. However, the study in Italy<sup>(9)</sup> portrayed different results. Merely 34% of women, slightly improved from 21%, would receive the vaccine after advised by their healthcare providers.

After the introduction of the DTP in EPI of Thailand in

1977, pertussis cases in Thai people have been progressively decreased from 6-12 per 100,000 persons between the years 1975-1985 to only 0.12 per 100,000 persons in 2019<sup>(10)</sup>. However, there are still pertussis outbreaks in Thailand, which might be underreported. One study demonstrated that almost 18% of Thai adults with prolonging coughs, were diagnosed with serologically positive for pertussis<sup>(11)</sup>. Besides, 19.6% of Thai children with persistent coughs, followed by symptoms such as paroxysm, inspiratory whooping, or post-tussive emesis, had *Bordetella* pertussis infection confirmed by reverse transcription polymerase chain reaction (RT-PCR)<sup>(12)</sup>. Furthermore, 75% of pertussis cases found in the study were that infants too young to complete with primary series of pertussis vaccination at the age of 6 months<sup>(12)</sup>. This implies that pertussis in Thailand is still an under-detected disease, exclusively the most vulnerable category such as infants.

In 2018, the Infectious Disease Association of Thailand pushed forward their pertussis vaccination recommendation for Thai pregnant women<sup>(13)</sup>. Thus far, the number of pertussis vaccination during the period of pregnancy at King Chulalongkorn Memorial Hospital (KCMH) in Bangkok of Thailand is considered still suboptimal. The present study was carried out to determine a proportion of pregnant women having the intention to receive pertussis vaccination. The secondary objectives were to explore levels of knowledge and attitudes toward the pertussis vaccination and identify factors associated with the intention to receive pertussis vaccination.

## Materials and Methods

This cross-sectional, descriptive study was conducted between February and August 2020. The study was approved by the Institutional Review Board of the Faculty of Medicine, Chulalongkorn University (IRB No. 360/62). Pregnant women attending the antenatal care clinic at the KCMH were approached to participate in the study by convenient sampling. Women aged 18 years old or older attending the clinic for the first visit, having gestational age before 20 weeks, and giving consents were recruited. They were excluded from the study if incapable to complete the questionnaire or allergic to the pertussis vaccine.

The eligible women were asked to complete a self-administered questionnaire before attending the prenatal class. The developed and validated questionnaire comprised of 4 parts where the first part collected demographic information. The second part of the questionnaire aimed to determine a level of knowledge of the participants regarding pertussis and the vaccine. There were 20 yes-no questions with a total score of 20 and the women having more than 10 corrected answers were defined as having enough knowledge. The third part of the questionnaire was about attitudes toward pertussis vaccination during pregnancy, which consisted of 15 statements with five-level Likert scales for each statement. Favorable attitudes toward pertussis vaccination during pregnancy defined as score 4 (agree) or 5 (strongly agree) for positive attitude questions and 1 (strongly disagree) or 2 (disagree) for negative attitude questions. The last part of the questionnaire aimed to evaluate intention to receive pertussis vaccination of the participants as well as the important influencers on decision to vaccinate during pregnancy. Test-retest reliability of the questionnaire showed a Pearson correlation of 0.72 for part of knowledge, Cronbach's alpha of 0.91 for part of attitudes, and 0.71 for part of intention to receive vaccination.

After eligible participants completed the questionnaire, the informative brochures about pertussis and pertussis vaccination were provided. The prenatal class also emphasized topic of maternal immunization including influenza, tetanus and pertussis vaccination.

A sample size of 385 was needed for estimating the infinite population proportion of pregnant women intending to receive the pertussis vaccination of 0.5 with the alpha of 0.05 and error of 0.05. IBM SPSS Statistics for Windows, version 22 (IBM Corp., Armonk, N.Y., USA) was used for data analysis. Mean and standard deviation for quantitative data and percentage for qualitative data were reported. The primary outcome was demonstrated in percentage with a 95% confidence interval (CI). Chi square or Fisher exact test was used to identify factors associated to receive the vaccination. The significant associated factors from the univariate analysis were included in the logistic regression model to determine the adjusted odds ratio (OR) of each variable. A p value of less than 0.05 was considered statistically significant.

## Results

Of a total of 429 women who participated in the study, there were 13 irresponsive data and 29 incomplete data. Consequently, data from 387 participants were analyzed. Demographic and baseline characteristics are demonstrated in Table 1. The mean age was  $31.2 \pm 5.5$  years and the mean gestational age was  $8.8 \pm 3.6$  weeks. Most participants were primigravida (53.1%), graduated (59.9%), and had a family income higher than 20,000 Baht per month (64.1%). One hundred and twenty participants (31.0%) had known about pertussis and 26 of 180 multigravidas (14.4%) received the pertussis vaccination in their previous pregnancies.

**Table 1.** Demographic and baseline characteristics of participants (n = 387).

Characteristics	
- Age (years)	$31.2 \pm 5.5$
- Gestational age (weeks)	$8.8 \pm 3.6$
- Primigravida	207 (53.5%)
- Education	
Primary	10 (2.6%)
Secondary	145 (37.5%)
Bachelor	201 (51.9%)
Master	31 (8.0%)
- Knowing pertussis	120 (31.0%)
- Feeling that pertussis is very harmful to children	105 (27.1%)
- Feeling that pertussis is very harmful to adults	73 (18.9%)
- Knowing that pertussis vaccination during pregnancy used for the prevention of the newborn	73 (18.9%)
- Received pertussis vaccine in a previous pregnancy	26/180 (14.4%)

The mean score of knowledge about pertussis and the vaccine among participants was  $11.8 \pm 2.1$  and 259 women (66.9%) had correct answers of more than 10 from 20 questions (Table 2). Most of the participants showed favorable attitudes towards pertussis vaccination during the pregnancy period. Of all, 284 participants (73.4%) believed that maternal vaccination would protect their babies from pertussis

and 261 women (67.4%) firmly believed that vaccination during pregnancy was safe. In contrast, only a small number of participants held negative attitudes towards pertussis vaccination during pregnancy. Forty-six women (11.9%) believed that unnecessary to have pertussis vaccination during pregnancy because of the low incidence of pertussis while 38 women (9.8%) suspected that vaccination could affect fetal growth.

**Table 2.** The participant's knowledge score regarding pertussis and attitude toward pertussis vaccination during pregnancy (n = 387).

Variables	
- Knowledge score (total = 20)	11.8 ± 2.1
- Knowledge score > 10	259 (66.9%)
- No need for pertussis vaccination during pregnancy because of the low incidence of pertussis in Thailand	46 (11.9%)
- No need for pertussis vaccination during pregnancy because newborn will get the vaccine at 2 months	124 (32.0%)
- Pertussis vaccination during pregnancy could prevent pertussis in newborn	284 (73.4%)
- Pertussis can cause severe disease and neonatal death	236 (60.9%)
- Pertussis vaccination during pregnancy is safe	261 (67.4%)
- Pertussis vaccination during pregnancy may affect the fetal growth	38 (9.8%)
- Maternal immunization may induce autoimmune disease in the woman	31 (8.0%)
- Maternal immunization increases the risk of abortion	21 (5.4%)

Intention to receive pertussis vaccination during pregnancy was found in 176 pregnant women (45.5%, 95%CI 40.5% to 50.4%) (Table 3). The proportion of participants having the intention to receive pertussis vaccination improved dramatically to 81.9% if the

vaccination had been recommended by their doctors with fetal safety assurance. The influencers on the decision to receive vaccination during pregnancy included doctors, husbands, parents, and online information.

**Table 3.** Intention to receive pertussis vaccination during pregnancy of the participants.

Variables	n = 387
- Intention to receive pertussis vaccination during pregnancy	
Yes	176 (45.5%)
Uncertain	202 (52.2%)
No	9 (2.3%)
- Intention to receive pertussis vaccination during pregnancy if the doctor recommends the vaccine and reassure fetal safety	317 (81.9%)
- Most required additional information	
Effects of vaccine to the fetus	150 (38.8%)
Risk of pertussis in newborn	91 (23.5%)
Risk of pertussis in a pregnant woman	71 (18.3%)
Side effects of the vaccine	50 (12.9%)
- The most important factor influencing the decision to vaccinate during pregnancy	
Doctor	197 (51.0%)
Husband	79 (20.3%)
Parent	54 (13.9%)
Internet	38 (9.8%)
Others	19 (5.0%)

Factors associated to receive the pertussis vaccination during the pregnancy period are shown in Table 4. After the multivariable analysis, the significant associated factors that would improve intention to receive

the pertussis vaccination during pregnancy were 'knowing the disease' (adjusted OR 1.74, 95%CI 1.08 to 2.79) and 'believing that pertussis vaccination during pregnancy being safe' (adjusted OR 2.03, 95%CI 1.20 to 3.43).

**Table 4.** Factors associated with intention to receive pertussis vaccination during pregnancy of participants.

Factors	OR	95% CI	Adjusted OR	95% CI
- Income > 20,000 Baht/months	1.79	1.16 to 2.80	1.48	0.92 to 2.39
- Knowing pertussis	2.14	1.37 to 3.35	1.74	1.08 to 2.79
- Believed that vaccine during pregnant is unneccesarry because newborn will get the vaccine at 2 months of age	0.64	0.40 to 0.99	0.67	0.41 to 1.09
- Believed that pertussis vaccination during pregnancy could prevent pertussis in the newborn	2.19	1.34 to 3.61	1.33	0.74 to 2.39
- Believed that pertussis can cause severe disease and death in the newborn	1.97	1.28 to 3.04	1.47	0.90 to 2.39
- Believed that pertussis vaccination during pregnancy is safe	2.46	1.55 to 3.90	2.03	1.20 to 3.43

OR: odds ratio, CI: confidence interval

## Discussion

The intention of receiving pertussis vaccination during pregnancy varies across countries worldwide. The study revealed that 45.5% of Thai pregnant women would receive the pertussis vaccination during the pregnancy period. To improve vaccine coverage among pregnant women, the doctor's recommendations extremely played the role of increasing the intention of Thai pregnant women to receive the vaccination (45.5% to 81.9%). This result was inconsistent with the study in Italy where physician's recommendation showed a little effect on acceptance rate of maternal immunization (increased from 21% to 34%)<sup>(9)</sup>. The difference may be explained by various factors including study population, cultures and health systems. Doctors were yet the most crucial factor that influences on decisions of Thai pregnant women to receive the pertussis vaccination while husbands, parents, and online information were less important respectively.

The study found that awareness of pertussis was associated with increasing participants' intention to receive pertussis vaccine during pregnancy, and not directly related to their knowledge. Although 66.9% of the pregnant women had enough knowledge regarding to pertussis, less than half of the women intended to receive the vaccine. Before participants started to

complete knowledge question, 31% mentioned that they had known pertussis and 25.7% were uncertain about this. Increasing Thai pregnant women's awareness of pertussis and benefit of the vaccine should be emphasized in the antenatal care to improve coverage of pertussis vaccination during the pregnancy.

Low case report rate, or no pertussis emergence, was one among many factors that Italian pregnant women grew low vaccine acceptance<sup>(9)</sup>. The aforementioned idea only held in 11.9% of Thai pregnant women. There was 32.0% of participants believed that the vaccination during the pregnancy period be unnecessary since newborn babies would receive the pertussis vaccine at 2 months after birth. This belief can be corrected by giving information regarding disease vulnerability during the early infancy period.

The large sample size as well as validated questionnaire were strengths of the present study. The study was conducted on only Thai pregnant women in the tertiary hospital. This was considered to be one of the limitations. The participants comprised those of higher education (59.9% graduated) and having more income than the average<sup>(14)</sup> (64.2% have family income more than 20,000 baht per month). The study results may not be generalized to the setting of general or smaller hospitals where women have lower education

or income. However, most of studies regarding maternal immunization showed that doctor's recommendation were the most important factor to improve vaccine acceptance.

The present study was conducted during the period of the coronavirus disease 2019 (COVID-19) pandemic, which would affect the concerning issue of infectious diseases in pregnant women. The present situation of the COVID-19 pandemic might influence the new normal behaviors further. Possibly, this study can be the first to study the knowledge, attitudes, and intentions of pregnant women to receive the pertussis vaccination during the COVID-19 pandemic.

## Conclusions

In conclusion, almost half of Thai pregnant women in the study intended to receive the pertussis vaccination. Campaign promotion to increase women's awareness are ways to improve pertussis vaccine coverage among Thai pregnant women. Moreover, providing information about fetus benefit and safety would improve greatly vaccine acceptance. Doctor's recommendations were the most crucial factor on decision to receive the vaccine.

## Potential conflicts of interest

The authors declare no conflicts of interest.

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## OBSTETRICS

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# Obstetricians' Attitudes toward Epidural Analgesia for Labor in a Single University Hospital in Thailand

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## ABSTRACT

**Objectives:** To elucidate obstetricians' attitudes toward epidural analgesia for labor regarding maternal outcomes and complications and to describe commentaries about the use of epidural analgesia.

**Materials and Methods:** This was a questionnaire paper-based, cross-sectional study. The questionnaire was made available over the period of February 2020 to August 2020. The questionnaire comprised 25 items and used a 5-point Likert scale for the responses. The respondents' attitudes stratified by their subspecialty, position (residents or graduate obstetricians), and work experience were also analyzed.

**Results:** Out of 124 obstetricians working in our institute, 75 completed and returned the questionnaire, for a response rate of 60.5%. Among the respondents, 44 (58.7%) agreed that patients with vaginal labor should receive epidural analgesia if there are no contraindications. Most the obstetricians agreed that epidural analgesia for labor prolonged the second stage of labor (71.2%) and led to an increased rate of instrumental delivery (67.1%). On the other hand, only 31.5% agreed that epidural analgesia increased the rate of cesarean delivery. Obstetricians in the maternal-fetal medicine subspecialty reported significantly more experience with epidural analgesia cases than the other specialties ( $p < 0.001$ ). The mean overall satisfaction score regarding the epidural analgesia for labor in our institute (0-100) was  $68.2 \pm 15.8$ .

**Conclusion:** This study revealed that a high proportion of obstetricians believed that epidural analgesia for labor mainly affects labor outcomes including the mode of delivery and side effects. There is also a need to ensure all staff involved in the labor suite have a greater understanding of various aspects regarding the use of epidural analgesia for labor.

**Keywords:** obstetrician, attitude, questionnaire, epidural analgesia, labor.

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# ทัศนคติของสูติแพทย์ที่มีต่อการใส่สายทางช่องเหนืออุ้ตราเพื่อระงับปวดจากการเจ็บครรภ์คลอดบุตร ในโรงพยาบาลมหาวิทยาลัยแห่งหนึ่ง ประเทศไทย

พัชรียา นิวัฒน์ภูมินทร์, ตรีกพ เลิศบรรณพงษ์, สันติ บุญพู

## บทคัดย่อ

**วัตถุประสงค์:** เพื่อศึกษาทัศนคติของสูติแพทย์ที่มีต่อการใส่สายทางช่องเหนืออุ้ตราเพื่อระงับปวดจากการเจ็บครรภ์คลอดบุตร ในแขวงผลต่อมาตราและภาวะแทรกซ้อน และรายงานความคิดเห็นที่มีต่อการใส่สายทางช่องเหนืออุ้ตรา

**วัสดุและวิธีการ:** การศึกษานี้เป็นในลักษณะการศึกษาภาคตัดโดยใช้แบบสอบถาม การศึกษาทำขึ้นในช่วงเดือนกุมภาพันธ์ ถึงเดือนสิงหาคม พศ.2563 แบบสอบถามประกอบด้วย 25 ข้อ โดยแบ่งความคิดเห็นเป็น 5 ระดับ และวิเคราะห์ตามการแบ่งกลุ่มผู้เข้าร่วมตอบแบบสอบถามตามหน่วยเฉพาะทาง ตำแหน่ง (แพทย์ประจำบ้านหรือสูติแพทย์ผู้ช่วยการศึกษาแล้ว) และแบ่งตามประสาบการณ์การทำงาน

**ผลการศึกษา:** อัตราการตอบกลับแบบสอบถามคือ 75 รายใน 124 ราย คิดเป็นร้อยละ 60.5 สูติแพทย์ 44 ราย (ร้อยละ 58.7) เห็นด้วยเรื่องผู้ป่วยที่มาคลอดบุตรทางช่องคลอด ควรได้รับการใส่สายการระงับปวดทางช่องเหนืออุ้ร้าก้าไม่มีข้อห้าม สูติแพทย์เห็นด้วยเรื่องการใส่สายการระงับปวดทางช่องเหนืออุ้ตราเพิ่มระยะเวลาอยู่ที่สองของการคลอดร้อยละ 71.2 และเพิ่มอัตราการใช้เครื่องมือช่วยคลอดร้อยละ 67.1 มีสูติแพทย์ร้อยละ 31.5 เห็นด้วยเรื่องการใส่สายการระงับปวดทางช่องเหนืออุ้ตราเพิ่มอัตราการผ่าคลอด สูติแพทย์ในหน่วยเวชศาสตร์มารดาและทารกมีประสบการณ์ในการพับผู้ป่วยที่ได้รับการใส่สายทางช่องเหนืออุ้รามากกว่าสูติแพทย์อื่นๆ อย่างมีนัยสำคัญ ( $p < 0.001$ ) คะแนนความพึงพอใจต่อการใส่สายทางช่องเหนืออุ้ราเพื่อระงับปวดจากการเจ็บครรภ์คลอดบุตรโดยรวมคือ  $68.2 \pm 15.8$  คะแนน

**สรุป:** สูติแพทย์ในอัตราส่วนที่สูงมีความคิดเห็นว่าการใช้สายทางช่องเหนืออุ้ราเพื่อระงับปวดจากการเจ็บครรภ์คลอดบุตรมีผลต่อมาตราในแขวงและภาวะแทรกซ้อน ควรให้ความเข้าใจต่อผลที่เกิดขึ้นในแขวงต่างๆ ของการใส่สายทางช่องเหนืออุ้รา เพื่อระงับปวดจากการเจ็บครรภ์คลอดบุตรแก่บุคลากรทุกท่านที่มีความเกี่ยวข้องกับผู้ป่วยที่มารับการคลอดบุตรในห้องคลอด

**คำสำคัญ:** ทัศนคติ, การใส่สายทางช่องเหนืออุ้รา, เจ็บครรภ์คลอดบุตร, สูติแพทย์, แบบสอบถาม

## Introduction

Epidural analgesia with local anesthetic and opioids is a widely used intervention for relieving labor pain<sup>(1)</sup>. A recent systematic review revealed epidural analgesia for labor provided superior pain relief as well as decreased the requirement for supplemental pain relief compared to opioid analgesics administered by other routes<sup>(2)</sup>. However, the obstetrical outcomes after epidural analgesia for labor are a general concern. Numerous studies have reported side effects of epidural analgesia, including prolongation of the second stage of labor<sup>(3)</sup> and an increase in the rate of instrumental delivery<sup>(2-4)</sup>. Another debatable issue with epidural analgesia is the rate of cesarean delivery. Nevertheless, one systematic review concluded that the rate of cesarean delivery was not increased after epidural analgesia for labor<sup>(2)</sup>.

Siriraj Hospital is the main referral tertiary level institute in Bangkok, the capital of Thailand. In total, there are approximately 7,500-8,000 deliveries per year in the hospital, with more than half of patients undergoing normal vaginal delivery. However, in our institute, the administration of epidural analgesia for labor is restricted to only for educational proposes. That is, the service of epidural analgesia has not been introduced in our hospital, mostly due to the fact that there is an inadequate number of anesthetic personnel in our hospital. Thus, the knowledge and experience of epidural analgesia for labor in our hospital is limited.

The attitudes of obstetricians toward epidural analgesia during labor have been widely studied in several countries<sup>(5-9)</sup>. Most of the studies concluded that obstetricians were mostly unfamiliar with the process and suggested there was a need to provide additional education to the involved personnel<sup>(5, 6, 8-10)</sup>. One recent study showed there

were differences in the interprofessional attitudes among anesthesiologists, nurses, and obstetricians in terms of their familiarity with the management of epidural analgesia for labor<sup>(10)</sup>. The same report mentioned there was significant less familiarity of epidural management among obstetricians than among anesthesiologists or nurses<sup>(10)</sup>.

The attitudes of the obstetricians in our institute toward epidural analgesia during labor have not been assessed. Consequently, the primary objective of this study was to describe the obstetricians' viewpoints toward epidural analgesia, particularly regarding the maternal outcomes and complications, together with their comments on the need for an epidural analgesia service in the present setting in our institute.

## Materials and Methods

This study was a questionnaire-based, cross-sectional study. The study was approved by Siriraj Institutional Review Board (protocol number 778/2562(IRB2), approval number Si 854/2019, date of approval December 4, 2019). The need for individual informed consent was waived by the ethics committee in order to maintain the confidentiality of the respondents. The questionnaires were distributed from February 2020 to August 2020. We included all the obstetrics residents, fellows, and consultants in the Department of Obstetrics and Gynecology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand. Exclusion criteria were international obstetricians who did not understand Thai, as all the data were retrieved from a written questionnaire paper in the Thai language. After the obstetricians had completed the questionnaire, the questionnaire paper could be returned by putting it in a prearranged box or by direct return to the research assistant. The questionnaire was

designed by the principal investigator and included questions to probe the respondents' demographic data, including age, gender, working experience (years), subspecialty, and the past and present number of epidural analgesia cases they were involved with. The questions regarding epidural analgesia for labor contained 25 items. Each item could be rated using a 5-point Likert scale (1: strongly disagree; 2: disagree; 3: mediocre; 4: agree; 5: strongly agree). A rating score of 4 or 5 showed agreement with that item. The questionnaire probed the respondents' attitude toward the effect of epidural analgesia in a number of obstetric aspects, including the prolongation of labor, routes of delivery, maternal side effects, fetal/neonatal outcomes, when to initiate epidural analgesia, and the confidence of being able to resolve possible complications that might arise after epidural analgesia. The content validity of the questionnaire was determined using the Item-Objective Congruence Index (IOC). The IOC of each item was rated by three senior obstetric anesthesiologists of the Department of Anesthesia, Faculty of Medicine, Siriraj Hospital, revealing  $IOC > 0.66$  for each item. Additionally, the questionnaire probed their satisfaction with the epidural analgesia service in our hospital. The open-ended question about this aspect was placed at the end of the questionnaire to generate qualitative suggestions regarding the use of epidural analgesia.

### **Statistical analysis**

The authors estimated that around 60% of the obstetricians in our institute agree with using epidural analgesia for relieving labor pain based on their ratings of 4 or 5 on the Likert scale. According to a confidence level of 95% and an acceptable error of 0.12, the sample size calculation

was performed using the formula  $n = Z (1- \alpha)^2 p(1-p) / d^2$ , and revealed the minimum sample size needed was 65 participants. As the number of obstetricians in our institute was 124 in the study period, it was considered that a response rate of approximately 50% would be sufficient for the study. PASW statistics (SPSS) version 18.0 (SPSS Inc., Chicago, IL, USA) for Window was used for all the statistical analyses. The categorical data were presented as the number and percentage and chi-square, linear-by-linear chi-square, and Fisher exact tests were used to compare the groups. Continuous data were reported as the mean and standard deviation. The student t-test was used to compare the mean of the average score of each item. We considered  $p$  values  $< 0.05$  to be statistically significant. Cronbach's alpha was used to express the internal reliability of the questionnaire.

## **Results**

Among the total 124 obstetricians in our institute, 75 returned the questionnaire, representing a response rate of 60.5%. The demographic data of the respondents are shown in Table 1. Approximately half the obstetrician respondents (39/75; 54.2%) reported experience with epidural analgesia in 1-10 patients, while 5 obstetricians (6.7%) had no experience with epidural analgesia for labor at all. Further, 20/75 obstetricians (26.7%) were currently not involved with patients with normal labor at the presenting day. The average age of the residents was  $28.7 \pm 2.5$  years old, compared with an older age for the graduate obstetricians ( $43.8 \pm 10.2$  years old);  $p < 0.001$ . The obstetricians in the maternal-fetal medicine (MFM) subspecialty had significantly more experience with epidural analgesia cases than the other subspecialties ( $p < 0.001$ ).

**Table 1.** Demographic data of the respondents, n = 75.

Parameter	Mean $\pm$ SD or number (%)
Age (years)	34.0 $\pm$ 10.1
Median (min, max)	30 (26, 67)
Gender	
Male	22 (29.3)
Female	52 (69.3)
No answer	1 (1.3)
Status, average age [mean $\pm$ SD]	
Resident	44 (58.7), 28.7 $\pm$ 2.5
Fellow	7 (9.3), 34.7 $\pm$ 4.6
Consultant	24 (32.0), 46.5 $\pm$ 9.9
Work experience	
0-3 years	29 (38.7)
> 3-5 years	11 (14.7)
> 5-10 years	11 (14.7)
> 10-20 years	9 (12.0)
> 20-30 years	10 (13.3)
> 30 years	5 (6.7)
Specialty*	
General OBGYN	49 (65.3)
Maternal-Fetal Medicine (MFM)	14 (18.7)
Reproductive medicine	5 (6.7)
Gynecologic Oncology	6 (8.0)
Urogynecology	1 (1.3)
Laparoscopic Surgery	5 (6.7)
Experience in epidural analgesia for labor patients (overall patient number)	
0	5 (6.7)
1-10	39 (52.0)
> 10-50	23 (30.7)
> 50-100	5 (6.7)
> 100-200	1 (1.3)
> 200-500	1 (1.3)
> 500-1,000	1 (1.3)
Currently work with normal labor cases (patient number/week)	
0	20 (26.7)
1-10	33 (44.0)
> 10-50	22 (29.3)

SD: standard deviation, OBGYN: Obstetrics and Gynecology, MFM: Maternal–Fetal Medicine

\*Specialty: 5 obstetricians reported 2 specialties (2 obstetricians - MFM with laparoscopic surgery; 2 obstetricians - gynecologic oncology with laparoscopic surgery; 1 obstetrician - urogynecology with laparoscopic surgery)

Table 2. presents the scores from the questionnaire for items 1 to 25 [I1-I25]; the overall average score of each item was presented as the

mean and standard deviation; median and range; and the percentage of obstetricians with an agree rating for each item (rating of 4-5 points).

**Table 2.** Overall mean score, median, and number of respondents who agreed with each questionnaire item (25 items), n = 75.

Item		Average score Mean $\pm$ SD	Median (min, max)	Number of respondents
				agreed (rated 4–5)
				Number (valid percent)
I1	Patients with vaginal labor should receive epidural analgesia if no contraindications	3.69 $\pm$ 0.92	4 (1, 5)	44 (58.7)
I2	Patients with vaginal labor should receive epidural analgesia only in case of an expectation of instrumental delivery	3.39 $\pm$ 1.16	3 (1,5)	37 (50.0)
I3	Epidural analgesia for labor leads to prolonging the first stage of labor	2.68 $\pm$ 1.12	3 (1,5)	19 (25.7)
I4	Epidural analgesia for labor leads to prolonging the second stage of labor	3.71 $\pm$ 1.02	4 (1,5)	52 (71.2)
I5	Epidural analgesia for labor increases the instrumental delivery rate	3.63 $\pm$ 0.84	4 (1,5)	49 (67.1)
I6	Epidural analgesia for labor increases the cesarean delivery rate	2.89 $\pm$ 1.01	3 (1,5)	23 (31.5)
I7	Epidural analgesia for labor causes intrauterine fetal distress	2.16 $\pm$ 0.87	2 (1,4)	4 (5.3)
I8	Epidural analgesia for labor causes birth asphyxia	2.05 $\pm$ 0.85	2 (1,4)	3 (4.0)
I9	Epidural analgesia for labor causes maternal nausea and vomiting	2.85 $\pm$ 1.04	3 (1,5)	22 (29.3)
I10	Epidural analgesia for labor causes maternal itching	2.93 $\pm$ 0.95	3 (1,5)	19 (25.3)
I11	Epidural analgesia for labor causes leg muscle weakness	2.88 $\pm$ 0.92	3 (1,5)	19 (25.3)
I12	Epidural analgesia for labor causes maternal fever	2.13 $\pm$ 0.81	2 (1,4)	2 (2.7)
I13	Epidural analgesia for labor causes maternal urinary retention	3.15 $\pm$ 0.91	3 (1,5)	26 (34.7)
I14	Epidural analgesia for labor causes increasing the dosage of oxytocin for augmenting labor	2.84 $\pm$ 1.13	3 (1,5)	23 (30.7)
I15	Epidural analgesia for labor should be placed when the patient starts having labor pain although cervical dilatation is less than 4 cm	2.55 $\pm$ 1.14	2 (1,5)	19 (25.3)
I16	Epidural analgesia for labor should be placed after the patient has cervical dilatation equal or more than 4 cm	3.77 $\pm$ 0.88	4 (1,5)	55 (73.3)
I17	Epidural analgesia for labor should be placed before oxytocin administration	3.20 $\pm$ 0.93	3 (1,5)	29 (38.7)
I18	Epidural analgesia for labor should be placed before a ruptured membrane	2.88 $\pm$ 0.85	3 (1,4)	18 (24.0)
I19	I am familiar with attending patients with epidural analgesia for labor	2.84 $\pm$ 0.89	3 (1,5)	16 (21.3)
I20	I am confident I can resolve the possible complications arising from epidural analgesia for labor	2.52 $\pm$ 1.12	2 (1,5)	17 (22.7)
I21	I believe that epidural analgesia for labor gives the patient good relief from labor pain	4.27 $\pm$ 0.74	4 (1,5)	69 (92.0)
I22	There should be an epidural analgesia for labor service available during both office hours and out-of-office hours	4.11 $\pm$ 0.91	4 (1,5)	61 (81.3)
I23	There should be an anesthesiologist available to attend patients with epidural analgesia placed for labor both during office hours and out-of-office hours	4.19 $\pm$ 0.77	4 (1,5)	66 (88.0)
I24	Obstetricians are able to attend patients after epidural analgesia placed for labor during both office hours and out-of-office hours	3.15 $\pm$ 1.16	3 (1,5)	27 (36.0)
I25	Labor room nurses are able to attend patients after epidural analgesia placed for labor during both office hours and out-of-office hours	3.00 $\pm$ 1.16	3 (1,5)	26 (35.6)
I16	Epidural analgesia for labor should be placed after the patient has cervical dilatation equal or more than 4 cm	3.77 $\pm$ 0.88	4 (1,5)	55 (73.3)
I17	Epidural analgesia for labor should be placed before oxytocin administration	3.20 $\pm$ 0.93	3 (1,5)	29 (38.7)
I18	Epidural analgesia for labor should be placed before a ruptured membrane	2.88 $\pm$ 0.85	3 (1,4)	18 (24.0)
I19	I am familiar with attending patients with epidural analgesia for labor	2.84 $\pm$ 0.89	3 (1,5)	16 (21.3)
I20	I am confident I can resolve the possible complications arising from epidural analgesia for labor	2.52 $\pm$ 1.12	2 (1,5)	17 (22.7)
I21	I believe that epidural analgesia for labor gives the patient good relief from labor pain	4.27 $\pm$ 0.74	4 (1,5)	69 (92.0)
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I23	There should be an anesthesiologist available to attend patients with epidural analgesia placed for labor both during office hours and out-of-office hours	4.19 $\pm$ 0.77	4 (1,5)	66 (88.0)
I24	Obstetricians are able to attend patients after epidural analgesia placed for labor during both office hours and out-of-office hours	3.15 $\pm$ 1.16	3 (1,5)	27 (36.0)
I25	Labor room nurses are able to attend patients after epidural analgesia placed for labor during both office hours and out-of-office hours	3.00 $\pm$ 1.16	3 (1,5)	26 (35.6)

The 5-point Likert scale comprised: 1: strongly disagree; 2: disagree; 3: mediocre; 4: agree; 5: strongly agree.

SD: standard deviation, cm: centimeter.

The number of respondents = 74 in items 2 and 3; the number of respondents = 73 in items 4, 5, 6, and 25.

The number of obstetricians (percent) stratified by the MFM subspecialty compared with the other subspecialties, the obstetricians' status (resident

versus graduate obstetrician, including fellow and consultant), and working experience who gave an agree rating for each item are shown in Table 3.

**Table 3.** Comparison of the number of respondents who agreed (gave a rating of 4-5) with each item between the maternal-fetal medicine subspecialty and others, as well as based on status and work experience; number (valid percent); n = 75.

Item	MFM sub-specialty (n = 14)	Others (n = 61)	p value	Resident (n = 44)	Fellow and consultant (n = 31)	p value	Work experience		p value
							< 10 years (n = 51)	> 10 years (n = 24)	
I1	11 (78.6)	33 (54.1)	0.094	20 (45.5)	24 (77.4)	0.006	28 (54.9)	16 (66.7)	0.334
I2	6 (46.2)	31 (50.8)	0.760	20 (45.5)	17 (56.7)	0.334	24 (47.1)	13 (56.5)	0.451
I3	3 (21.4)	16 (26.7)	1.000	12 (27.9)	7 (22.6)	0.605	13 (26.0)	6 (25.0)	0.927
I4	10 (71.4)	42 (71.2)	1.000	32 (76.2)	20 (64.5)	0.276	36 (73.5)	16 (66.7)	0.546
I5	10 (71.4)	39 (66.1)	1.000	26 (61.9)	23 (74.2)	0.269	32 (65.3)	17 (70.8)	0.637
I6	3 (21.4)	20 (33.9)	0.526	14 (33.3)	9 (29.0)	0.696	15 (30.6)	8 (33.3)	0.814
I7	0	4 (6.6)	1.000	4 (9.1)	0	0.138	4 (7.8)	0	0.299
I8	0	3 (4.9)	1.000	3 (6.8)	0	0.263	3 (5.9)	0	0.547
I9	1 (7.1)	21 (34.4)	0.053	14 (31.8)	8 (25.8)	0.573	15 (29.4)	7 (29.2)	0.983
I10	3 (21.4)	16 (26.2)	1.000	10 (22.7)	9 (29.0)	0.536	10 (19.6)	9 (37.5)	0.097
I11	3 (21.4)	16 (26.2)	1.000	13 (29.5)	6 (19.4)	0.318	13 (25.5)	6 (25.0)	0.964
I12	1 (7.1)	1 (1.6)	0.341	1 (2.3)	1 (3.2)	1.000	1 (2.0)	1 (4.2)	0.541
I13	1 (7.1)	25 (41.0)	0.026	17 (38.6)	9 (29.0)	0.389	17 (33.3)	9 (37.5)	0.724
I14	3 (21.4)	20 (32.8)	0.529	11 (25.0)	12 (38.7)	0.205	15 (29.4)	8 (33.3)	0.731
I15	2 (14.3)	17 (27.9)	0.496	8 (18.2)	11 (35.5)	0.090	9 (17.6)	10 (41.7)	0.026
I16	9 (64.3)	46 (75.4)	0.504	34 (77.3)	21 (67.7)	0.358	37 (72.5)	18 (75.0)	0.823
I17	6 (42.9)	23 (37.7)	0.721	15 (34.1)	14 (45.2)	0.332	17 (33.3)	12 (50.0)	0.167
I18	2 (14.3)	16 (26.2)	0.496	10 (22.7)	8 (25.8)	0.758	10 (19.6)	8 (33.3)	0.194
I19	5 (35.7)	11 (18.0)	0.161	6 (13.6)	10 (32.3)	0.053	8 (15.7)	8 (33.3)	0.082
I20	6 (42.9)	11 (18.0)	0.073	5 (11.4)	12 (38.7)	0.005	7 (13.7)	10 (41.7)	0.007
I21	13 (92.9)	56 (91.8)	1.000	39 (88.6)	30 (96.8)	0.391	46 (90.2)	23 (95.8)	0.657
I22	12 (85.7)	49 (80.3)	1.000	34 (77.3)	27 (87.1)	0.282	42 (82.4)	19 (79.2)	0.758
I23	12 (85.7)	54 (88.5)	0.672	38 (86.4)	28 (90.3)	0.728	44 (86.3)	22 (91.7)	0.710
I24	8 (57.1)	19 (31.1)	0.068	13 (29.5)	14 (45.2)	0.165	18 (35.3)	9 (37.5)	0.853
I25	5 (35.7)	21 (35.6)	1.000	16 (38.1)	10 (32.3)	0.607	19 (38.8)	7 (29.2)	0.421

MFM: Maternal - Fetal Medicine.

Table 4 shows the comparison of the average scores for the obstetricians in the MFM subspecialty and the others regarding the respondents' status and working experience. The MFM obstetricians had higher confidence in resolving possible complications derived from epidural analgesia for labor than the obstetricians in the other subspecialties [I20] (p = 0.009). The average rating scores of the residents concerning the side effects

of epidural analgesia for labor on intrauterine fetal distress [I7] (p = 0.006) and birth asphyxia [I8] (p = 0.003) were significantly higher than the average scores of the graduate obstetricians. The overall Cronbach's alpha of the questionnaire from all the participants was 0.603. More specifically, the individual Cronbach's alpha scores from the residents, fellows, and consultants groups were 0.691, 0.780, and 0.327, respectively.

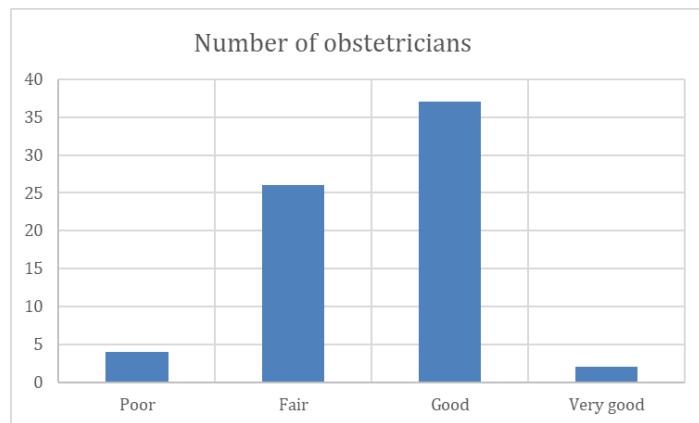
**Table 4.** Comparison of the average score of each item between the maternal-fetal medicine sub-specialty and others, as well as based on status and work experience; mean  $\pm$  SD; n = 75.

Item	MFM sub-specialty (n = 14)	Others (n = 61)	p value	Resident (n = 44)	Fellow and consultant (n = 31)	p value	Work experience < 10 years (n = 51)	Work experience > 10 years (n = 24)	p value
I1	4.0 $\pm$ 1.0	3.6 $\pm$ 0.9	0.166	3.6 $\pm$ 0.9	3.9 $\pm$ 0.9	0.096	3.7 $\pm$ 0.9	3.8 $\pm$ 1.0	0.716
I2	3.5 $\pm$ 1.4	3.4 $\pm$ 1.1	0.813	3.3 $\pm$ 1.0	3.5 $\pm$ 1.3	0.389	3.4 $\pm$ 1.1	3.4 $\pm$ 1.3	0.832
I3	2.1 $\pm$ 1.2	2.8 $\pm$ 1.8	0.048	2.9 $\pm$ 1.0	2.4 $\pm$ 1.2	0.096	2.8 $\pm$ 1.1	2.4 $\pm$ 1.3	0.171
I4	3.6 $\pm$ 1.3	3.7 $\pm$ 1.0	0.779	3.8 $\pm$ 0.8	3.5 $\pm$ 1.2	0.184	3.7 $\pm$ 1.0	3.7 $\pm$ 1.0	0.982
I5	3.6 $\pm$ 1.2	3.6 $\pm$ 0.7	0.774	3.6 $\pm$ 0.8	3.7 $\pm$ 0.9	0.897	3.6 $\pm$ 0.9	3.7 $\pm$ 0.8	0.582
I6	2.3 $\pm$ 1.3	3.0 $\pm$ 0.9	0.011	3.1 $\pm$ 0.8	2.7 $\pm$ 1.2	0.090	2.9 $\pm$ 1.0	2.9 $\pm$ 1.1	0.877
I7	1.9 $\pm$ 0.9	2.2 $\pm$ 0.9	0.150	2.4 $\pm$ 0.9	1.8 $\pm$ 0.8	0.006	2.3 $\pm$ 0.9	1.8 $\pm$ 0.8	0.025
I8	1.7 $\pm$ 0.8	2.1 $\pm$ 0.8	0.099	2.3 $\pm$ 0.9	1.7 $\pm$ 0.7	0.003	2.2 $\pm$ 0.9	1.8 $\pm$ 0.8	0.068
I9	2.3 $\pm$ 1.0	3.0 $\pm$ 1.0	0.022	2.9 $\pm$ 1.0	2.8 $\pm$ 1.1	0.582	2.9 $\pm$ 1.0	2.8 $\pm$ 1.2	0.557
I10	2.8 $\pm$ 1.1	3.0 $\pm$ 0.9	0.522	2.8 $\pm$ 0.9	3.1 $\pm$ 1.1	0.318	2.8 $\pm$ 0.9	3.1 $\pm$ 1.1	0.233
I11	2.6 $\pm$ 1.1	3.0 $\pm$ 0.9	0.163	3.1 $\pm$ 0.8	2.7 $\pm$ 1.1	0.077	2.9 $\pm$ 0.9	2.8 $\pm$ 1.0	0.402
I12	2.2 $\pm$ 1.0	2.1 $\pm$ 0.8	0.682	2.2 $\pm$ 0.8	2.0 $\pm$ 0.8	0.368	2.2 $\pm$ 0.8	2.1 $\pm$ 0.8	0.717
I13	2.6 $\pm$ 0.9	3.3 $\pm$ 0.9	0.008	3.2 $\pm$ 0.9	3.0 $\pm$ 0.9	0.365	3.2 $\pm$ 1.0	3.1 $\pm$ 0.8	0.889
I14	2.4 $\pm$ 1.2	3.0 $\pm$ 1.1	0.075	2.8 $\pm$ 1.0	2.9 $\pm$ 1.3	0.843	2.9 $\pm$ 1.1	2.8 $\pm$ 1.2	0.801
I15	2.2 $\pm$ 1.1	2.6 $\pm$ 1.1	0.230	2.4 $\pm$ 1.0	2.8 $\pm$ 1.3	0.167	2.5 $\pm$ 1.1	2.8 $\pm$ 1.3	0.293
I16	3.6 $\pm$ 1.1	3.8 $\pm$ 0.8	0.542	3.8 $\pm$ 0.8	3.7 $\pm$ 1.0	0.797	3.7 $\pm$ 0.8	3.9 $\pm$ 1.0	0.336
I17	2.8 $\pm$ 1.3	3.3 $\pm$ 0.8	0.166	3.3 $\pm$ 0.8	3.1 $\pm$ 1.1	0.609	3.2 $\pm$ 0.8	3.2 $\pm$ 1.2	0.963
I18	2.6 $\pm$ 0.9	3.0 $\pm$ 0.8	0.135	2.9 $\pm$ 0.8	2.9 $\pm$ 0.9	0.845	2.9 $\pm$ 0.8	2.9 $\pm$ 1.0	0.975
I19	3.1 $\pm$ 0.9	2.8 $\pm$ 0.9	0.157	2.8 $\pm$ 0.7	2.9 $\pm$ 1.1	0.437	2.8 $\pm$ 0.8	3.0 $\pm$ 1.0	0.178
I20	3.2 $\pm$ 1.0	2.4 $\pm$ 1.1	0.009	2.2 $\pm$ 0.9	2.9 $\pm$ 1.3	0.010	2.3 $\pm$ 0.9	2.9 $\pm$ 1.4	0.069
I21	4.5 $\pm$ 0.7	4.2 $\pm$ 0.8	0.194	4.1 $\pm$ 0.8	4.6 $\pm$ 0.6	0.005	4.1 $\pm$ 0.8	4.6 $\pm$ 0.6	0.010
I22	4.4 $\pm$ 1.0	4.0 $\pm$ 0.9	0.143	3.9 $\pm$ 0.9	4.4 $\pm$ 0.9	0.024	4.0 $\pm$ 0.9	4.3 $\pm$ 1.0	0.352
I23	4.4 $\pm$ 1.0	4.2 $\pm$ 0.7	0.359	4.0 $\pm$ 0.7	4.4 $\pm$ 0.8	0.026	4.1 $\pm$ 0.8	4.3 $\pm$ 0.8	0.258
I24	3.7 $\pm$ 1.2	3.0 $\pm$ 1.1	0.041	3.0 $\pm$ 1.1	3.4 $\pm$ 1.3	0.132	3.1 $\pm$ 1.1	3.2 $\pm$ 1.2	0.919
I25	3.2 $\pm$ 1.3	3.0 $\pm$ 1.1	0.444	3.1 $\pm$ 1.1	2.9 $\pm$ 1.3	0.685	3.2 $\pm$ 1.1	2.7 $\pm$ 1.2	0.084

MFM: Maternal-Fetal Medicine, SD: standard deviation

Overall, 69/75 obstetricians gave a rating regarding the satisfaction with the epidural analgesia for labor provided by the anesthesiologist in our hospital. The overall satisfaction is demonstrated in Fig. 1. Approximately half the obstetricians (52%) reported good to very good satisfaction. In terms of the satisfaction score ranging between 0-100, approximately one-third of the obstetricians (21/69; 30.4%) rated their satisfaction score as > 80. The mean satisfaction score was 68.2  $\pm$  15.8, and the median score (interquartile range) was 70 (65-80). The free responses revealed a range of opinions

regarding the use of epidural analgesia. Six obstetricians proposed there should be an epidural analgesia service in our institute for both in and out-of-office hours. Five obstetricians demanded that epidural analgesia should be used in the case of it being the patient's preference or in the private labor suite. Two obstetricians explained that epidural analgesia should be performed in patients with heart disease and who require a shortened second stage of labor. Lastly, two obstetricians described that the anesthesiologist should be present all the time after epidural analgesia has been administered.



**Fig. 1.** Obstetricians' satisfaction with the use of epidural analgesia for labor (n = 69).

## Discussion

Our study had a moderate response rate for the questionnaire (60.5%) compared with much higher response rates for Vandendriesen et al (68%)<sup>(5)</sup> and Pirdubak et al (94.7%)<sup>(9)</sup>. We postulated that the unfamiliarity of the obstetricians in our institute regarding epidural analgesia might have made them reluctant to reply to the questionnaire. As we can see from the data, a considerable number of the obstetricians (44/75; 58.7%) reported experience with epidural analgesia cases for only 10 or fewer patients. The gynecologic subspecialties, such as laparoscopic or oncology specialty, also included some obstetricians who were not currently involved with laboring parturients. Another reason is that there is limited epidural analgesia service in our institute, in which it is almost exclusively only applied for academic purposes in training anesthesia residents. Consequently, only a small number of patients receive epidural analgesia in our institute, equating to approximately 0-2 cases per day and with the service only available in limited working hours (roughly 100-120 cases per year out of approximately 3,500-4,000 labor cases, thus accounting for only 2.5-3.4% of cases).

There exist a large number of conflicting data regarding the obstetric outcomes after epidural analgesia<sup>(2-4, 11-13)</sup>. The Cochrane database systematic review concluded that epidural analgesia for labor led

to a prolongation of the second stage of labor and increased the rate of instrumental delivery, including vacuum and forceps-assisted extraction<sup>(2)</sup>. The rate of cesarean delivery after epidural analgesia has also been extensively studied<sup>(13-16)</sup>. Bannister-Tyrrell et al conducted a large population-based cohort study and reported an increase in the rate of cesarean delivery in patients receiving epidural analgesia for labor (risk ratio [RR] 2.5; 95% confidence interval [95% CI] 2.5-2.6)<sup>(16)</sup>. This may be due to the fact that local anesthetic drugs given in the epidural space can cause motor weakness and may affect the rotation and flexion of the fetal head when initiating the epidural analgesia in the early labor phase<sup>(14)</sup>. On the other hand, the systematic review reported that there was no difference between the rate of cesarean delivery in laboring women with and without epidural analgesia (RR 1.07; 95%CI 0.96-1.18)<sup>(2)</sup>. Controversy about the labor outcomes has led to a difference in the viewpoints of obstetricians regarding epidural analgesia. Kamakshi et al revealed that more than half of obstetricians tend to consider that epidural analgesia increases the rate of cesarean delivery<sup>(6)</sup>; however, our study showed that 71.2%, 67.1% and 31.5% of the obstetricians in our hospital agreed that epidural analgesia leads to a prolongation of the second stage of labor, increases the instrumental delivery rate, and increases the cesarean delivery rate [I4-I6, Table 2], respectively.

The different obstetrician subspecialties presented variations in their attitudes toward the use of epidural analgesia for labor. The average score from the other subspecialty obstetricians about whether epidural analgesia for labor increases the cesarean delivery rate [I6, Table 4] was higher than the average score from the MFM specialty obstetricians ( $p = 0.011$ ). Besides, the MFM obstetricians had higher confidence in their ability to resolve possible complications derived from epidural analgesia for labor more than the obstetricians in the other subspecialties, which is not surprising as the MFM specialty obstetricians had significantly more experience with parturients receiving epidural analgesia.

Opinions about the timing of placing epidural analgesia varied broadly, as can be seen in Table 2 (I15–I18). The American Society of Anesthesiologist Task Force on Obstetric Anesthesia and the Society for Obstetric Anesthesia and Perinatology regarding the most appropriate time to initiate epidural analgesia recommended that the epidural should be provided to patients in early labor (cervical dilatation less than 5 cm) if the service is available and that epidural analgesia should be offered on an individualized basis<sup>(17)</sup>. Wang et al conducted a study of almost 13,000 deliveries, which revealed that the initiation of epidural analgesia in the latent phase of labor compared to initiating it at 4 cm cervical dilatation was neither associated with a prolonged progression of labor nor an increase in the cesarean delivery rate<sup>(18)</sup>. However, our survey showed that most our obstetricians (55/75; 73.3%) agreed with the initiation of epidural analgesia after cervical dilatation of 4 cm [I16, Table 2].

Regarding the fetal and neonatal outcome after epidural analgesia, the average rating scores of the residents about the side effects of epidural analgesia leading to intrauterine fetal distress and birth asphyxia (I7–I8, Table 4) were significantly higher than those of the graduate obstetricians. The systematic review showed no difference between the epidural analgesia group compared with the parenteral opioid group in neonatal outcomes, including admission to the neonatal

intensive care unit and an Apgar score less than 7 at 5 minutes<sup>(2)</sup>.

In addition, there was a disparity in the average rating score concerning epidural analgesia giving patients good relief from labor pain [I21, Table 4] between obstetricians with working experience of less than or equal to 10 years and those with working experience of more than 10 years. Working experience and age differences may partly explain the different attitudes as the mean age of the residents was significantly lower than that of the graduate obstetricians. Similarly, Klein et al described dissimilar attitudes between young obstetricians ( $\leq 40$  years old) and older obstetricians ( $> 40$  years old) regarding the use of epidural analgesia for labor<sup>(19)</sup>. Younger obstetricians tend to be more comfortable with the routine use of epidural analgesia and fewer consider that epidural analgesia interferes with the progression of labor<sup>(19)</sup>.

In the free responses, some obstetricians suggested the establishment of an epidural analgesia service in our institute in order to provide epidural analgesia in both normal and private labor suites. Besides, the availability of anesthesiologists to attend patients with epidural analgesia both in and out-of-office hours was a significant suggestion considering the results from I19, I20, and I24 in Table 2, which showed that most the obstetricians were not comfortable in attending patients after they have undergone epidural analgesia for labor. Similarly, several surveys in various countries have reported that many obstetricians are unfamiliar with epidural management and have suggested there is a need for further interprofessional education and greater collaboration<sup>(5, 7, 9, 10)</sup>.

There were several limitations of this study to note. First, there was a relatively low response rate from obstetricians. Second, we did not provide the questionnaire to the labor ward nurses, despite their more regular encounters with laboring patients or to the anesthesiologists involved with those patients. Furthermore, details behind the reasons for each item were not explored, such as the reason why some obstetricians consider that there will be intrauterine fetal and neonatal effects after laboring patients have

received epidural analgesia. Future research should be performed utilizing the questionnaire format together with focus group discussions to investigate the attitudes of labor ward nurses and anesthesiologists. A multicenter or national survey regarding epidural analgesia for labor in Thailand should be conducted as currently there are dissimilarities in epidural analgesia practices in individual institutions. The single center data in our study may not reflect the practice in the entire country regarding the use of epidural analgesia for labor. Besides the aforementioned, the authors suggest it is essential to promote the understanding of maternal clinical outcomes and possible complications regarding the use of epidural analgesia for labor to all staff involved in the labor suite.

## Conclusion

Our study revealed that 58.7% of the obstetricians in our institute agreed that if there are no contraindications, patients with labor pain should receive epidural analgesia. However, a high number of the obstetricians believed that the use of epidural analgesia for labor will affect maternal obstetric outcomes, including prolonging the second stage of labor and increasing the rate of instrumental delivery. The development of an epidural analgesia service for supporting the widespread use of epidural analgesia for labor in our institute should be undertaken when possible.

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## Potential conflicts of interest

The authors declare no conflicts of interest.

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## GYNAECOLOGY

# Reliability and Validation of Thai-version of Urge-Urinary Distress Inventory Questionnaire

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## ABSTRACT

**Objectives:** To develop and test the reliability of a Thai version of the urge-urinary distress inventory (U-UDI) questionnaire and to correlate with overactive bladder symptom score (OABSS) and overactive bladder validated 8 question screener (OAB-V8) questionnaires.

**Materials and Methods:** During June 2019 and July 2020, 100 Thai women attending the female pelvic medicine clinic at King Chulalongkorn Memorial Hospital with overactive bladder were recruited. The original English of U-UDI was forward translated into a Thai version by one linguist from Chulalongkorn University and backward translated by another linguist then the content was validated by two urogynecologists at our department. The patients were asked to complete the Thai version of U-UDI, OABSS and OAB-V8 questionnaires at first visit and only Thai version U-UDI questionnaire at 2-week interval.

**Results:** All patients completed the study. The mean  $\pm$  standard deviation (SD) of age were  $61.1 \pm 11.8$  years. The mean  $\pm$  SD of the urge domain U-UDI summary score was  $1.6 \pm 0.8$  (first visit) and  $1.4 \pm 0.9$  (at 2 weeks). The weighted Kappa coefficients of the 9 items were 0.4-0.5. Test-retest reliability showed good reliability with intraclass correlation 0.8 (95% confidence interval 0.7, 0.8). The Cronbach's alpha of U-UDI was 0.8. The Pearson's correlation ( $r$ ) of U-UDI to OABSS and OAB-V8 was 0.6 and 0.6.

**Conclusion:** A Thai version of U-UDI questionnaire was reliable and valid. It could be used as a tool for urinary urgency evaluation in Thai women.

**Keywords:** Thai version, Urgency, Urge, U-UDI, OABSS, OAB-V8

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## ความเที่ยงและความตระของแบบสอบถามความรุนแรงของการปัสสาวะเร่งรีบ (Urge Urinary Distress Inventory questionnaire)

กฤษณ์ กังสตารพร, สุวิทย์ บุณยะเวชชีวิน, ปุริม เรือนภู

### บทคัดย่อ

**วัตถุประสงค์:** เพื่อหาความเที่ยงของแบบสอบถามความรุนแรงของการปัสสาวะเร่งรีบ (Urge Urinary Distress Inventory, U-UDI) ฉบับภาษาไทย และหาสัมพันธ์เทียบกับแบบสอบถามคัดกรองอาการปัสสาวะเร่งรีบ (Overactive Bladder Symptom Score, OABSS และ Overactive Bladder Validated 8 Question Screener, OAB V-8) ฉบับภาษาไทย

**วัสดุและวิธีการ:** ระหว่างเดือนมิถุนายน 2019 ถึงกรกฎาคม 2020 ได้ทำการศึกษาในสตรีไทย 100 คนที่ถูกวินิจฉัยว่ามีภาวะกระเพาะปัสสาวะไวเกินที่มารับการรักษาที่คลินิกเวชศาสตร์เชิงการสตรีและศัลยกรรมช่องเริม โรงพยาบาลจุฬาลงกรณ์ สภากาชาดไทย โดยสตรีทุกคนจะตอบแบบสอบถามความรุนแรงของการปัสสาวะเร่งรีบ 9 หัวข้อ (Urinary Urgency Distress Inventory, U-UDI) เป็นฉบับภาษาไทยที่แปลโดยนักภาษาศาสตร์จากสถาบันภาษา จุฬาลงกรณ์มหาวิทยาลัย และแปลกลับเป็นภาษาอังกฤษโดยนักภาษาศาสตร์อีกท่าน โดยมีการตรวจสอบโดยนรีแพทย์ทางเดินปัสสาวะจากภาควิชาสูติศาสตร์นรีเวชวิทยา คณแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย โดยผู้เข้าร่วมวิจัยจะทำแบบสอบถามความรุนแรงของอาการปัสสาวะเร่งรีบ (Urge Urinary Distress Inventory, U-UDI) ฉบับภาษาไทย และแบบสอบถามคัดกรองอาการปัสสาวะเร่งรีบ (Overactive Bladder Symptom Score, OABSS และ Overactive Bladder Validated 8 Question Screener, OAB V-8) ฉบับภาษาไทยในสัปดาห์แรก จากนั้นจะมีการทำแบบสอบถามความรุนแรงของการปัสสาวะเร่งรีบ (Urge Urinary Distress Inventory, U-UDI) ฉบับภาษาไทยซ้ำอีกรังวิงเมื่อครบ 2 สัปดาห์

**ผลการศึกษา:** ผู้เข้าร่วมวิจัยทั้งหมด 100 คน ได้ทำแบบสอบถามและตอบกลับ พบว่าอายุเฉลี่ยคือ  $61.1 \pm 11.8$  ปี และมีค่าเฉลี่ยของแบบสอบถามความรุนแรงของการปัสสาวะเร่งรีบ (Urge Urinary Distress Inventory, U-UDI) ฉบับภาษาไทยอยู่ที่  $1.6 \pm 0.8$  ในครั้งแรก และ  $1.4 \pm 0.9$  ใน 2 สัปดาห์ถัดมา และมีความสอดคล้องโดยใช้สัมประสิทธิ์ Kappa ของแบบสอบถามทั้ง 9 หัวข้ออยู่ที่ 0.4 ถึง 0.5 และมีความเที่ยงของการทดสอบซ้ำอยู่ที่ โดยใช้สัมประสิทธิ์สหสัมพันธ์ภายนอกในชั้นอยู่ที่ 0.8 โดยมีค่าความสอดคล้องของแบบสอบถาม (Cronbach's Alpha) อยู่ที่ 0.8 ส่วนค่าความสอดคล้องสัมประสิทธิ์สหสัมพันธ์เชิงอันดับ Pearson เมื่อเทียบกับแบบสอบถามคัดกรองอาการปัสสาวะเร่งรีบ (Overactive Bladder Symptom Score, OABSS และ Overactive Bladder Validated 8 Questions Screener, OAB V-8) ฉบับภาษาไทยอยู่ที่ 0.6

**คำสำคัญ:** ปัสสาวะเร่งรีบ, แบบสอบถามภาษาไทย, ปัสสาวะไวเกิน

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## Introduction

Overactive bladder (OAB) is defined as a symptom syndrome of urinary urgency, with or without urge incontinence, usually with urinary frequency and nocturia, in the absence of infection or obvious pathologic features<sup>(1)</sup>. It has a negative impact on the quality of life, interfering with daily activities, travel, and sleep<sup>(2-4)</sup>. Urinary urgency definition is the complaint of a sudden compelling desire to pass urine, which is difficult to defer<sup>(5,6)</sup>. Currently, the diagnosis of OAB is based on urinary urgency symptom rather than objective measure so the clarify symptoms is the best way to assessed the patient understanding and severity of the symptoms. Many questionnaire are developed to measure the patient's symptoms such as overactive bladder symptom score questionnaire (OABSS) and overactive bladder validated 8 question screener questionnaire (OAB V-8)<sup>(7,8)</sup>. The English version of OABSS was reported with the intraclass correlation coefficient of the total OABSS score of 0.7 and the Cronbach's alpha coefficient of 0.5<sup>(7)</sup>. The Thai version of OABSS was reliable and valid, had an intraclass correlation coefficient of the total OABSS score of 0.8 and the Cronbach's alpha coefficient of 0.3<sup>(9)</sup>, while the Thai version of OAB V-8 had the Cronbach's alpha coefficient above 0.7 and the intraclass correlation coefficient of 0.6<sup>(8)</sup>. Both Thai version OABSS and OAB V-8 have been used as screening and follow-up tools<sup>(10, 11)</sup>. Those two OAB questionnaires contained only one question per each questionnaire about the urgency symptom. In order to focus specifically on urgency symptom, a specific questionnaire is required. The International Consultation on Incontinence (ICI) has recommended the standard questionnaire for measure urinary urgency symptoms such as an urge-urinary distress inventory (U-UDI)<sup>(12)</sup>. The U-UDI questionnaire is designed specifically for urinary urgency evaluation. This questionnaire is beneficial for the comparison of the urinary urgency symptoms domain for the evaluation of OAB disease treatment due to the good

psychometric property and easy to use format. It is a grade A questionnaire recommended by ICI which comprised of nine questions. It composed of two domains. A urinary urgency domain is questions number 1, 2, 3, 5, 8 and 9. Also, Urinary incontinence domain is questions number 4, 6 and 7. The scores ranged from 0 (no symptom) to 4 (most bothersome) according to the degree of bothersomeness. The summary score was calculated by averaging the non-missing scores. In the original study, a U-UDI questionnaire has a good reliability, validity and responsiveness (Cronbach's alpha 0.7, test-retest reliability 0.5). Consequently, it is commonly used in urinary urgency studies as comparison of urgency symptoms before and after treatment<sup>(13-16)</sup>. Currently, there is no study or translation of U-UDI questionnaire in Thailand. Therefore, we realized the importance of the urinary urgency symptoms. This study aimed to develop and test the reliability of a Thai version U-UDI questionnaire. Besides, we also studied the correlation with OABSS and OAB V-8 as the secondary objective.

## Materials and Methods

This psychometric test, cross-sectional study was conducted at The Female Pelvic Medicine and Reconstructive Surgery Clinic, King Chulalongkorn Memorial Hospital (KCMH), a tertiary care center in Bangkok, Thailand, between June 2019 and July 2020. The inclusion criteria was patients with OAB symptoms for more than three months and at least one episode of urgency with or without urinary incontinence in a past week during the study period. A total of 100 female participants were recruited based on a volunteer basis. All participants must be able to read and write in Thai language. The exclusion criteria were: patients with indwelling catheters, practicing intermittent self-catheterization, evidence of a symptomatic urinary tract infection, chronic inflammation, previous or current malignant disease of the pelvic organs, bladder stones, any neurological bladder disease, diabetic neuropathy,

quitted or changed.

### **Translation process**

After permission from the original study's authors, the English version of U-UDI was forward translated into Thai language by a linguist from Language institute, Chulalongkorn University and backward translated by another linguist. The content validation was done by the two urogynecologists (SB, PR). Two urogynecologists reviewed all the translations to confirm that the meanings were similar to the original version. In case of any discrepancy to the original questionnaire, the translation questionnaire was sent back to the linguists for the correction until there was no discrepancy. The final translated Thai version of U-UDI questionnaire was pretested in 20 participants. Each subject completed the questionnaire, and was interviewed to probe about what she thought was meant by each questionnaire item and the chosen response. Both the meaning of the items and responses were explored to confirm the understanding meaning of the original English version by the authors. The OABSS and OAB-V8 questionnaires were used for score correlation for the criterion validity.

The patients were asked to complete the self-administration Thai version of U-UDI, OABSS and OAB-V8 questionnaires at first visit. The thirty minutes period was given for all questionnaire completion. The completeness of all items was checked and only Thai version U-UDI questionnaire were given and sent back by mail at 2-week interval.

### **Statistical analysis**

Descriptive statistics (mean, median standard deviation, interquartile range). The weighted Kappa coefficients were used for item analysis. Intraclass correlation was used for the test-retest reliability. Pearson's correlation was used for criterion validation. Cronbach's alpha was used for the internal consistency. The statistical analysis was

done by SPSS version 22.0. For sample size calculation, rule of thumb formula for estimation of sample size for psychometric test study were used<sup>(17)</sup>. Total of 90 participants were needed. After adding 10% dropout, therefore 100 participants in total were needed.

## **Results**

Between June 2019 and July 2020, 100 patients from the Female Pelvic Medicine and Reconstructive Surgery Clinic, King Chulalongkorn Memorial Hospital (KCMH) completed the Thai version U-UDI, OABSS and OAB V-8 questionnaires at first visit whereas Thai version U-UDI questionnaire was given and sent back at 2-week interval. There was no drop out at the second week of the study. All participants completed the questionnaires at first and two weeks interval. The mean  $\pm$  standard deviation (SD) of age were  $61.1 \pm 11.8$  years, 62% were Buddhist, 6% were Islam, and 1% was Christianity. Most women (63%) had middle level of education. The majority were primary school (36%), secondary school (16%) and vocational certificate (11%), with the remainder having had bachelor degree or higher (37%). Sixty-two percent of women had body mass index of 18-25 kg/m<sup>2</sup>. Fifty-two percent of women were married. Most of the participants were currently employed (50%), retired (40%). Multiparous was documented in 59 women (59%). Fifty percent of women had symptoms within a year. The other demographic and clinical characteristics are shown in Table 1.

The mean  $\pm$  SD of the total U-UDI summary score was  $1.5 \pm 0.7$  (first visit) and  $1.4 \pm 0.8$  (at 2 weeks interval) while the urge domain U-UDI summary score was  $1.6 \pm 0.8$  (first visit) and  $1.4 \pm 0.9$  (at 2 weeks interval) (Table 2). For the primary outcome, the test retest reliability of the Thai version U-UDI questionnaire was 0.8 (95% confidence interval 0.7, 0.8).

**Table 1.** Patient's characteristics (n = 100).

	Mean ± SD
Age at informed consent	61.1 ± 11.8
	<b>n (%)</b>
Body mass index	
Less than 18 kg/m <sup>2</sup>	1 (1)
18 to 25 kg/m <sup>2</sup>	62 (62.6)
25 to 30 kg/m <sup>2</sup>	26 (26.3)
More than 30 kg/m <sup>2</sup>	10 (10.1)
Education	
Vocational certificate	11 (11)
Primary school	36 (36)
Secondary school	16 (16)
Bachelor degree or higher	37 (37)
Occupation	
Business career	29 (32.2)
Employee	21 (23.3)
Retired	40 (44.4)
Religion	
Buddhist	91 (92.9)
Islam	6 (6.1)
Christianity	1 (1)
Number of children	
Nulliparous	27 (27)
1 children	14 (14)
2 children	28 (28)
3 children	20 (20)
More than 3 children	11 (11)
Duration of symptoms	
Within 1 year	50 (50)
1-2 years	25 (25)
More than 2 years	25 (25)

**Table 2.** Item response of Thai version U-UDI scores (n = 100).

Items	Visit	
	week 0 (n (%))	week 2 (n (%))
1. Do you experience frequent urination?		
Not disturb at all	9 (9)	11 (11)
Slightly disturbed	31 (31)	32 (32)
Moderately disturbed	27 (27)	26 (26)
Greatly disturbed	13 (13)	5 (5)
No	20 (20)	26 (26)
2. Do you experience a strong feeling of urgency to empty your bladder?		
Not disturb at all	11 (11)	14 (14)
Slightly disturbed	29 (29)	27 (27)
Moderately disturbed	25 (25)	22 (22)
Greatly disturbed	12 (12)	9 (9)
No	23 (23)	28 (28)

**Table 2.** Item response of Thai version U-UDI scores (n = 100). (Cont.)

Items	Visit	
	week 0 (n (%))	week 2 (n (%))
3. Do you experience difficulty in holding your urine?		
Not disturb at all	17 (17)	12 (12)
Slightly disturbed	27 (27)	29 (29)
Moderately disturbed	20 (20)	19 (19)
Greatly disturbed	12 (12)	9 (9)
No	24 (24)	31 (31)
4. Do you experience any urine leakage?		
Not disturb at all	19 (19)	21 (21)
Slightly disturbed	35 (35)	25 (25)
Moderately disturbed	16 (16)	21 (21)
Greatly disturbed	4 (4)	0 (0)
No	26 (26)	33 (33)
5. Do you experience urine leakage related to the feeling of urgency?		
Not disturb at all	12 (12)	11 (11)
Slightly disturbed	30 (30)	22 (22)
Moderately disturbed	15 (15)	22 (22)
Greatly disturbed	6 (6)	3 (3)
No	37 (37)	42 (42)
6. Do you experience urine leakage related to physical activity, coughing or sneezing?		
Not disturb at all	14 (14)	20 (20)
Slightly disturbed	28 (28)	22 (22)
Moderately disturbed	9 (9)	11 (11)
Greatly disturbed	9 (9)	7 (8)
No	40 (40)	40 (40)
7. Do you experience urine leakage not related to urgency or activity?		
Not disturb at all	17 (17)	16 (16)
Slightly disturbed	18 (18)	23 (23)
Moderately disturbed	14 (14)	12 (12)
Greatly disturbed	1 (1)	2 (2)
No	50 (50)	47 (47)
8. Do you experience nighttime urination?		
Not disturb at all	16 (16)	17 (17)
Slightly disturbed	31 (31)	37 (37)
Moderately disturbed	33 (33)	27 (27)
Greatly disturbed	10 (10)	10 (10)
No	10 (10)	9 (9)
9. Do you experience bedwetting?		
Not disturb at all	22 (2)	26 (26)
Slightly disturbed	5 (5)	4 (4)
Moderately disturbed	3 (3)	3 (3)
Greatly disturbed	0 (0)	1 (1)
No	70 (70)	66 (66)
<b>Mean ± SD</b>		
Total (Items 1-9) U-UDI summary score	1.5 ± 0.7	1.4 ± 0.8
Urge domain (Items 1, 2, 3, 5, 7 and 9) U-UDI summary score	1.6 ± 0.8	1.4 ± 0.9

U-UDI: urge-urinary distress inventory; SD: standard deviation

The weighted Kappa coefficients of the 9 items were ranged between 0.4-0.5. The Cronbach's alpha was 0.8 (Table 3). For the

secondary outcome, the Pearson's correlation (r) of U-UDI to OABSS and OAB-V8 was 0.6 and 0.6 (Table 4).

**Table 3.** Reliability of Thai version U-UDI score.

Items	weighted Kappa (95%CI)
1. Do you experience frequent urination?	0.5 (0.4 - 0.6)
2. Do you experience a strong feeling of urgency to empty your bladder?	0.5 (0.4 - 0.6)
3. Do you experience difficulty in holding your urine?	0.5 (0.3 - 0.6)
4. Do you experience any urine leakage?	0.5 (0.4 - 0.6)
5. Do you experience urine leakage related to the feeling of urgency?	0.5 (0.4 - 0.6)
6. Do you experience urine leakage related to physical activity, coughing or sneezing?	0.5 (0.4 - 0.7)
7. Do you experience urine leakage not related to urgency or activity?	0.4 (0.3 - 0.6)
8. Do you experience nighttime urination?	0.5 (0.4 - 0.6)
9. Do you experience bedwetting?	0.4 (0.3 - 0.6)
ICC (95%CI)	
Test-retest reliability (ICC = Intraclass correlation)	0.8 (0.7 - 0.8)

U-UDI: urge-urinary distress inventory, SD: standard deviation

**Table 4.** Correlation of Thai version U-UDI score with other measurements.

Items	Pearson's Correlation Coefficient (r)	p value
Total U-UDI total score vs OAB-v8 total score	0.6	< 0.001
Total U-UDI total score vs OABSS total score	0.6	< 0.001
Urge domain U-UDI summary score vs OAB V-8 total score	0.6	< 0.001
Urge domain U-UDI summary score vs OABSS total score	0.6	< 0.001

U-UDI: urge-urinary distress inventory, OABSS: overactive bladder symptom score, OAB-v8: 8-item overactive bladder symptoms score questionnaire.

Total U-UDI item = items 1-9, Urge domain U-UDI items = items 1, 2, 3, 5, 8 and 9

## Discussion

Findings from the current study demonstrated that this Thai version U-UDI questionnaire had a good test-retest reliability (The ICC is 0.8) which was consistent with the original study of U-UDI questionnaire that had a test-retest reliability of 0.59<sup>(12)</sup>. The Cronbach's alpha (0.8) in this study was also consistent with the original study<sup>(12)</sup>. When compared to the previous study of the test-retest reliability of U-UDI questionnaire reported by Borello-France<sup>(18)</sup>, the mean scores of the urge domain U-UDI summary score (1.8 at baseline and 1.7 at the re-test period) were similar to our study (1.6 at baseline and 1.4 at the re-test period).

These low U-UDI total score and urge domain score reflect the mild symptoms of urinary urgency domain. However, these findings were not affected the psychometric property in this study. The test-retest reliability (ICC) from our study was 0.8 which was also higher than the ICC of 0.6 as reported by Borello-France<sup>(18)</sup>. The higher ICC from our study can be explained the better understanding when translated into Thai for Thai women with OAB. When compared to the other urgency questionnaires that translated into Thai language such as OABSS, we found the similar test-retest reliability<sup>(9)</sup>. This supports the good understanding of Thai language translation of the OAB questionnaire.

And also the small numbers of the items (Only 9 items) made it easy to administer. We also found the similar good internal consistency (Cronbach's alpha 0.8) from our study when compared to the OAB V-8 questionnaire<sup>(8)</sup>. We found similar weighted Kappa (0.4-0.5) in all items of Thai version U-UDI which showed moderate agreement to the original study<sup>(12)</sup>. And when compared to the scores to the other OAB questionnaires, there was a moderate correlation between Thai version U-UDI questionnaire vs OABSS and OAB V-8 questionnaires (these are the standard questionnaires for urinary symptoms of OAB). From these psychometric test results, we can confirm that this translated questionnaire is reliable and can reflect the urinary urgency symptoms in Thai patients. As up to now, there is no translation in other language, our report is the first international translation of this U-UDI questionnaire so that there might be more translation process for using this urinary urgency questionnaire in the future. As this questionnaire is recommended by International Consultation on Incontinence (ICI) for urgency evaluation and research (grade A recommendation) and focused specifically in the urinary urgency symptoms. Although this questionnaire should be used in the evaluation of urinary urgency symptoms in the treatment of overactive bladder rather than using general questionnaire for OAB symptoms such as OABSS or OAB V-8 questionnaires, it was designed specifically for urinary urgency evaluation so it was not directly suitable for evaluation of other OAB symptoms such as urinary frequency or urinary incontinence when compared to OABSS or OAB V-8 questionnaire.

#### **Strengths in this study**

This study was the first translated Thai version of the standard questionnaire specifically focused on the urinary urgency questionnaire in Thailand and there was no missing data in our study.

#### **Limitation in this study**

Due to the time restraint, there was no study of the responsiveness conducted in this study. Further prospective study with correlation to the changes of clinic symptoms of OAB is advocated.

## **Conclusion**

This study demonstrated that this Thai version U-UDI had a good reliability, validity and correlated with OABSS and OAB V-8. It could be used as a tool for urinary urgency evaluations such as screening patients, determining the severity of symptoms and using in further clinical research.

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## **Potential conflicts of interest**

The authors declare no conflict of interest.

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## GYNAECOLOGY

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# Reliability and Validity of Thai-version of Female Genital Self-image Scale (FGSIS) Questionnaire

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## ABSTRACT

**Objectives:** The female genital self-image scale questionnaire (FGSIS) was constructed to measuring feeling towards female's own genital in a broader spectrum. The purposes of the study were to assessing reliability and validity of the Thai version FGSIS.

**Materials and Methods:** After the institutional review board approval, 77 Thai women attending the gynecologic outpatient clinic at King Chulalongkorn Memorial hospital were recruited between February and July 2020 in this study. Seven participants drop-out because they did not answer the second questionnaire. The original English-version of FGSIS was translated into Thai version and backward translated by another linguist then the content was validated by the two urogynecologists at our department. After the informed consent were done, the patients were asked to complete the Thai version of FGSIS and female sexual function index (FSFI) questionnaire at first visit and only Thai version of FGSIS questionnaires at 2-week interval were completed and sent back by mail.

**Results:** Our findings indicated good reliability of the Thai-version of FGSIS (Cronbach's alpha 0.80, test-retest reliability 0.79 (0.67-0.87)). Good correlation was found between the Thai-version of FGSIS and the Thai-version of FSFI (Pearson's correlation coefficient = 0.62).

**Conclusion:** The Thai-version of FGSIS was found to be reliable and valid. It could be used for evaluating the satisfaction of genital appearance in Thai women for research and clinical use.

**Keywords:** genital self-image, sexual function, Thai-version questionnaire

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# ความเที่ยงและความตรงของแบบสอบถามระดับความรู้สึกที่ผู้หญิงมีต่อภาพลักษณ์อวัยวะเพศหญิงของตน (Female genital self image scale)

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## บทคัดย่อ

**วัตถุประสงค์:** แบบสอบถามระดับความรู้สึกที่ผู้หญิงมีต่อภาพลักษณ์อวัยวะเพศหญิงของตน (Female genital self image scale) ถูกสร้างขึ้นเพื่อตัววัดระดับความรู้สึกของผู้หญิงที่มีต่อภาพลักษณ์อวัยวะเพศหญิงของตนเองในบริบทที่หลากหลาย โดยวัตถุประสงค์ของงานวิจัย คือ เพื่อหาความเที่ยงของแบบสอบถามระดับความรู้สึกที่ผู้หญิงมีต่อภาพลักษณ์อวัยวะเพศหญิงของตน (Female genital self image scale) ฉบับภาษาไทย และหาสหสัมพันธ์เทียบกับเทียบกับแบบสอบถามการตอบสนองทางเพศในสตรี (Female sexual function index) ฉบับภาษาไทย

**วัสดุและวิธีการ:** หลังจากการวิจัยผ่านการรับรองจากคณะกรรมการจริยธรรมการวิจัย อาสาสมัครจำนวน 77 คนที่เข้ารับการรักษาเป็นผู้ป่วยนอกในแผนกนรีเวชกรรม โรงพยาบาลจุฬาลงกรณ์ระหว่างเดือนกุมภาพันธ์ 2020 ถึงกรกฎาคม 2020 (อาสาสมัครจำนวน 7 คนได้ออกจากงานวิจัยเนื่องจากไม่ได้ตอบแบบสอบถามครั้งที่สอง) แบบสอบถามระดับความรู้สึกที่ผู้หญิงมีต่อภาพลักษณ์อวัยวะเพศหญิงของตน (Female genital self image scale) ฉบับภาษาอังกฤษต้นฉบับจะถูกแปลโดยนักภาษาศาสตร์จากสถาบันภาษา จุฬาลงกรณ์มหาวิทยาลัย และแปลกลับเป็นภาษาอังกฤษโดยนักภาษาศาสตร์อีกท่าน โดยมีการตรวจสอบความตรงของแบบสอบถามที่แปลไปกลับโดยนรีแพทย์ทางเดินปัสสาวะจากภาควิชาสูติศาสตร์นรีเวชวิทยา คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย โดยผู้เข้าร่วมวิจัยซึ่งได้ให้ความยินยอมเข้าเป็นอาสาสมัคร วิจัยจะตอบแบบสอบถามระดับความรู้สึกที่ผู้หญิงมีต่อภาพลักษณ์อวัยวะเพศหญิงของตน (Female genital self image scale) ฉบับภาษาไทย จำนวน 7 ข้อ และแบบสอบถามการตอบสนองทางเพศในสตรี (Female sexual function index) ฉบับภาษาไทย จำนวน 19 ข้อ ในส่วนหนึ่งจะจากนั้นผู้เข้าร่วมวิจัยจะตอบแบบสอบถามระดับความรู้สึกที่ผู้หญิงมีต่อภาพลักษณ์อวัยวะเพศหญิงของตน (Female genital self image scale) ฉบับภาษาไทยซึ่งอีกครั้งเมื่อครบ 2 สัปดาห์ และส่งกลับทางไปรษณีย์

**ผลการศึกษา:** ผลการวิจัยพบว่าแบบสอบถามมีค่าความตรงที่ดี โดยค่าความสอดคล้องของแบบสอบถาม (Cronbach Alpha) อยู่ที่ 0.8 และมีความเที่ยงของการทดสอบซ้ำ (สัมประสิทธิ์สหสัมพันธ์ภายในชั้น (Intraclass correlation) (95% CI)) อยู่ที่ 0.79 (0.67-0.87) ค่าความสอดคล้องสัมประสิทธิ์สหสัมพันธ์เชิงอันดับ (Pearson 's Correlation) เมื่อเทียบกับแบบสอบถามการตอบสนองทางเพศในสตรี (Female sexual function index) ฉบับภาษาไทย อยู่ที่ 0.62

**สรุป:** แบบสอบถามระดับความรู้สึกที่ผู้หญิงมีต่อภาพลักษณ์อวัยวะเพศหญิงของตน (Female genital self image scale) ฉบับภาษาไทย มีความเที่ยงและความตรงที่ดี เหมาะสมที่จะนำไปใช้เป็นเครื่องมือในการประเมินความพึงพอใจต่ออวัยวะเพศในสตรีไทยทั้งเพื่อการรักษาและงานวิจัยต่อไป

**คำสำคัญ:** อัตตภาพลักษณ์ทางเพศ, สมรรถภาพทางเพศ, แบบสอบถามภาษาไทย

## Introduction

Women's sexual esteem is a component of psychological and behavioral aspects of sexual and perceived physical well-being<sup>(1)</sup>. Women's sexual function may be influenced by various factors including relationship-factor, mood, health status sexual esteem and sexual image<sup>(2)</sup>. Women, who satisfied with their own body image, report more sexual activity, orgasm and confidence with their sexual life. A negative sexual image, such as menopausal women or pregnant women, relates with impair sexual function<sup>(3)</sup>. Women find sexual image to be very important and increase more concern, probably due to the influence of media<sup>(4)</sup>. Female elective genital cosmetic surgeries have become increasingly popular. Valid scales are necessary to describe the need for or success of treatment such as the female sexual function index (FSFI)<sup>(5)</sup>. But sexual image may not be always related with sexual function<sup>(1)</sup>. Many women requires genital cosmetic surgery to improve appearance, not for only sexual function. Therefore, specific genital appearance questionnaire is more appropriate evaluation tool in this group.

The female genital self-image scale (FGSIS) questionnaire was developed by Herbenick D, to measure feelings toward her sexual image<sup>(6)</sup>. The FGSIS composed of 7 questions using 4-point response scale (strongly agree = 4, agree = 3, disagree = 2, strongly disagree = 1). Participant's score on each item were summed for a total sum score ranging from 7 to 28 with higher scores indicating more positive genital self-image. The reliability and validation of many languages of FGSIS was reported<sup>(4,7-11)</sup>. Up to now, there is no Thai language translation and psychometric test of this questionnaire. The purposes of the study were to translate and assess reliability and validity of the Thai-version of FGSIS for future clinical and research purpose.

### **Female sexual function index (FSFI)<sup>(5)</sup>**

The FSFI is a multiple trait scoring, self-reported document for assessing female sexual function consists of 19 items that encompass six separate domains

including desire, arousal, lubrication, pain, satisfaction and orgasm. The FSFI was translated and reported for the good reliability and good internal consistency in many languages<sup>(4,7-11)</sup>. The Thai version of FSFI by Peeyananjarassri et al<sup>(12)</sup> was used for correlation with Thai version of FGSIS at the first visit.

## Materials and Methods

After the institutional review board (IRB) approved, the study was conducted in general gynecology outpatient clinic and female pelvic medicine and reconstructive surgery division clinic, Faculty of Medicine, King Chulalongkorn Memorial Hospital during February 2020 to July 2020.

### **Translation process**

After permission from the original study's authors, the English version of FGSIS was forward translated into Thai language by a linguist from Language institute, Chulalongkorn University and backward translated by another linguist. Final draft was accomplished after a small group interview and content validation by the two urogynecologists of our department.

The Thai-version of FGSIS questionnaires were administered to 77 female participants on a volunteer basis (77 participants with 7 participants dropout, not returning the second questionnaires at two weeks). Inclusion criteria were patients in general gynecology outpatient clinic and The female pelvic medicine and reconstructive surgery division clinic at King Chulalongkorn Memorial hospital, aged 18-65 years, sexually active, and able to read and write in Thai language. Women who were pregnancy, having history of current malignancy of pelvic organ and having evidence of bladder disease and urinary tract infection were excluded.

The Thai-version of FGSIS and Thai-version of FSFI were completed by themselves at clinic and repeated only Thai version of FGSIS at next two weeks and sent back by mail.

### **Statistical analysis**

The mean, standard deviation (SD), median and interquartile range were used for descriptive statistics. Reliability and validity of Thai-version of FGSIS were performed by using weighted kappa, test-retest reliability, Cronbach alpha, Pearson's correlation coefficient with statistically significant at p value less than 0.05. IBM SPSS Statistics for Windows, version 22 statistical software was used for statistical analysis. Sample size estimation was calculated from the "rule of ten" for psychometric test sample size estimation of the questionnaire (13). The Thai version of FGSIS comprised of 7 questions, the patients needed to complete the questionnaire was 70 cases. Seven cases

(10% of 70 cases) were added, in case of dropouts. The total cases required in this study was 77 cases.

## Results

Seventy-seven participants were enrolled in this study. Seven participants completed questionnaire only the first visit. The participants' characteristics are shown in Table 1. The mean  $\pm$  SD of age of participants was  $41.19 \pm 11.69$  years. Most participants had the body mass index of 18 to 25 kg/m<sup>2</sup> (67.1%). Most were graduated in Bachelor's degree or higher (71.4%). Most participants were married (74.3%) and in the premenopausal status (74.3%).

**Table 1.** Patient's characteristics.

<b>Patient's characteristics (n = 70)</b>		<b>mean <math>\pm</math> SD</b>
Age at informed consent		$41.19 \pm 11.69$
Number of children		<b>median (IQR)</b>
	0 (0-1)	
Body mass index		<b>n (%)</b>
	Less than 18 kg/m <sup>2</sup>	5 (7.1%)
	18 to 25 kg/m <sup>2</sup>	47 (67.1%)
	25 to 30 kg/m <sup>2</sup>	10 (14.3%)
	More than 30 kg/m <sup>2</sup>	8 (11.4%)
Education		
	Primary school	0 (0%)
	Secondary school	20 (28.6%)
	Bachelor's degree or higher	50 (71.4%)
Marital status		
	Single	17 (24.3%)
	Married	52 (74.3%)
	Divorce or widow	1 (1.4%)
Menopausal status		
	Pre-menopause	52 (74.3%)
	Post-menopause	18 (25.7%)

SD: standard deviation, IQR: interquartile range

The mean  $\pm$  SD of total score of Thai version of FGSIS at first visit and at the 2 weeks interval were  $19.97 \pm 3.16$  and  $20.06 \pm 2.54$ , respectively (Table 2). The Thai-version of FGSIS had the good

test-retest reliability (the intraclass correlation (95% confidence interval) 0.79 (0.67-0.87)) (Table 3). The Cronbach alpha was 0.8. Each item of FGSIS showed the weighted kappa ranged 0.27 to 0.72.

The lowest weighted kappa was 0.27 in the item: "I feel comfortable letting a healthcare provider examine my genitals." The highest weighted kappa was 0.72 in the item: "I think my genital smell fine."

The Thai version of FGSIS and the Thai version of FSFI correlated well in total scores and in all domains with Pearson's correlation coefficient of 0.62 (Table 4).

**Table 2.** Item response of Thai version of FGSIS score (n = 70).

Item	Visit	
	Week 0 (n (%))	Week 2 (n (%))
1. I feel positively about my genital		
Strongly disagree	1 (1.4%)	0 (0%)
Disagree	12 (17.1%)	8 (11.4%)
Agree	45 (64.3%)	53 (75.7%)
Strongly agree	12 (17.1%)	9 (12.9%)
2. I am satisfied with the appearance of my genital		
Strongly disagree	0 (0%)	0 (0%)
Disagree	17 (24.3%)	8 (11.4%)
Agree	41 (58.6%)	55 (78.6%)
Strongly agree	12 (17.1%)	7 (10%)
3. I would feel comfortable letting a sexual partner look at my genitals		
Strongly disagree	5 (7.1%)	1 (1.4%)
Disagree	20 (28.6%)	17 (24.3%)
Agree	39 (55.7%)	47 (67.1%)
Strongly agree	6 (8.6%)	5 (7.1%)
4. I think my genital smell fine		
Strongly disagree	1 (1.4%)	0 (0%)
Disagree	8 (11.4%)	8 (11.4%)
Agree	51 (72.9%)	56 (80%)
Strongly agree	10 (14.3%)	6 (8.6%)
5. I think my genitals work the way they are supposed to work		
Strongly disagree	2 (2.9%)	1 (1.4%)
Disagree	11 (15.7%)	9 (12.9%)
Agree	45 (64.3%)	51 (72.9%)
Strongly agree	12 (17.1%)	9 (12.9%)
6. I feel comfortable letting a healthcare provider examine my genitals		
Strongly disagree	2 (2.9%)	2 (2.9%)
Disagree	15 (21.4%)	17 (24.3%)
Agree	43 (61.4%)	48 (68.6%)
Strongly agree	10 (14.3%)	3 (4.3%)
7. I am not embarrassed about my genitals		
Strongly disagree	3 (4.3%)	2 (2.9%)
Disagree	28 (40%)	27 (38.6%)
Agree	34 (48.6%)	40 (57.1%)
Strongly agree	5 (7.1%)	1 (1.4%)

FGSIS: female genital self-image scale

**Table 3.** Reliability of Thai version FGSIS score.

Item	Weighted kappa (95%CI)
1. I feel positively about my genital	0.60 (0.39-0.80)
2. I am satisfied with the appearance of my genital	0.59 (0.37-0.80)
3. I would feel comfortable letting a sexual partner look at my genitals	0.63 (0.42-0.83)
4. I think my genital smell fine	0.72 (0.51-0.93)
5. I think my genitals work the way they are supposed to work	0.51 (0.29-0.74)
6. I feel comfortable letting a healthcare provider examine my genitals	0.27 (0.01-0.53)
7. I am not embarrassed about my genitals	0.45 (0.26-0.63)

FGSIS: female genital self-image scale, CI: confidence interval

**Table 4.** Correlation of Thai version FGSIS score with other measurement.

Measurement	Correlation coefficient	
	Pearson's correlation coefficient	p value
FGSIS score vs FSFI score		0.62
FGSIS score VS FSFI (Desire domain)	0.64	< 0.05
FGSIS score VS FSFI (Arousal domain)	0.51	< 0.05
FGSIS score VS FSFI (Lubrication domain)	0.57	< 0.05
FGSIS score VS FSFI (Orgasm domain)	0.56	< 0.05
FGSIS score VS FSFI (Satisfaction domain)	0.48	< 0.05
FGSIS score VS FSFI (Pain domain)	0.54	< 0.05

FGSIS: female genital self-image scale, FSFI: Female Sexual Function Index

## Discussion

From our study, we found the good reliability of Thai version of FGSIS (test-retest reliability 0.79 (0.67-0.87)) with the good internal consistency (Cronbach's alpha coefficient 0.80). These results were found similarly to the other languages versions<sup>(5,8,14)</sup>. We also found the good correlation of Thai-version of FGSIS with the Thai-version of FSFI (Cronbach's alpha coefficient 0.62). But there were reported the better (excellent) correlation between the FSFI and FGSIS in other languages (Cronbach's alpha coefficient 0.81-0.95)<sup>(8,10,14,15)</sup>. The better correlation of FSFI and FGSIS in other languages translation can be explained by the differences on the cultures and the partner-related factors rather than only self-sexual image of women. Thai cultures about the sexual image perceptions may be different from other countries' cultures.

The good instrument for evaluating the female

genital image is important for clinical use for the follow-up and to reflect the response after the treatment. The good questionnaire to evaluate the satisfaction of the genital appearance will be useful for both clinical use and the research purpose of the medical and surgical treatment concerning the genital appearance. From our study, we confirm the good reliability and validity of the Thai version of FGSIS questionnaire. It can be used for evaluating the satisfaction of genital appearance in Thai women.

### Strengths of this study

This study was conducted with the strict validated process with the development process fully compatible with standard protocol. The questionnaire translation was done by experienced linguists. The content validation was done by two urogynecologists to confirm that the translation version still represented the theoretical construct of the original version.

### **Limitation of this study**

The study of responsiveness was not included in our study. Therefore, further studies in women before and after the treatment for genital appearance such as medical treatment or genital cosmetic surgery are advocated.

## **Conclusion**

The Thai-version of FGSIS was found to be reliable and valid. It could be used for evaluating the satisfaction of genital appearance in Thai women for research and clinical use.

## **Potential conflicts of interest**

The authors declare no conflict of interest.

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## GYNAECOLOGY

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# Sexual Health Status of Gynecological Cancer Survivors in King Chulalongkorn Memorial Hospital

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## ABSTRACT

**Objectives:** The primary objective was to evaluate sexual health status of gynecological cancer survivors. The secondary objective was to identify the benefits of sexual health counselling in cancer survivors.

**Materials and Methods:** A prospective study was performed from June 2019 to February 2020. Inclusion criteria were sexually active patients before diagnosis of gynecological cancer, aged 18 years or more and could understand Thai language. Patients who refused to participate or answer the questionnaire or had an active psychiatric disorder were excluded. The questionnaire was created and used as a tool to assess the sexual health status of gynecological cancer survivors. The questionnaire was tested for validity and reliability before use. Questionnaires were given to participants and the participants answered the questionnaire by themselves. Baseline characteristics and details of the questionnaire were collected.

**Results:** One hundred and five participants were recruited. Mean age was  $50.31 \pm 10.26$  years. Sixty-one patients (58.1%) had anxiousness and sexual health concerns. More than half of the participants never received sexual health information from physicians. Menopausal symptoms occurred in 53% of women. Sixty-two patients (59%) resumed sexual activity after complete treatment with mean duration of  $9.23 \pm 7.13$  months. Factors related to the resumption of sexual activity was pre-menopausal status before treatment.

**Conclusion:** More than half of gynecological cancer survivors have sexual health concerns and need counselling. Gynecologic oncologists should discuss this aspect with patients to improve the quality of life of the patients.

**Keywords:** sexual health, gynecological cancer, cancer survivor, counselling.

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# สุขภาพทางเพศในผู้ป่วยหลังการรักษามะเร็งนรีเวชในโรงพยาบาลจุฬาลงกรณ์

ลลิตา ใจมิตรกิจกุล, นิพนธ์ เขมเพชร, ชนิ โอพารรัตนพันธ์

## บทคัดย่อ

**วัตถุประสงค์:** วัตถุประสงค์หลักของการศึกษานี้เพื่อประเมินสุขภาพทางเพศของผู้ป่วยหลังการรักษามะเร็งทางนรีเวช และวัตถุประสงค์รองเพื่อประเมินประยุกต์ในการให้คำแนะนำเกี่ยวกับเรื่องสุขภาพทางเพศแก่ผู้ป่วยเหล่านั้น

**วัสดุและวิธีการ:** เป็นการศึกษาแบบไปที่บ้านนำทำการศึกษาระหว่าง มิถุนายน 2562 ถึงกุมภาพันธ์ 2563 โดยมีเกณฑ์คัดเข้าคือ ผู้ป่วยมะเร็งนรีเวชที่มีเพศสัมพันธ์อยู่เป็นประจำก่อนที่จะได้รับการนิจฉัยว่าเป็นมะเร็งทางนรีเวช อายุ 18 ปีขึ้นไป และเข้าใจภาษาไทย โดยผู้ป่วยที่ปฏิเสธการตอบแบบสอบถาม หรือมีโรคทางจิตเวชที่กำลังได้รับการรักษาอยู่จะถูกคัดออกจากการศึกษาแบบสอบถามได้ถูกสร้างมาเพื่อการวิจัยนี้และได้รับการทดสอบความถูกต้องและความน่าเชื่อถือก่อนนำมาใช้ โดยผู้เข้ารับการวิจัยจะตอบแบบสอบถามด้วยตนเอง ปัจจัยพื้นฐานของผู้ป่วยรวมทั้งรายละเอียดในแบบสอบถามจะถูกเก็บเพื่อวิเคราะห์ผลการศึกษา: มีผู้เข้าร่วมวิจัยทั้งหมดหนึ่งร้อยห้าคน อายุเฉลี่ย 50.31 ปี ค่าเบี่ยงเบนมาตรฐาน 10.26 ปี มีผู้เข้าร่วมวิจัย 61 ราย (ร้อยละ 58.1) มีความกังวลเกี่ยวกับสุขภาพทางเพศและมากกว่าครึ่งของผู้เข้าร่วมวิจัยไม่เคยได้รับคำปรึกษาหรือแนะนำเกี่ยวกับสุขภาพทางเพศจากแพทย์ ร้อยละ 53 ของผู้เข้าร่วมวิจัยมีอาการของวัยทอง และร้อยละ 59 กลับไปมีเพศสัมพันธ์หลังการรักษาสิ้นสุดลง ระยะเวลาโดยเฉลี่ยตั้งแต่การรักษาสิ้นสุดลงจนเริ่มมีเพศสัมพันธ์คือ 9.23 เดือน ค่าเบี่ยงเบนมาตรฐาน 7.13 เดือน ปัจจัยที่มีผลต่อการกลับมา มีเพศสัมพันธ์ คือ อยู่ในวัยก่อนหมดประจำเดือนในช่วงก่อนการรักษามะเร็ง

**สรุป:** กว่าครึ่งของผู้ป่วยหลังการรักษามะเร็งนรีเวชมีความกังวลเกี่ยวกับสุขภาพทางเพศและต้องการคำแนะนำ แพทย์ผู้รักษามะเร็งนรีเวชควรจะให้คำแนะนำในประเด็นดังกล่าวพื่อเพิ่มคุณภาพชีวิตของผู้ป่วย

**คำสำคัญ:** สุขภาพทางเพศ, มะเร็งนรีเวช, ผู้ป่วยหลังการรักษามะเร็ง, การให้คำปรึกษา

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## Introduction

Gynecological cancer makes up nearly 25% of total cancer cases in Thailand with 14.2% accounting for cervical cancer, 5.3% endometrial cancer and 3.1% ovarian cancer<sup>(1, 2)</sup>. Current advancements in gynecological cancer treatment offer better outcomes of the disease treatment and improves the five-year survival rate of gynecological cancer patients to as high as 65%<sup>(3)</sup>. However, cancer treatment modality such as surgery, chemotherapy and radiotherapy have many consequences including shortening of vaginal length, loss of elasticity or moisture of vaginal mucosa, changes of body appearance, hair loss and hormone depletion<sup>(4)</sup>. These consequences have impacts on quality of life and sexual health. The World Health Organization (WHO) defined sexual health as a state of physical, emotional, mental and social wellbeing in relation to sexuality<sup>(5)</sup>.

Previous studies found that 40-60% of gynecological cancer survivors have sexual health problems, whether physical, quality of life or psychological issues<sup>(4-7)</sup>. Moreover, cancer survivors did not get adequate information or treatment about sexual health after cancer treatment<sup>(3, 4, 8)</sup>. Some patients do not dare to consult a doctor about sexual health problems. Moreover, some doctors focus only on the disease and are not concerned about sexual health of the patients. Therefore, sexual health problems would be underestimated and under treated. This study focused on some aspects of sexual health such as sexual concern, sexual resumption and associated factors in addition to sexual issues such as having concerns that the disease affected the family relationship, feeling loss of femininity, ability to talk or discuss sexual desire with their partner, etc.

This study mainly evaluated the proportion of anxiety and sexual health concerns in gynecological cancer survivors at King Chulalongkorn Memorial Hospital (KCMH) and secondary outcomes were aimed to evaluate the factors associated with resumption of sexual activity and the identification of the benefits from sexual health counselling for patients.

## Materials and Methods

This prospective study was conducted after gaining approval from the Ethics Committee of the Institutional Review Board, Faculty of Medicine at Chulalongkorn University (IRB No. 235/62). Patients who attended the Gynecologic Oncology Clinic and Radiotherapy Clinic at KCMH between June 2019 and February 2020 were recruited. Sampling was performed by convenience sampling technique. The first 5 patients that the investigator met in each outpatient clinic session were asked to participate the study. The Inclusion criteria were gynecological cancer patients who completed treatment for at least 3 months. Patients were more than 18 years old and had to be sexually active before diagnosis of gynecological cancer. Patients were also required to understand Thai language. The exclusion criteria were patients who refused to participate or answer the questionnaire or had an active psychiatric disorder (such as schizophrenia, depressive disorder, or undergoing treatment of stress disorder). Patients who did not have a sexual partner were also excluded.

The sample size was calculated from the infinitive population proportion formula from a previous study which found that 48% of patients that had concerns that their cancer treatment affected their sexual health ( $(p) = 0.48$ )<sup>(6)</sup> calculated with error ( $d$ ) = 0.10 and alpha ( $\alpha$ ) = 0.05. The required sample size was 96. Ten percent was added to the sample size for patients who might be loss to follow-up.

All patients who met all the inclusion criteria and came for a follow-up visit at the out-patient department were informed about the objectives and details of the study by the researcher. Informed consent was signed voluntarily.

The questionnaire, which was designed and created this study, consisted of 2 parts. The first part was general information and sexual status such as age, education, menopausal status, sexual activity before and after cancer treatment, source of sexual health information and their feeling of anxiousness and concerns about sexual health, which was the primary objective of this study. The second part consisted of

14 questions inquiring about sexual health issues such as concern that the disease affected the family and other relationships, vaginal dryness, sexual activity issues and ability to talk or discuss about sexual desire with their partners (Appendix 1). Each item rating scale was scored from 1-5 rating by severity of the problem. The questionnaire was tested for validity by 3 Thai gynecologic oncologists. After that, the reliability was tested by test-retest analysis with 21 gynecological cancer patients who had similar characteristics to the study population. The reliability of this questionnaire was tested with intraclass correlation coefficient (ICC) using SPSS version 22 (SPSS Inc., Chicago, IL, USA). The reliability score for the questionnaire was 0.946 (Appendix 1). The questionnaires were completed by the patients in a private room at the out-patient department of the Gynecologic Oncology Clinic and Radiotherapy Clinic. Time to complete the questionnaire was approximately 10-15 minutes. After that, a counselling session was performed. Every counselling session was performed by single gynecologic oncologist fellow. Each session period was 15-20 minutes. Details of the counselling session included details of their disease, complications, general and sexual health problem including those that participants raised during the questionnaire such as fear that sexual activity may aggravate their disease or feeling anxious or depressed. The second visit was 12 weeks later. Questionnaires distributed and patients were asked to complete them again. The difference between first and second answers of the questionnaire were then analyzed. General characteristics and sexual health statuses were summarized and presented as primary outcomes (Table 1). This study also presented the characteristics that may be associated with sexual activity resumption after completion of treatment (Table 2). The variation of sexual health answer between the both queries within the 12-week interval were summarized and reported as a part of secondary outcomes (Table 3). Variations between the first and second answers may represent the effect of sexual health counselling.

Data was analyzed by SPSS version 22 (SPSS

Inc., Chicago, IL, USA). Descriptive statistics were used for demographic data and summarized as mean with standard deviation, median with range or frequency as appropriate. The secondary outcome, variation between the first and second answers of the 14 items, was analyzed with repeated Analysis of Variance (ANOVA) test. The different characteristics that may be associated with sexual activity resumption were analyzed with prevalence rate ratios (PRR) using Fisher's exact test.

## Results

One hundred and six participants were recruited. All the patients that the researcher approached to participate in the study accepted the invitation. One participant was excluded due to incomplete data filling. Therefore, 105 cases were included. Mean age was  $50.31 \pm 10.26$  years. Sixty-nine patients (65.7%) were in a pre-menopausal state at the time of diagnosis and treatment of cancer. Participants in the study had been diagnosed with ovarian cancer 43.8%, cervical cancer 28.6%, uterine cancer 16.2%, Gestational Trophoblastic Neoplasia (GTN) 7.6 % and other rare cancer 3.9%. Primary treatment, education level and sexual health status for gynecological survivors are reported in Table 1.

More than half of the participants had a husband as a current partner and caretaker. Fifty-six women (53.3%) had menopausal symptoms after cancer treatment. The frequency of pre-treatment sexual activity was reported. Sixty-two participants (59%) had resumed sexual activity. Forty-six participants (43.8%) reported that they had sexual activity more than once a week and 16 participants (15.2%) had less than once a week. The interval between completed treatment and resumption of sexual activity averaged about 9 months (range 1-36 months). Women who did not resumed sexual activity after treatment (41%) gave various reasons, such as being separated from her partner, fear of recurrent disease, or the lack of interest in sexual activity, etc. Fifty-eight participants (56%) had never received information or counselling from physicians or medical personnel. Sixty-one women

(58.1%) reported in the questionnaire that they felt anxious and concerned about their sexual health, while 59 women (56.2%) reported that they felt depressed because of concerns about their sexual health and their cancer disease. For those who reported that they

felt anxious or depressed in the questionnaire, the researcher proposed to consult a psychiatrist. However, most participants preferred to observe themselves and preferred to visit a psychiatrist when the symptoms get worse.

**Table 1.** Demographic characteristics and sexual status of women attending a gynecologic cancer clinic.

Characteristics (n = 105)	n (%)
Age (year), mean (SD)	50.31 ± 10.26
Education	
Primary school	31 (29.5%)
High school	30 (28.6%)
Bachelor's degree	44 (41.9%)
Treatments	
Surgery alone	23 (21.9%)
Chemotherapy alone	3 (2.8%)
Radiotherapy alone	5 (4.8%)
Multimodality	74 (70.5%)
Surgery and chemotherapy	45 (42.9%)
Surgery and radiotherapy	17 (16.2%)
Chemotherapy and radiotherapy	12 (11.4%)
Menopause status	
Post-menopause	36 (34.3%)
Pre-menopause	69 (65.7%)
Menopausal symptoms	56 (53.3%)
Hormonal replacement therapy	11 (10.5%)
Pre-treatment sexual frequency	
≤ 1 / week	82 (78.1%)
> 1 / week	23 (21.9%)
Post-treatment sexual activity	
No sexual activity after cancer treatment	43 (41.0%)
Resumption sexual activity	62 (59.0%)
Source of sexual health information ever obtain	
Physician, nurse	47 (44.8%)
Internet, magazine, book	18 (17.1%)
Other (friends, neighbors, etc.)	23 (21.9%)
None	36 (34.3%)
Anxiousness, concern about sexual health	61 (58.1%)
Depress mood	59 (56.2%)

SD: standard deviation

The different characteristics that may associate with sexual activity resumption are presented in Table 2. Different cancer diagnosis, modality of treatment and

education were not associated with resumption of sexual activity. Only pre-menopause status before treatment was associated with the resumption of sexual activity.

**Table 2.** Characteristics associated with resumption of sexual activity (n = 105).

Variables	Resume (n=62) n (%)	Not resume (n=43) n (%)	PRR (95%CI)	p value
Multimodality Treatments				
Surgery and chemotherapy	23 (37.1%)	22 (51.2%)	0.79 (0.56, 1.11)	0.166
Surgery and radiotherapy	11 (17.7%)	6 (14.0%)	1.12 (0.75, 1.65)	0.789
Chemo and radiotherapy	6 (9.7%)	6 (14.0%)	0.83 (0.46, 1.50)	0.544
Education				
Primary school	14 (22.6%)	17 (39.5%)	0.7 (0.46, 1.06)	0.082
High school	21 (33.9%)	9 (20.9%)	1.28 (0.94, 1.75)	0.189
Bachelor's degree	27 (43.5%)	17 (39.5%)	1.07 (0.78, 1.47)	0.694
Menopause status				
Post-menopause	13 (21%)	23 (53.5%)	0.51 (0.32, 0.81)	0.001
Pre-menopause	49 (79%)	20 (46.5%)	1.97 (1.24, 3.11)	0.001
Pre-treatment sexual frequency				
≤ 1 / week	44 (71%)	38 (88.4%)	0.69 (0.51, 0.92)	0.053
>1 / week	18 (29%)	5 (11.6%)	1.46 (1.09, 1.96)	0.053
Menopausal symptoms	36 (58.1%)	20 (46.5%)	1.21 (0.87, 1.68)	0.320
Hormone replacement therapy	6 (9.7%)	5 (11.6%)	0.92 (0.52, 1.61)	0.756

Data are presented as n (%) and prevalence rate ratios (PRR).

Comparing the score of sexual health items between the first and second queries and comparing scores between groups of resumption and non-resumption of sexual activity is shown in Table 3. The requirement for health information and counselling was significantly increased in both resume and never resume sexual activity groups, mean change + 0.6 (95% confidence interval (CI) 0.5-0.69, p < 0.001) (repeated ANOVA test). Anxiety/sexual health concern and depression symptoms were significantly lower in the resumed sexual activity group, with mean change -0.13 (95%CI -0.25--0.01, p 0.031) (repeated ANOVA test). Women who did not resume sexual activity showed a significantly poorer ability to talk about sexual

activity with their partners.

Almost all women were satisfied with their participation in this study. The women felt comfortable about discussing their symptoms regarding their sexual health as well as their disease aspects. Most participants preferred to complete the questionnaires in a private setting and needed counselling from a physician. They requested more time to discuss some issues about their sexual health. The most common topic that women raised for discussion was whether sexual activity could do harm to their cancer disease or affect the recurrence of the disease. After counselling, patients who did not resume sexual activity still did not resume sexual activity at the time of the follow-up visit.

**Table 3.** Differences of sexual health scores between patients who resumed sexual activity and did not resume sexual activity before and after counselling (first and second queries).

Items	Total (n=105) mean $\pm$ SD	Resume (n=62) mean $\pm$ SD	Not resume (n=43) mean $\pm$ SD	p value <sup>a</sup>
Requirement of information, counselling				
First query	0.38 $\pm$ 0.49	0.44 $\pm$ 0.50	0.30 $\pm$ 0.46	0.165
Second query	0.98 $\pm$ 0.14	1.00 $\pm$ 0.00	0.95 $\pm$ 0.21	0.160
p value <sup>b</sup>	< 0.001	< 0.001	< 0.001	
Anxiety symptoms, sexual health concern				
First query	0.85 $\pm$ 0.82	0.81 $\pm$ 0.76	0.91 $\pm$ 0.89	0.538
Second query	0.73 $\pm$ 0.71	0.68 $\pm$ 0.62	0.81 $\pm$ 0.82	0.360
p value <sup>b</sup>	0.004	0.031	0.044	
Depression symptoms				
First query	0.78 $\pm$ 0.78	0.77 $\pm$ 0.73	0.79 $\pm$ 0.86	0.919
Second query	0.66 $\pm$ 0.70	0.61 $\pm$ 0.61	0.72 $\pm$ 0.83	0.467
p value <sup>b</sup>	0.001	0.006	0.083	
Concern that the disease affected to work				
First query	3.52 $\pm$ 1.32	3.52 $\pm$ 1.29	3.54 $\pm$ 1.38	0.939
Second query	3.58 $\pm$ 1.32	3.60 $\pm$ 1.27	3.56 $\pm$ 1.40	0.893
p value <sup>b</sup>	0.014	0.024	0.323	
Have sexual activity problems				
First query	3.70 $\pm$ 1.34	3.32 $\pm$ 1.32	4.32 $\pm$ 1.16	<0.001
Second query	3.76 $\pm$ 1.32	3.42 $\pm$ 1.30	4.33 $\pm$ 1.17	0.001
p value <sup>b</sup>	0.033	0.033	NA	
Vaginal dryness				
First query	3.12 $\pm$ 1.32	2.81 $\pm$ 1.27	3.69 $\pm$ 1.23	0.001
Second query	3.21 $\pm$ 1.34	2.90 $\pm$ 1.31	3.76 $\pm$ 1.21	0.002
p value <sup>b</sup>	0.032	0.057	0.325	
Dyspareunia / painful intercourse				
First query	NA	3.13 $\pm$ 1.32	NA	NA
Second query	NA	3.21 $\pm$ 1.34	NA	NA
p value <sup>b</sup>	NA	0.096	NA	NA
Trouble about orgasm				
First query	NA	3.03 $\pm$ 1.15	NA	NA
Second query	NA	3.05 $\pm$ 1.19	NA	NA
p value <sup>b</sup>	NA	0.659	NA	NA
Ability to talk / discuss about sexual desire with partner				
First query	2.84 $\pm$ 1.34	2.36 $\pm$ 1.05	3.93 $\pm$ 1.30	<0.001
Second query	2.56 $\pm$ 1.09	2.23 $\pm$ 0.96	3.30 $\pm$ 1.03	<0.001
p value <sup>b</sup>	<0.001	0.010	0.001	

**Table 3.** Differences of sexual health scores between patients who resumed sexual activity and did not resume sexual activity before and after counselling (first and second queries). (Cont.)

Items	Total (n=105) mean $\pm$ SD	Resume (n=62) mean $\pm$ SD	Not resume (n=43) mean $\pm$ SD	p value <sup>a</sup>
Interested in sexual activity				
First query	3.81 $\pm$ 0.98	3.42 $\pm$ 0.86	4.55 $\pm$ 0.75	< 0.001
Second query	3.80 $\pm$ 1.03	3.42 $\pm$ 0.86	4.52 $\pm$ 0.94	< 0.001
p value <sup>e</sup>	0.657	1.000	0.662	
Pleasure with sexual activity				
First query	NA	3.21 $\pm$ 0.93	NA	NA
Second query	NA	3.18 $\pm$ 0.94	NA	NA
p value <sup>b</sup>	NA	0.159	NA	NA
Pleasure with everyday life				
First query	1.91 $\pm$ 0.93	1.81 $\pm$ 0.85	2.07 $\pm$ 1.02	0.153
Second query	1.90 $\pm$ 0.93	1.81 $\pm$ 0.85	2.05 $\pm$ 1.03	0.196
p value <sup>b</sup>	0.320	1.000	0.323	

Data are presented as mean  $\pm$  standard deviation (SD), and mean change (95%CI). P value corresponds to repeated ANOVA test.

NA = Not applicable

p value<sup>a</sup> of test between column Resume and Not resume

p value<sup>b</sup> of mean change between first and second query

## Discussion

Sexual health is an important aspect of quality of life for gynecological cancer survivors. However, routine discussion about sexual health is limited as it may be due to the nature of Thai or Asian culture which implies that topics related to sex or sexual activity are impolite and private issues, rarely share with others. There are only a few studies about sexual health of gynecological cancer survivors in Thailand. Incidence of anxiousness and sexual health concerns in this study was 58.1% and as high as in previous Western studies<sup>(4-7)</sup>. Less than half of the women in this study received sexual health information from physician or healthcare personnel, which was similar to previous studies (40-70%)<sup>(3, 4, 7, 9)</sup>. Common symptoms were vaginal dryness, vaginal pain or dyspareunia, as similarly reported in previous study<sup>(7, 10)</sup>.

The outcomes in this study may not represent all sexual health status of gynecological cancer survivors because there are many related physical, mental and

cultural aspects should be considered. From our results, the frequency of pre-treatment sexual activity  $> 1$  / week tended to associate with resumed sexual activity PRR 1.46 (95%CI 1.09-1.96, p= 0.053). Moreover, the score of "Interested in sexual activity" was significantly higher in women who did not resume sexual activity. This problem may need further exploration.

This study found that resumption of sexual activity was associated with age, menopause status and pre-treatment sexual activity frequency. Older age and post-menopause status had negative impacts on sexual activity resumption which was the same finding as the study of Tangjitgamol et al<sup>(9, 11)</sup>. Pre-treatment sexual activity frequency  $> 1$ /week in this study had a positive impact on the resumption of sexual activity which was different from the results of Tangitgamol et al. However, these results may not be clearly comparable because of the difference in study population where Tangitgamol et al conducted their study in cervical cancer patients after treatment with

radical hysterectomy, while a majority participant from this study were ovarian cancer survivors.

The differences between the first and second query answers may represent the effect of sexual health counselling. Anxiety and depressive symptoms were significantly decreased after counselling. However, the rate of resumption of sexual activity did not increase after counselling. From the results of this study, most of the participants needed sexual health counselling but hesitated to start the conversation about this topic, which was similar with the results from previous studies<sup>(9-12)</sup>. Therefore, physicians should consider initiating discussions with women on topics of sexual health as routine surveillance to explore problems and offer further treatment as needed. The questionnaire may be used as an initiation tool of the sexual health counselling session to begin the conversation and reduce the patients' embarrassment. We found that the requirement for health information and counselling was significantly increased in both resumed and not resumed sexual activity groups. That means the single visit counselling may not be adequate. Counselling should be performed as a continuous process in multiple sessions.

To the best of our knowledge, only a few studies on sexual health in Thai gynecological cancer survivors have been conducted. However, since we evaluated the sexual health status of gynecological cancer survivors, our results may be useful for counselling and surveillance in this patient population. This study did have some limitations. For example, the stage of disease may affect sexual health. The sample size per each disease and each stage were too small to perform a subgroup analysis. Sexual performance of participant partners was not evaluated in this study as well. There were very few participants who had rare cancer such as vulva cancer, GTN or sarcoma therefore, application to those rare cancers may not be implied. Further study to explore the details of each disease, stage or rare cancer type is warranted. Moreover, this study was conducted in the manner of pre and post-intervention

evaluation. Therefore, response shift bias may have occurred even though the questionnaire was performed 12 weeks apart.

## Conclusion

Gynecological cancer survivors had sexual health concerns and needed sexual health counselling. Gynecologic oncologists should discuss these matters with patients to improve their quality of life.

## Potential conflicts of interest

The authors declare no conflicts of interest.

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**Appendix 1.** Reliability analysis-scale with intraclass correlation coefficient (ICC).

Items	ICC	95%CI
Concern that the disease affected to family, relationship	0.992	(0.981, 0.997)
Concern that the disease affected to work	0.981	(0.954, 0.992)
Feeling loss of femininity	0.994	(0.984, 0.997)
Have sexual activity problems	0.988	(0.970, 0.995)
Vaginal dryness	0.96	(0.901, 0.984)
Dyspareunia / painful intercourse	0.957	(0.894, 0.983)
Trouble about orgasm	0.941	(0.854, 0.976)
Ability to talk / discuss about sexual desire with partner	0.949	(0.875, 0.979)
Appreciate in body, appearance that may change due to disease or treatment	0.959	(0.899, 0.983)
Felt that her partner understood the disease	1	(1.000, 1.000)
Interested in sexual activity	1	(1.000, 1.000)
Pleasure with sexual activity	0.946	(0.866, 0.978)
Pleasure with everyday life	1	(1.000, 1.000)
Proud of herself	1	(1.000, 1.000)
Reliability	0.946	(0.881, 0.967)

CI: confidence interval

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## CASE REPORT

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# Seizure Secondary to Hyponatremia Following a Urogynaecological Surgery: A case report

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## ABSTRACT

Postoperative urinary retention after urogynaecological surgery is common. However urinary retention and hyponatremia is an association that is not known by many. Hyponatremia can be life threatening if it is not picked up early and managed appropriately. We reported a case of seizure following urogynaecological surgery due to severe hyponatremia caused by urinary retention. Early detection, patient education, postoperative bladder care and pain control are important measures to prevent this complication.

**Keywords:** urogynaecological surgery, seizure, hyponatremia, urinary retention.

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## Introduction

Postoperative urinary retention after urogynaecological surgery is common and it can cause significant discomfort and anxiety to patients and may lead to various complications<sup>(1)</sup>. The incidence is quoted as 2.5% to 24% and may be as high as 55% for colpocleisis and 61.9% for mid-urethral sling<sup>(2,3)</sup>. However urinary retention leading to severe hyponatremia causing seizure are very rare. Hyponatremia is defined as serum sodium < 135 mEq/L and it is more common in the elderly population which is the main cohort of urogynaecological

patients<sup>(4)</sup>. Hyponatremia is a life threatening medical condition if it is not managed properly. Correction should be gradual and not too rapid to avoid osmotic demyelination syndrome (ODS). Case of seizure following urogynaecological surgery is presented, where severe hyponatremia was caused by urinary retention. Different presentations of hyponatremia include general weakness, reduced alertness, nausea and vomiting, altered mental status, and even seizure<sup>(5)</sup>. Hyponatremia should be an important different diagnosis in postoperative delirium<sup>(6)</sup>, especially for urogynaecological surgery.

## Case Report

A 64-year-old lady with underlying hypertension on amlodipine underwent vaginal hysterectomy and total colpocleisis for procidentia (Fig. 1). She has been healthy and her preoperative investigations were normal. Her serum sodium (141 mmol/L) and potassium (4 mmol/L) were within normal range. The 90-minute surgery was uncomplicated with a blood loss of 100 ml. Postoperatively, she was recovering well and vital signs were normal. Urinary catheter was removed and trial of void was carried out on day 2 post operation. She was able to pass 50 ml of urine and subsequently developed difficulty in voiding. In and out catheterisation was carried out and 600 ml of clear urine was drained. Reinsertion of urinary catheter was offered, however she insisted for another trial of void. She started to complain of giddiness and body weakness at 10 hours post urinary catheter removal. Nurses noticed that she was confused and had slurring of speech. She was attended immediately. Vital signs

were stable and blood sugar was normal. On examination her Glasgow Coma Scale (GCS) was E4M4V4, pupils were reactive and her bladder was distended. Indwelling urinary catheter was inserted and 1,000 ml of urine was drained. While arranging for computerized tomography (CT) brain, she developed generalised tonic-clonic seizure which lasted for 3 minutes. Her airway was secured and resuscitative measures were carried out. The seizure aborted following intravenous diazepam.

Her CT brain was normal. Serum sodium (112 mmol/L) and urine sodium (144 mmol/L) were low. Her serum (259 mOsm/kg) and urine (144 mOsm/kg) showed hypoosmolarity. She was transferred to intensive care unit, and hyponatremia was corrected with hypertonic 3% saline and fluid restriction. Her serum sodium level was normalised in a gradual manner to avoid ODS. She was intubated for 3 days and her recovery was uneventful. She was discharged well with no neurological deficit.



**Fig. 1.** Examination prior to surgery showed procidentia.

## Discussion

Postoperative urinary retention and hyponatremia are complications that we should be familiar with. Both are interlinked. High index of suspicion, early detection and aggressive treatment are important to prevent fatal consequences.

Postoperative hyponatremia can occur after gynaecologic surgeries such as laparoscopy, hysterectomy and hysteroscopy. Death from acute hyponatremia following uneventful abdominal hysterectomy has been reported by George Villos et al<sup>(7)</sup>. It can be provoked by

surgical stress and pain, other causes such as edematous states, renal failure, volume depletion and hyperglycemia need to be ruled out as appropriate treatment will depend on the cause of hyponatremia<sup>(8)</sup>. This case report highlighted postoperative urinary retention as one of the causes of hyponatremia that is always forgotten. Preoperative baseline electrolytes, intake output charting and judicious use of intravenous fluid and distention media are among the preventive measures of postoperative hyponatremia.

Management and treatment of hyponatremia

depend on the types of hyponatremia: hypovolemic, euvolemic or hypervolemic. Urinary retention, water intoxication and syndrome of inappropriate secretion of antidiuretic hormone (SIADH) cause euvolemic hyponatremia. Acute symptomatic hyponatremia needs to be corrected with bolus hypertonic 3% saline (1-2 ml/kg/ hour) with the goal of serum sodium correction 6-8 mmol/L in 24 hours. Serum sodium need to be checked 2 hourly until stable because rapid correction of sodium can lead to ODS. The role of vasopressin-receptor antagonists in the treatment of hyponatremia is still controversial<sup>(9)</sup>.

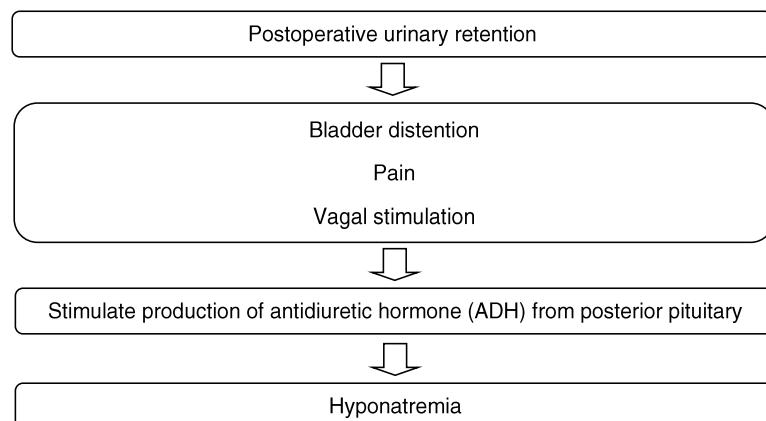
Postoperative urinary retention after urogynaecological surgery is common and multifactorial. This may be due to the dissection and manipulation over the paravesical and paravaginal areas. Pubocervical plication and closure of paravaginal space may lead to bladder and urethral dysfunction. Some patients are afraid to urinate because of the pain over the surgical site. In our experience over 6 weeks, 3 out of 12 (25%) patients who underwent vaginal surgery has voiding dysfunction that require prolonged indwelling catheterisation. All these 3 patients had procidentia. We have hypothesized that the greater the prolapse, the higher the chance of voiding dysfunction postoperatively. In procidentia, urinary tract is pulled down and stretched out with the bladder exposed to the external environment. This may lead to inflammation and edema of the bladder and innervation of the urinary tract may be disturbed.

Postoperative bladder care and pain management

are essential in urogynaecological surgery. Trial of void, residual urine measurement, clean intermittent self-catheterisation (CISC) and prolonged indwelling catheterisation are important components of postoperative management. These must be included in the preoperative counselling. House officer, residents and nurses must be educated on these as urogynaecology is a subspecialty that they might have limited exposure to. Protocols and algorithms must be in place.

On the other hand, patient must be educated and made aware of post-operative bladder care. Many patients may get upset and stressed out when they are unable to void after removal of catheter. Close monitoring, input output charting and palpation of the abdomen are important to ensure that the patients are not retaining urine. Reassurance and support must be given to the patients. Patients that have voiding dysfunction, early CISC and reinsertion of indwelling catheter maybe considered.

Many patients are not aware of the correct drinking habit and the daily water intake requirement of 1.5-2 litres<sup>(10)</sup>. They have the misconception that the more they drink the better it is and not seldom we come across patients that drink 4-6 litres of water per day. These may lead to urgency, frequency, nocturia and causing distress to the patients. In postoperative patient with voiding dysfunction, this can be dangerous as rapid filling of the bladder with urinary retention may lead to inappropriate release of antidiuretic hormone (ADH) that leads to hyponatremia (Fig. 2).



**Fig. 2.** Pathophysiology of hyponatremia in urinary retention<sup>(11)</sup>.

## Conclusion

Urinary retention can be a common yet fatal complication following urogynaecological surgery if not managed well. We recommend monitoring of electrolyte levels in patient with urinary retention. Clinically, signs and symptoms of hyponatremia should be watched for. Patient and staff education is important.

## Potential conflicts of interest

The authors declare no conflict of interest.

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