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EDITORIAL

This third issue of Thai Journal of Obstetrics and Gynaecology (TJOG) contains many interesting articles. The special article in this issue is "**Management of borderline ovarian tumors"**.

RTCOG Annual Meeting 2018 will be held during 23-26 October 2018 at Dusit Thani Pattaya Hotel, Pattaya Beach Road, Pattaya City, Chonburi, Thailand. The theme of this meeting is "**CHAT before CARE @SEA**". 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, 2018. Our editorial team and constructive reviewers will let them know the results before December 28, 2018.

Editor in Chief and managing will attend the Thai Journal Citation Index meeting: "**Powering your journal into the Web of Science Core Collection**" on July 13, 2018 at 10th Floor, The Knowledge Exchange: KX Building, Krung Thon Buri Rd, Khwaeng Bang Lamphu Lang, Thon Buri, Bangkok, Thailand. Editorial Board of TJOG prepare journal for submission to be index in Scopus index this year. Thus, there are many changes of the journal during this time

Wish to see you at RTCOG Annual Meeting 2018 at Dusit Thani Pattaya Hotel, Pattaya Beach Road, Pattaya City, Chonburi, Thailand.

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

Thai Journal of Obstetrics and Gynaecology
April 2018, Vol. 26, pp. 70-74

SPECIAL ARTICLE

Management of Borderline Ovarian Tumors

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ABSTRACT

Borderline ovarian tumors are similar to the other adnexal masses in terms of clinical presentation. Surgery is the main treatment. Because of the young age of the patients and early stage of diseases at the time of diagnosis, fertility-sparing surgery is favorable. If the intraoperative frozen section reports a borderline tumor, surgical staging should be performed. The surgical staging includes cytologic washing or ascites fluid collection, omentectomy and peritoneal biopsies. The routine lymphadenectomy is not recommended. In terms of fertility-sparing surgery, the unilateral salpingo-oophorectomy is preferred if the other site of ovary is not affected. However, if there are bilateral ovarian involvements, unilateral salpingo-oophorectomy with ovarian cystectomy or bilateral ovarian cystectomy can be considered. The prognostic factors include the stage of disease, the presence of micropapillary in serous tumor, the presence of microinvasion, and the presence of peritoneal implants. Post-operative chemotherapy should be discussed and administrated, similar to the treatment of low grade serous epithelial ovarian cancer if the invasive implantation is detected.

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This group of ovarian tumor was described for the first time in 1929 by Taylor, the clinical term was semimalignant tumor which derived from hyperplastic ovarian tumors without evidence of stromal invasion but with peritoneal implants[1]. Then the International Federation of Gynecology and Obstetrics (FIGO) retitled to carcinoma of low malignant potential because of recognition of the distinct clinical presentation and prognosis[2]. The World Health Organization (WHO) implemented the recent terminology of borderline malignancies, thus those have been accepted and evolved the studies about the natural of diseases. Nowadays, the terms refer to this kind of ovarian tumor including: borderline, atypical proliferative, and tumors of low-malignant potential[3]. These tumors represent about 15-20% of all epithelial ovarian malignancies[4]. The trend of borderline ovarian tumors (BOT) is increasing that might cause by the improvement in accuracy and standardization of the pathological diagnosis. The 70-80% of BOT patients present with early stage tumor at the time of diagnosis. The diseases also occur not only 10 years earlier than epithelial

ovarian cancer that is 45 years old, but also exhibit the better prognosis. In addition, around one-third of women diagnosed with a BOT are younger than 40 years old. Thus, the ovarian function and fertility preservation issues should be concerned.

The majority of the BOT histopathology is serous or mucinous type. Other histopathology types such as endometrioid, clear cell, or transitional cell tumors are rare. In serous type, which is approximately 70% of BOT, more common in Western than Asian countries[5], characterized by edematous papillae with focally covered by stratified epithelium with various degree of nuclear atypia and absence of destructive stromal invasion, and bilateral tumor involvement 30-50%. However, 70% of the serous BOT are diagnosed with stage I. The micropapillary features which contain complex micropapillae and mild nuclear atypia with marked epithelial cell proliferation, are associated with the microinvasive foci, bilateral tumors, advanced stage at diagnosis, invasive implantation, lymph node involvement and recurrence of disease[6]. Microinvasion at this point is diagnosed when the stromal invasion is limited to an area of no more than 10 mm. On the other hands, mucinous BOT makes up 30% of all BOTs. Approximately 90% of all mucinous BOT are stage I. The bilaterality was reported at 10-20%. There are two subtypes: the intestinal type (85%) and the endocervical type (15%), which have different clinical features. The intestinal type mucinous BOT often presents in older age and unilateral. The ultrasonographic findings demonstrate large multiloculated cysts and sometimes pseudomyxoma peritonei. The endocervical type mucinous BOT occurs at younger age and one-third are bilateral. The ultrasonographic features are uniloculated cysts. The prognosis of this subtype is worse than the intestinal type, the patients have more advanced stage, more chance of invasive implantation, or lymph node metastasis[7].

The preoperative diagnosis of BOT is problematic. The patients always present with asymptomatic adnexal mass which is unspecified and incidental finding. Serum CA125 and ultrasonographic imaging do not play role in the diagnostic evaluation. Intraoperative findings of the ovarian appearance possibly mimic the features of ovarian cancer. The role of frozen section is also limited. The accuracy of the frozen section diagnosis of BOT is only 65-70% which is lower when compare with 98-99% of benign or malignancy. The underestimation from frozen section is 20-30%, whereas 5% is over-diagnosed[8-10]. The large size of BOTs, especially for mucinous BOT, is also one of the factors that lower the sensitivity of frozen section diagnosis because of requirement of a larger number of sections. Thus it is difficult to decide on the surgical direction based only on the results of frozen section. Preoperative counseling should include discussion with patients and family's preferences such as fertility preservation needs which the ovarian cystectomy can be an option in BOT early stage or radically complete surgical staging for the one who does not desire for the fertility and less concern about the ovarian hormonal function than the poorer of ovarian cancer's prognosis. The topics of counseling also involve the limitation of preoperative evaluation, all possibilities of the intraoperative findings, and decision-making plans. Gynecologists, most of the times, have to deal with the unexpected post-operative pathological reports. There are some controversial practical points in the management of BOT that will be formulated as some of the clinical questions at the following parts of this article.

- Is it necessary to perform the complete surgical staging? How comprehensive surgical staging is appropriate?

In contrast to patients with invasive ovarian carcinoma, the BOT patients tend to be younger, are often diagnosed with stage I disease, and are candidates for fertility-spring surgery. Surgery is the primary treatment for BOTs, including standard staging surgery or fertility-sparing surgery, depends on intraoperative evaluation, the histology, the patients' age, and whether invasive implants are existent. If it is possible, the patients should be evaluated by a gynecologic oncologist. However, the systematically surgical staging for BOTs is the same as for ovary, fallopian tube,

or peritoneal cancers except the lymphadenectomy. Patients who desired to maintain their fertility may limit the surgery to a unilateral salpingo-oophorectomy with resection of residual disease[11-13]. If the patients do not desire fertility-sparing surgery, the complete staging procedure which is comprised the entire abdominal cavity examination, total abdominal hysterectomy (TAH) and bilateral salpingo-oophorectomy (BSO) with peritoneal washing, omentectomy and excision of all suspicious lesions should be performed. Although the correlation of stage with survival was generally informed, staging procedures for

BOT is not supported by the best available evidence. Guidelines in support of staging based their recommendations on a few regional studies and conflict with better-quality data that do not support staging procedures[14]. The recent meta-analysis indicated a reduced recurrence risk among complete surgical staging patients with the odds ratio of 0.64 (95% confidence interval [CI]: 0.47-0.87, $p < 0.05$) when compared with incomplete surgical staging. However, no significant between group difference in mortality was observed (OR=0.98; 95% CI: 0.42-2.29, $p = 0.97$). The heterogeneity along these included studies was in mild degree. In subgroup analysis by histology, the complete surgical staging was associated with a reduced recurrence risk in 16 studies of all histologic types (OR =0.66; 95% CI: 0.48-0.91, $p < 0.05$) but not in two studies of only mucinous disease (OR= 0.41; 95% CI: 0.13-1.30)[15].

The lymphadenectomy can be omitted in BOT because of many reasons. The incidence of lymph node involvement is quite low[16]. From the clinical evidence, data do not show increased survival with lymphadenectomy for BOT, although upstaging does occur[9,16,17]. The National Comprehensive Cancer Network (NCCN) guidelines for ovarian cancer version 2.2018 make a conclusion that the lymph node evaluation may be considered on a case-by-case basic. The removal of enlarged or suspicious lymph nodes is appropriated.

- Is restaging necessary when the final pathological diagnosis results indicate BOT in the incomplete surgical cases?

It has been reported that about 15% of the patients who underwent restaging after a diagnosis of BOT with incomplete staging were upstaged[18]. As the presence of the peritoneal implants is a key prognosis in oncologic outcomes, and the most common sites of implants include the omentum and peritoneal surfaces, hence the primary surgery with cytologic washing, omentectomy and peritoneal biopsy is highly recommended. Although the evidence does not show increased survival benefit from omentectomy, for patients with known BOT who had incompletely staged at the time of their initial surgery, recommendations depend on whether invasive implants are present at primary surgery. The NCCN guidelines suggest the metastasis workup including the computerized tomographic scan with contrast for chest and whole abdomen. If the residual disease is detected from the imaging or noted from previous surgical record, reoperation with resection of residual tumor should be highly concerned then follow by the adjuvant treatment according to the final clinical risks and pathological reports. The clinical observation can be an option with the lower level of evidence. Some clinicians who worried about the appearance of invasive implants on the peritoneal surfaces can consider and counsel the patients about the adjuvant postoperative chemotherapy as the management of low-grade serous epithelial ovarian cancer[19]. Carboplatin with docetaxel or paclitaxel for 3-6 cycles according to the stage is the standard protocol. The benefit of chemotherapy is controversial. Moreover, the clinical significance of invasive implantation is still investigational[20]. On the other hand, if the imaging or the primary operative finding does not suggest of the residual disease, the management whether restaging or observation can be weighted between risks and benefits and discussed with the patients. For the lymph node issue, in incomplete surgical cases, the lymphadenectomy can be abandoned because of the similar survival and recurrent prognosis between positive and negative

results.

• Can we select minimally invasive approach? For the primary surgery, factors to be considered in this issue include size of the ovarian mass, extension of tumor metastasis, history of previous abdominal surgery, and the surgeon competency. The feasibility and safety of the minimally invasive approach in BOT surgery has been documented[21,22]. Likewise the principles of other ovarian cancer surgery, the removal of intact ovarian specimens and the complete excision of all suspicious peritoneal lesions should be preferred. It is more recommended a minimally invasive approach, if restaging surgery is performed.

• Do we need to perform the unilateral salpingo-oophorectomy in the previous cystectomy BOT patients? For women with unilateral ovarian involvement, either ovarian cystectomy or unilateral salpingo-oophorectomy is appropriate. Those with bilateral ovarian involvement, the procedures depend on intraoperative findings. The procedures are unilateral salpingo-oophorectomy with ovarian cystectomy or bilateral ovarian cystectomy. The recurrence for ovarian cystectomy of a BOT has been reported in 12-36% which is more than the unilateral salpingo-oophorectomy[23,24]. The treatment of choice after recurrence which is common in the residual ovary is repeated the surgical procedure[25]. In the previous ovarian cystectomy BOT, the risks between recurrence of disease and the risks of operation should be concerned.

• Is it mandatory to perform the appendectomy in mucinous BOT?

An appendectomy during the staging procedure for mucinous BOT has come to be established as best practice in the hypothesis that the appendiceal histology helps to distinguish between a primary ovarian BOT and metastases from a primary appendiceal carcinoma or from the gastrointestinal tract[26]. This has remained controversial, especially in early stages, where the incidence of finding disease in a macroscopically normal appendix is very uncommon[27]. From recent evidences, in the mucinous BOT, an abnormal appearing appendix should be excised. If the appendix is grossly normal, the evidences do not support performing an appendectomy as part of a surgical staging procedure[28].

The management of BOT is still controversy. More studies are needed and longer follow-up and better characterization of clinical risk factors are important to better understand long-term risk of BOT.

Potential conflicts of interest

The author declare no conflict of interest.

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OBSTETRICS

Effect of Ethyl Chloride Spray for Pain Reduction during Amniocentesis: A non – blinded randomized controlled trial

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ABSTRACT

Objectives: To evaluate the cryo-analgesic effect of ethyl chloride spray on reducing pain during second-trimester amniocentesis.

Materials and Methods: A non-blinded randomized controlled trial was performed to compare the post-procedural pain scores during second-trimester amniocentesis between pregnant women who received and did not receive ethyl chloride spray immediately before amniocentesis needle penetration. Outcome was mean of post-procedural pain score measured by using visual analogue scale (VAS).

Results: The study was performed between May and November 2016. One hundred and forty-eight participants were randomly divided into two groups received cryo-analgesia using ethyl chloride spray and did not receive. There were no differences between demographic data and pre-procedural pain scores (anticipated pain) ($p = 0.6$). Mean post-procedural pain score in the cryo-analgesia group was significantly lower than the control group ($p = 0.01$). Six participants in cryo-analgesia group had frostbite skin rash (8%) which was self-limiting condition and persists for about one month with no scar. Most participants (98%) willingly accepted to undergo the procedure again if indicated.

Conclusion: Ethyl chloride spray may be an alternative method for amniocentesis procedural pain management. Women should be informed about the potential risk of complications.

Keywords: Amniocentesis, pain, ethyl chloride spray, visual analogue scale.

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การศึกษาผลของยาชาชนิดพ่นเอทธิลคลอไรด์ (Ethyl chloride) ต่อการลดความเจ็บปวดจากการเจาะน้ำคร่ำในไตรมาสที่สองของการตั้งครรภ์

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บทคัดย่อ

วัตถุประสงค์: *เพื่อศึกษาผลของยาชาชนิดพ่นเอทธิลคลอไรด์ (ethyl chloride) ต่อการลดความเจ็บปวดจากการเจาะน้ำคร่ำในไตรมาสที่สองของการตั้งครรภ์*

วัสดุและวิธีการ: *ทำการศึกษาแบบควบคุมสุ่มแบบไม่อำพราง (Non-blinded randomized controlled trial) เพื่อเปรียบเทียบคะแนนความเจ็บปวดหลังจากการเจาะน้ำคร่ำในไตรมาสที่สองของการตั้งครรภ์ ระหว่างหญิงตั้งครรภ์ที่ได้รับ และไม่ได้รับยาชาชนิดพ่นเอทธิลคลอไรด์ (ethyl chloride) ก่อนแทงเข็มเจาะน้ำคร่ำ คะแนนความเจ็บปวดวัดด้วยการใช้ visual analogue scale (VAS)*

ผลการศึกษา: *ทำการศึกษาระหว่างเดือนพฤษภาคม ถึง พฤศจิกายน พ.ศ. 2559 ผู้เข้าร่วมการศึกษาจำนวน 148 คน ถูกแบ่งเป็นสองกลุ่มโดยการสุ่ม ได้แก่ กลุ่มทดลองที่ได้รับยาชาชนิดพ่นเอทธิลคลอไรด์ และกลุ่มควบคุม ไม่พบความแตกต่างกันของลักษณะข้อมูลพื้นฐานของผู้เข้าร่วมการศึกษาและคะแนนความเจ็บปวดที่คาดคะเนก่อนทำหัตถการ (p = 0.6) ค่าเฉลี่ยของคะแนนความเจ็บปวดหลังทำหัตถการในกลุ่มที่ได้รับยาชาชนิดพ่นเอทธิลคลอไรด์น้อยกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ (p = 0.01) ผู้เข้าร่วมการศึกษาจำนวน 6 คน ในกลุ่มที่ได้รับยาชาชนิดพ่นเอทธิลคลอไรด์เกิดรอยผื่นน้ำแข็งกัด (8%) ซึ่งเป็นภาวะที่สามารถหายได้เอง โดยใช้เวลาประมาณหนึ่งเดือนและจางหายไปไม่มีรอยแผลเป็น ส่วนใหญ่ของผู้เข้าร่วมการศึกษาทั้งหมด (98%) ยินดีเข้ารับการเจาะน้ำคร่ำอีกครั้งหากมีข้อบ่งชี้*

สรุป: *ยาชาชนิดพ่นเอทธิลคลอไรด์ อาจเป็นทางเลือกหนึ่งในการจัดการความเจ็บปวดจากการเจาะน้ำคร่ำโดยผู้ที่จะรับการใช้ยาชาชนิดพ่นนี้ควรได้รับคำแนะนำอย่างเหมาะสมถึงความเสี่ยงต่อภาวะแทรกซ้อน*

คำสำคัญ: *เจาะน้ำคร่ำ, ปวด, เอทธิลคลอไรด์, ยาชาชนิดพ่น*

Introduction

Amniocentesis is a common prenatal diagnosis procedure which is at risks such as abortion (0.2-0.3%), infection, and membrane leakage[1]. This procedure also causes pain which leads to anxiety and some patients may request pain controller or refuse to undergo this procedure.

There are two pathways of amniocentesis-associated pain i.e. somatic and visceral pain[2]. Previous studies evaluated pain-related factors during amniocentesis found that parity, gestational age, body mass index (BMI), previous surgery, needle penetration through the placenta, the thickness of the abdominal wall, and depth of needle penetration have no correlation with the degree or severity of pain[3]. One study had divided uterus into three areas (upper, middle, and lower) and evaluated the degree and severity of pain when needle penetrated through each site and found that pain from penetration in upper part had less pain score than other sites[4].

There have been many previous studies to evaluate analgesic methods. Two studies comparing xylocaine injection and without anesthesia found no difference in pain score between both groups[5, 6]. Other two studies that used a sub-freezing needle and light leg rubbing technique reported the same result[7, 8].

The aim of cryo-analgesia is to inhibit local pain reception by using the cold-producing instrument. One study using cold gel pack placed on skin 5 minutes before needle insertion compared with room temperature gel pack found the lower pain score in cold gel pack group[9]. However, amniocentesis procedural time must be prolonged and cold gel pack may cause unnecessary wide anesthetic area. Ethyl chloride spray is a vapor coolant which induces skin cooling, reduces the sensitivity of pain receptor and causes decreased pain perception[10]. It is used as cryo-analgesia for venipuncture in both adults and children[11, 12]. Although ethyl chloride spray is not sterile, one study showed that ethyl chloride spray did not change sterility on the sprayed skin[13]. This spray is recommended for fetal scalp blood stimulation in fetal scalp blood sampling procedure and had no reports of mutagenicity, embryotoxicity, teratogenicity and reproductive toxicity in human[14-16]. With the benefits of cryo-analgesia and safety in human, this ethyl chloride spray could be one of analgesic methods that improve the amniocentesis pain control. The objective of this study was to assess cryo-analgesic effect of ethyl chloride spray on pain reduction in second trimester amniocentesis.

Materials and Methods

A prospective non-blinded randomized controlled trial was conducted from May to November 2016 at the Prenatal Diagnostic Unit, Ramathibodi Hospital. Pregnant women with indications for amniocentesis were recruited. Inclusion criteria were women who never undergone amniocentesis and no fetal gross structural abnormalities identified by ultrasonographic evaluation. Exclusion criteria included women who had known allergy to cold, ethyl chloride spray, received pain killer for previous 4 hours, required more than 1 puncture in the same procedure, and could not understand the study process or had a poor ability in communication. This study was reviewed and approved by the Committee on Human Rights Related to Research Involving Human Subjects, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, based on the Declaration of Helsinki.

Pregnant women were informed about the amniocentesis procedure and complications by Maternal-Fetal Medicine (MFM) fellows. Then, the study was explained to patients for participation. They were given ample time for questions and decision and had voluntarily consented to join the study. Then, a visual analogue scale was introduced to all participants. The visual analogue scale (VAS) is a method for pain measurement which consists of a 10-centimeter line with two terminals. The left terminal refers to “no pain” (score=0) and another terminal refers to “full pain in life” (score=10). Each participant must mark a point that represents the level of pain on the 10-centimeter line prior to and

immediately after amniocentesis for anticipated pain and post-procedural pain measurement, respectively. The anticipated pain was level of pain from amniocentesis that they expected and the post-procedural pain was level of pain they truly had from this procedure. General demographic data were collected, including maternal age, body weight, height, gestational age, parity, previous delivery, previous vaginal operation, history of abortion and dilatation and curettage, history of cesarean section, and history of abdominal surgery. They also had to answer a questionnaire about their concern of, or anxiety to amniocentesis.

Block of four was used for randomization to assign study population into 2 groups: cryo-analgesia and control group. For a significant difference in mean pain score, this study needed a sample size of at least 74 cases per group to gain power of 80% at 95% confidence interval. After randomization, participants entered a procedural room for ultrasonographic fetal anomaly screening. An area on skin was marked for needle insertion and applied with an aseptic agent. Spinal needle gauge 22 and a 20 ml syringe were used. Participants in the cryo-analgesic group were sprayed with ethyl chloride on the marked area immediately before needle insertion. The distance of 30 centimeters in perpendicular position from marked skin must be maintained for ethyl chloride spraying and the duration of spray was 4 seconds until a thin snow was coated over the skin. Amniotic fluid was drawn for amount of 15 ml. After needle withdrawing, participants must mark a point that represents the level of their pain on VAS line. Fetal heart activity and immediately procedural associated complications were observed before leaving. Each participant received a card describing possible cryo-analgesia complications and symptoms for self-monitoring and contact information. Participants were asked about overall severity of pain measured by 5-points likert scale that categorized from minimal to marked severe pain. A few days after amniocentesis, participants were followed-up by phone. Participants who had skin lesions with suspected frostbite were counseled and scheduled for further evaluation and treatment by dermatologist. All participants were observed for maternal and fetal complications until postnatal period.

Statistical analysis

Statistical analyses were performed by using Stata version 14.2. Demographic data were presented and compared by using Student t-test and Mann-Whitney U test for continuous variables and Pearson chi-square test and Fisher exact test for categorical variables. Continuous data were presented as mean and standard deviation (SD). Categorical data were presented as frequencies (n (%)). $P < 0.05$ was considered as a significant difference.

Results

One hundred forty-eight participants were recruited. Each group consisted of 74 participants. No participant was excluded from eligibility assessment. Demographic data included maternal age, weight, height, BMI, gestational age, location of placenta, parity, history of vaginal operation, abortion, dilation and curettage, cesarean section, abdominal surgery, showed no difference between both groups (Table 1). All procedures were performed by a single attempt. No participant was excluded. The clear color amniotic fluid samples were obtained from all participants and no immediate post-procedural complication was observed.

Pre-procedural VAS pain score (Table 2) between cryo-analgesic and control showed no significant difference (VAS 5.92 ± 2.00 and 5.67 ± 2.56, respectively, $p = 0.6$). Post-procedural VAS pain score showed a significant difference (VAS 2.42 ± 2.17 and 3.54 ± 2.68, respectively, $p = 0.01$). Most participants in cryo-analgesia group had mild degree of overall pain compared to moderate degree in control group (Fig. 1). Most participants (98%) had voluntarily willing to undergo amniocentesis again if clinically indicated (Table 3). Six out of 74 participants in the cryo-analgesic group (8%) had mild frostbite rash with only itching and superficial skin burn. All

affected participants were scheduled for evaluation, treatment, and follow-up at the outpatient clinic. All frostbite lesions were improved within a few days and completely recovered within a month without any scar. In addition, there were no abortion, infection, and amniotic fluid leakage in the study.

Table 1. Demographic data.

Characteristics	Cryo-analgesia group (n=74)	Control group (n=74)	p value
Age, yr*	37.80 (2.83)	37.35 (2.54)	0.71
Weight, kg*	60.01 (10.59)	60.75 (10.34)	0.72
Height, kg*	156.97 (5.24)	158.69 (6.05)	0.22
Body mass index, kg/m^2*	24.34 (4.07)	24.11 (3.82)	0.68
GA, wk*	21.95 (0.88)	22.02 (0.80)	0.86
Placental Location**			0.50
- Anterior	33 (44.59)	29 (39.19)	
- Posterior	41 (55.41)	45 (60.81)	
Parity**			0.38
- Nulliparous	22 (29.73)	27 (36.49)	
- Multiparous	52 (70.27)	47 (63.51)	
Route of previous delivery**			0.83
- No	30 (40.54)	33 (44.59)	
- Normal delivery	23 (31.08)	23 (31.08)	
- Cesarean section	21 (28.38)	18 (24.32)	
Previous intrapartum procedure**	2 (2.27)	1 (1.35)	1.00
Previous abortion**	24 (32.43)	20 (27.03)	0.47
Previous curettage**	10 (13.51)	13 (17.57)	0.50
Previous cesarean section**	21 (28.38)	18 (24.32)	1.00
Previous abdominal surgery**	10 (13.51)	8 (10.81)	0.62

* Data were presented in mean (SD) and using Student t-test and Mann-Whitney U test
** Data were presented in n (%) and using Pearson chi-square test and Fisher exact test
GA = gestational age

Table 2. Visual analogue scale pain score.

Group	Cryo-analgesia group (n=74)	Control group (n=74)	p value
Anticipated pain*	5.92 (2.00)	5.67 (2.56)	0.60
Post-procedural pain*	2.42 (2.17)	3.54 (2.68)	0.01

* Data were presented in Mean (SD) and using Mann-Whitney U test

Table 3. Voluntarily willing to undergo amniocentesis again if indicated.

Group	Cryo-analgesia group (n=74)	Control group (n=74)
Yes*	73 (98.65)	73 (98.65)
No*	1 (1.35)	1 (1.35)

* Data were presented in n (%)

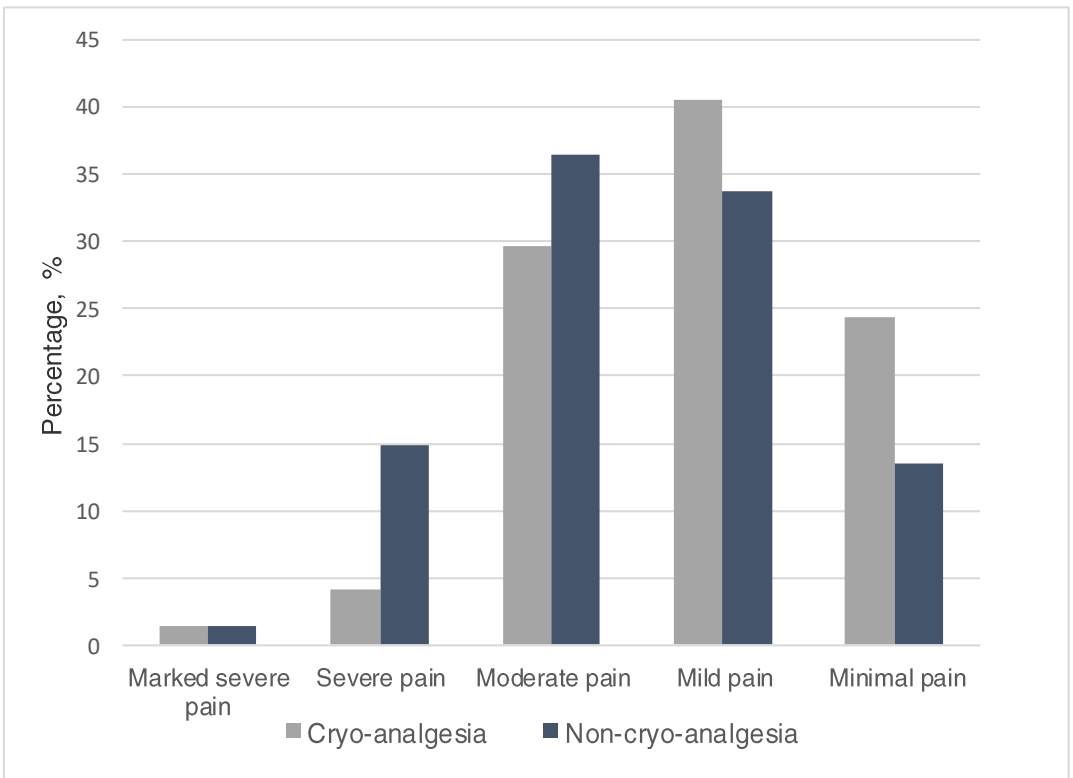

Fig. 1. Overall severity of pain in cryo-analgesia and control group.

Discussion

Amniocentesis associated pain is a common problem that some women are reluctant to undergo this procedure. This study found that cryo-analgesia with ethyl chloride spray significantly decreased post-procedural VAS pain score. Most participants (98%) demonstrated their willingness to undergo the amniocentesis again if clinically indicated.

Amniocentesis-associated pain controlling methods were previously studied by comparing xylocaine injection to no intervention, sub-freezing needle, and legs rubbing, all methods had no significant difference in pain reduction[5-8]. The subsequent study comparing xylocaine injection to placebo found that xylocaine injection can control pain during amniocentesis[17]. This result, however, was conflicted with other previous studies[5,6] due to anesthetic injection-associated pain. Another study of cryo-analgesia used cold gel pack placing on the marked skin for 5 minutes before needle penetration[9]. The

cold gel pack decreased post-procedural VAS pain score significantly and participants had no anesthetic injection-associated pain, but the procedural time was prolonged and it might cause unnecessary analgesic area. Likewise, ethyl chloride spray is a quick and easy method that can reduce VAS pain score without injection-associated pain. The mechanism of ethyl chloride spray might reduce somatic pain at superficial layer of skin by inducing skin cooling and therefore reduce the sensitivity of pain receptor.

All procedures in this study were performed by attending staffs and MFM-fellows in Maternal-Fetal Medicine Unit, Ramathibodi Hospital. Participants did not know whether they had cryo-analgesia or not until a few seconds before needle penetration. So, there was no Hawthorne effect and no significant difference in anticipated VAS pain score. Amniocentesis was performed in all participants with a single attempt. No complication from amniocentesis, such as abortion, procedural site infection, and membrane leakage was found. Although this study was a randomized controlled trial, there was still limitation regard to the placebo effect of spraying. There had a study suggested that needle penetration through upper one-third part of uterus had less pain score than other sites, however, the penetration site could not be controlled due to the position of placenta and fetus. The major adverse effect of ethyl chloride spray is frostbite. The frostbite lesion occurred in 8%, with a small decrease in pain score, but all affected participants had mild symptoms and self-limited course of this type of skin complication. The lesions were limited in dermis layer and classified as 1st degree frostbite that could be improved by moisturizer. These skin lesions were subsided within one month without any scar.

Ethyl chloride spray significantly decreased post-procedural VAS pain score by reducing somatic pain at superficial layer of skin. However, other mechanisms of amniocentesis associated pain including somatic pain at deep layer of skin and visceral pain could not be controlled by this method. Also, this anesthetic method might provide a psychological support which affects pain perception.

Although, there were statistical significantly difference in post-procedural VAS pain scores. Pain scores were categorized as mild pain in both groups, so, it might not showed a clinical significant. The difference of mean between both groups might be needed 13 mm. of VAS to represent the minimal change in acute pain that was clinically significant[18].

Conclusion

Ethyl chloride spray might be an alternative method for amniocentesis procedural pain management. A small decrease in pain scores in this study must be interpreted with caution; this was possibly caused by Hawthorne effect because of non-blinded approach. Women should be informed about the potential risk of complications.

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Potential conflicts of interest

The authors declare no conflict of interest.

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OBSTETRICS

Knowledge, Attitudes and Practices of Ramadan Fasting in Pregnant Thai-Muslim Women

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ABSTRACT

Objectives: To assess the basic religious knowledge regarding the Islamic law, attitudes and practices of Ramadan fasting during pregnancy in Thai-Muslim women.

Materials and Methods: Multicenter, cross-sectional descriptive study was conducted between July 2016 and January 2017 on 619 pregnant Muslim women at antenatal care clinic from six hospitals in the three southernmost provinces of Thailand. Non-probability convenient sampling technique and a questionnaire were used to collect data from pregnant women who had experienced pregnancy during Ramadan at least once in their lives.

Results: Most participants (85.5%) reported to have knowledge regarding the Islamic law clear exemption from fasting for pregnant women, and the missed fasts must be completed later. Majority of pregnant women believed the fasting during pregnancy did no harm to maternal health. Overall, 87.1% observed fasting during pregnancy. Mean fasting days was 24.56 ± 5.66 days and 63.0% observed fasting between 21-30 days. Logistic regression analysis demonstrated that their age ≥ 35 years and Islamic education increased the fasting during pregnancy (Adjusted OR 2.478, 95%CI 1.174–5.230, p = 0.017 and 2.244, 95%CI 1.236–3.988, p = 0.006, respectively). The main adversities from Ramadan fasting during pregnancy were weakness and fatigue.

Conclusion: Most pregnant women knew Islamic law clear exemption from fasting during pregnancy, however many of pregnant women preferred fasting during Ramadan and they believed the fasting during pregnancy did no harm to maternal health. Healthcare providers are required to understand the religious beliefs of Muslim pregnant women, and design the standard guideline about managing lifestyle changes of Ramadan fasting during pregnancy.

Keywords: Knowledge, attitudes, practices, Ramadan, Fasting, pregnant Thai-Muslim women.

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ความรู้ ทัศนคติ และการปฏิบัติตนของหญิงตั้งครรภ์ไทยมุสลิมกับการถือศีลอดในเดือนรอมฎอน

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บทคัดย่อ

วัตถุประสงค์: *เพื่อประเมินความรู้เกี่ยวกับบทบัญญัติของศาสนาอิสลาม ทัศนคติ และการปฏิบัติตนของหญิงตั้งครรภ์ไทยมุสลิมกับการถือศีลอดในเดือนรอมฎอน*

วัสดุและวิธีการ: *เป็นการศึกษาเชิงพรรณนาแบบตัดขวางจากหลายสถาบัน ดำเนินการระหว่างเดือนกรกฎาคม 2016 ถึงเดือนมกราคม 2017 ทำการศึกษาวิจัยในหญิงตั้งครรภ์มุสลิม จำนวน 619 ราย ที่มารับบริการ ณ คลินิกฝากครรภ์ จาก 6 โรงพยาบาลในสามจังหวัดชายแดนภาคใต้ของประเทศไทย โดยใช้เทคนิคการสุ่มตัวอย่างแบบง่าย และใช้แบบสอบถามในการเก็บรวบรวมข้อมูล จากหญิงตั้งครรภ์ไทยมุสลิมที่มีประสบการณ์การตั้งครรภ์ในเดือนรอมฎอนอย่างน้อยหนึ่งครั้งในชีวิต*

ผลการศึกษา: *ผู้เข้าร่วมการศึกษาส่วนใหญ่ (85.5%) มีความรู้เกี่ยวกับบทบัญญัติของศาสนาอิสลามที่อนุญาตให้หญิงตั้งครรภ์ยกเว้นการถือศีลอดได้ โดยต้องถือศีลอดชดเชยในภายหลัง ส่วนใหญ่เชื่อว่าการถือศีลอดขณะตั้งครรภ์ไม่เป็นอันตรายต่อสุขภาพของมารดา จากการศึกษาพบว่าร้อยละ 87.1 ของผู้เข้าร่วมการศึกษาได้ทำการถือศีลอดขณะตั้งครรภ์ ซึ่งมีจำนวนวันถือศีลอดเฉลี่ย 24.56 ± 5.66 วัน และร้อยละ 63 ทำการถือศีลอดเป็นจำนวน 21-30 วัน จากการวิเคราะห์การถดถอยโลจิสติก พบว่าหญิงตั้งครรภ์ที่มีอายุเท่ากับหรือมากกว่า 35 ปี และมีการศึกษาด้านศาสนาอิสลาม จะเพิ่มโอกาสการถือศีลอดขณะตั้งครรภ์ (Adjusted OR 2.478, 95%CI 1.174–5.230, p = 0.017 and 2.244, 95%CI 1.236–3.988, p = 0.006 ตามลำดับ) ส่วนผลข้างเคียงที่พบได้บ่อยจากการถือศีลอดขณะตั้งครรภ์ในเดือนรอมฎอน ได้แก่ ความอ่อนเพลียและความเหนื่อยล้า*

สรุป: *หญิงตั้งครรภ์ส่วนใหญ่มีความรู้เกี่ยวกับบทบัญญัติของศาสนาอิสลามที่อนุญาตให้หญิงตั้งครรภ์ยกเว้นการถือศีลอดได้ อย่างไรก็ตามหญิงตั้งครรภ์จำนวนมากยังคงต้องการถือศีลอดขณะตั้งครรภ์ในช่วงเดือนรอมฎอน โดยพวกเขาเชื่อว่าการถือศีลอดระหว่างตั้งครรภ์ไม่เป็นอันตรายต่อสุขภาพของมารดา ดังนั้นผู้ให้บริการด้านสาธารณสุขควรมีความรู้ความเข้าใจเกี่ยวกับความเชื่อด้านศาสนาของหญิงตั้งครรภ์มุสลิม และจัดทำแนวทางเกี่ยวกับการปรับเปลี่ยนพฤติกรรมให้เหมาะสมในการถือศีลอดระหว่างตั้งครรภ์ในเดือนรอมฎอน*

คำสำคัญ: *ความรู้, ทัศนคติ, การปฏิบัติตน, รอมฎอน, การถือศีลอด, การตั้งครรภ์, ไทยมุสลิม, ผู้หญิง*

Introduction

Ramadan, the name of the ninth lunar month of the Islamic calendar. During this month Muslims across the world are required to complete abstinence from foods, drinks, smoking, and sexual activity at daytime hour from sunrise to sunset1-4 for a period of 29 or 30 days[2-6]. The duration of fasting time depends on geographic area and season. It may vary from 12 to 19 hours per day[5,7].

Ramadan fasting is one of the five pillars of Muslim's faith which means that it is compulsory for all healthy Muslim adults[1-4]. However, Islamic law clear exemption from fasting is permitted for pregnant women who are worried or believes that fasting may cause harm to their health and/or fetal health[3,4,6]. Then she must make up the missed days by fasting or feeding a poor person for each day missed a later time[2,4,5].

Although pregnant Muslim women can be exempted from fasting, but evidence from researches around the world showed that 50-90% of the pregnant Muslim women preferred fasting during Ramadan[2,3,5-9]. While, 93.3% of pregnant Thai-Muslim women chose to fast during pregnancy[8].

Several studies have shown the reasons why most Muslim women chose to fast during pregnancy; because of faith in God, a sense of religious duty, positive attitude on fasting, cultural reasons, familial support, perceiving no harm, and difficulty to fast alone at another time[1-3].

The characteristic behaviors of Ramadan fasting, compared to the remaining months of the year, are not similar. These modifications are accompanied by changes of meal frequency and eating pattern, daily activity, the rhythm of life and disturbances of the sleep cycle, which may affect different aspects of human health[10].

Many studies have examined the health effects of fasting in healthy pregnant women, there were little or no effects of fasting on pregnancy outcomes, fetal well-being parameter, fetal health and development, mean birth weight, preterm birth, APGAR score, or intellectual development in children of fasting pregnant women[11-15].

However, some studies reported contrasting results. Fasting increased risk of hypoglycemia, ketosis and ketonuria, vomiting, diarrhea, dizziness[16], urinary tract infection, hyperemesis gravidarum, relative risk of lower birth weight[6,17-19], reduced fetal biophysical profile and reduced breathing movements[6,20].

Several studies have shown the fasting during pregnancy may be associated with poor weight gain, increased frequencies of gestational diabetes mellitus, hypertension, pre-eclampsia, preterm labor, cesarean delivery, and neonatal admission to the intensive care unit[6,21].

Exposure to fasting during fetal period was associated with slow placental growth. Changes in placental growth during Ramadan could be associated with altered fetal programming, and might increase the later risk of adult chronic diseases, such as coronary heart disease, hypertension and type 2 diabetes mellitus[4,6,10,22].

Pregnant women can make decision about fasting during Ramadan. However, many of the pregnant Muslim women fast due to the family and social pressures or lack of proper information. Although the health effects of Ramadan fasting on pregnancy outcomes are still unclear, it is important for healthcare providers to be aware of potential risks that may be associated with Ramadan fasting during pregnancy.

This study aimed to assess the basic religious knowledge regarding the Islamic law of Ramadan fasting during pregnancy, attitudes concerning Ramadan fasting during pregnancy and practice of Ramadan fasting among pregnant Thai-Muslim women, based on the prevalence in relation to factors such as maternal age, education, occupation, economic circumstances, gravida, parity and gestational age at Ramadan. It also analysed the characteristic fasting behaviors, factors that influence the decision to fasting, and adversities of fasting on maternal health.

Materials and Methods

This study was a multicenter, cross-sectional descriptive study conducted between July 2016 and January 2017. The target population was pregnant

Thai-Muslim women in the three southernmost provinces of Thailand, who visited antenatal care clinic in six hospitals. The hospitals covered in this multicenter study were Pattani Hospital, Yala Hospital, Narathiwat Hospital, Crown Prince Saiburi Hospital, Crown Prince Yaha Hospital and Chanae Hospital. This region is one of the largest Muslim populations in Thailand, making it an ideal location to study religion influenced knowledge, attitudes and practices. The study protocol has been approved by Institutional Review Board of the Faculty of Medicine, Chulalongkorn University.

The inclusion criteria were: 1) Pregnant Thai-Muslim women who had experienced pregnancy during Ramadan at least once; 2) Healthy pregnant women; 3) Can write and read Thai language and/or Yawi language. The exclusion criteria were: 1) Pregnant Thai-Muslim women who had history of any illnesses or medical problems or drug consumption during their pregnancies.

The pilot study was conducted to obtain the accurate sample size. In total, 30 pregnant Thai-Muslim women were recruited.

Then sample size was calculated based on the proportion of pregnant Thai-Muslim women who had the basic religious knowledge regarding the Islamic law of Ramadan fasting during pregnancy from pilot study (0.83) when alpha error at 0.05 and acceptable error was 3%. The calculated sample size added 10% estimated dropout were 663. The providers or nurses at antenatal clinic introduced the study to the pregnant women. Non-probability convenience sampling was used to approach the participants. A self-administered questionnaire was used to collect the data. The questionnaire was designed after a through literature review, the content validity was tested by 3 experts and pilot study on 30 pregnant Thai-Muslim women was performed. The reliability of the questionnaire was measured by calculating Cronbach's alpha (0.72). The questionnaire's structure used simple Thai language or Yawi language, medical term was avoided. The final version of the questionnaire was composed of 6 pages, divided into 5 sections including demographic information, obstetric information, pregnant Thai-Muslim women' knowledge, attitude and practices about Ramadan fasting during pregnancy, with a Likert scale for ranking importance of the characteristics.

Demographic data and obstetric data were determined as frequency, mean with standard deviation, and percentage. Data were analyzed using IBM SPSS software for Windows version 22 (IBM Corp, Armonk, NY, USA). Descriptive statistics test were applied for all data. Chi-square tests, independent sample t-tests, Fisher's exact test were used to compare differences in the variables between groups and $p < 0.05$ was considered statistically significant. Univariate and multivariate logistic regression models were used to evaluate factors that contributed to the knowledge, attitudes and practices of Ramadan fasting in pregnant Thai-Muslim women.

Results

A total of the 663 eligible healthy pregnant Thai-Muslim women who matched inclusion criteria were enrolled into this study. All of them provided their informed consent and data were collected. The questionnaires were completed by 619 participants, giving a response rate of 93.4%. The flow chart of data collection is shown in Fig. 1.

Pregnant women in this study had a mean age of 29.2 ± 6.16 years and 97.7% were married. Regarding education, 35.9% graduated from high school and 84.2% had Islamic education. In all, 195 (31.5%) of the participants were housewife and 37.5% had a household income about 5,001-10,000 bahts per month.

There were 71.2% multigravidas, while 35.5% of the participants had two to five children. The majority of respondents (43.1%) were in the 2nd trimester of gestational age, and 55.5% of participants who fasted during their 3rd trimester of gestational age had increasing total weight gain during Ramadan fasting more than participants who fasted in 1st trimester (44.0%) and 2nd trimester (44.9%).

Overall, 87.1% of participants observed fasting during pregnancy. Mean fasting time was 24.56 ± 5.66 days and most of them (63.0%) observed fasting

between 21-30 days. Multigravidas fasted (72.9%) more than primigravidas (27.1%).

Result of baseline characteristic of participants and their relationship with fasting are shown in Table 1. Characteristics of pregnant women with respect to their age ≥ 35 years, Islamic education, multigravida and being in 3rd trimester of gestational age during Ramadan were significantly higher in the fasting group than in the non-fasting group (p = 0.005, 0.002, 0.016 and 0.034 respectively).

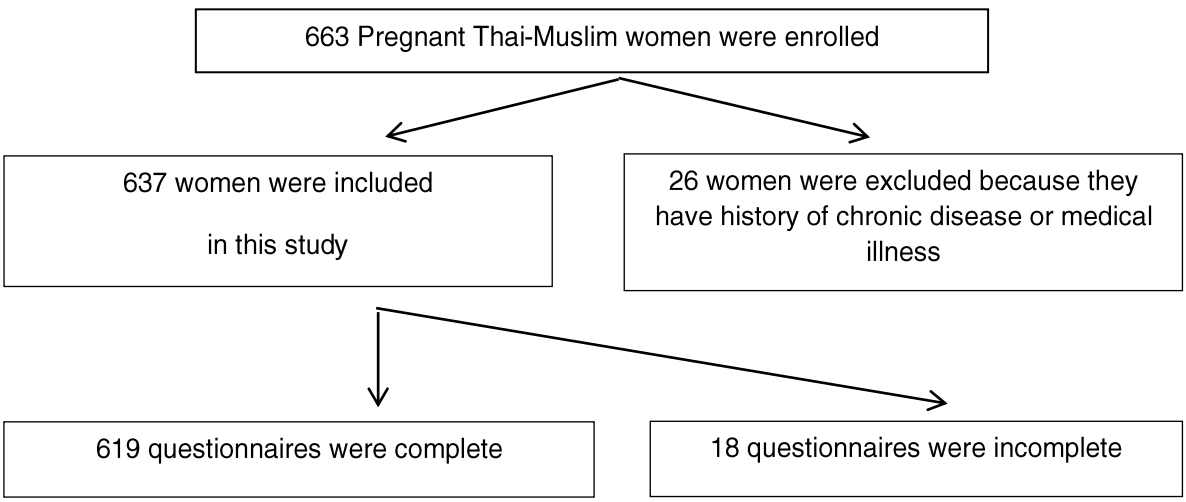

Fig. 1. Flow chart of data collection.

Table 1. Baseline characteristic of participants and their relationship with fasting.

Characteristic	Fasting		p value
	Yes (%) n = 539	No (%) n = 80	
Age (year)			0.012[b*]
< 35	411 (85.3%)	71 (14.7%)	
≥ 35	128 (93.4%)	9 (6.6%)	
Mean ± SD	29.44 ± 6.16	27.39 ± 5.90	0.522[c]
Status			0.522[c]
Single	7 (1.3%)	2 (2.5%)	
Married	527 (97.8%)	78 (97.5%)	
Divorce	5 (0.9%)	0 (0.0%)	
Education			0.464[b]
No education	21 (3.9%)	3 (3.8%)	
Primary school	116 (21.5%)	10 (12.5%)	
High school	190 (35.3%)	32 (40.0%)	
Diploma	76 (14.1%)	13 (16.2%)	
Bachelor's degree or higher	136 (25.2%)	22 (27.5%)	

Table 1. Baseline characteristic of participants and their relationship with fasting. (Cont.)

Characteristic	Fasting		p value
	Yes (%) n = 539	No (%) n = 80	
Islamic education			0.002[b*]
No education	76 (14.1%)	22 (27.5%)	
Education	463 (85.9%)	58 (72.5%)	
Occupation			0.350[b]
Housewife	165 (30.6%)	30 (37.5%)	
Employed	95 (17.6%)	11 (13.8%)	
Professional	126 (23.4%)	23 (28.7%)	
Farmer	31 (5.8%)	4 (5.0%)	
Business owner	122 (22.6%)	12 (15.0%)	
Income (bath per month)			0.161[b]
0-5,000	163 (30.2%)	20 (25.0%)	
5,001-10,000	194 (36.0%)	38 (47.5%)	
10,001-20,000	81 (15.0%)	13 (16.2%)	
20,001-30,000	44 (8.2%)	6 (7.5%)	
>30,000	57 (10.6%)	3 (3.8%)	
Gravida			0.016[b*]
Primigravida	145 (26.9%)	32 (40.0%)	
Multigravida	394 (73.1%)	48 (60.0%)	
Parity			0.080[b]
Nulliparous	146 (27.1%)	32 (40.0%)	
One	188 (34.9%)	23 (28.8%)	
Two to five	195 (36.2%)	25 (31.2%)	
More than five	10 (1.8%)	0 (0.0%)	
Gestational age at Ramadan			0.034[b*]
First trimester	119 (22.1%)	22 (27.5%)	
Second trimester	226 (41.9%)	41 (51.3%)	
Third trimester	194 (36.0%)	17 (21.2%)	
Total weight gain during Ramadan		0.079b	
Decrease	114 (21.2%)	18 (22.5%)	
Same	156 (28.9%)	32 (40.0%)	
Increase	269 (49.9%)	30 (37.5%)	

Data are presented as mean ± standard deviation in case of continuous variables and n (%) in case of frequencies compared between fasting group and non-fasting group,

* $p < 0.05$ is considered significant,

[a] = p-value from independent t-tests,

[b] = p-value from chi-squared tests,

[c] = p-value from Fisher's Exact Test

Summary of participant's knowledge about the Islamic law of Ramadan fasting during pregnancy are shown in Table 2. The results of participants' knowledge about the Islamic law of Ramadan fasting during pregnancy in the fasting group did not differ from the non-fasting group with respect to all knowledge's statement. The majority of participants knew that Ramadan fasting is a religious obligation for the healthy pregnant women (83.2%) and Islamic law clear exemption from fasting for pregnant women, then must make up the missed days later (85.5%). Approximately half of them reported to have correct knowledge about the conditions in which they could exempt from Ramadan fasting during pregnancy.

Table 2. Pregnant Thai-Muslim knowledge about the Islamic law of Ramadan fasting during pregnancy.

Statement	Pregnant women fasting group	Islamic law knowledge		p value
		Yes (%)	No (%)	
1. The Ramadan fasting is a religious obligation for the healthy pregnant women	Fasted	453(84.0%)	86(16.0%)	0.144
	Nonfasted	62 (77.5%)	18 (22.5%)	
2. Islamic law clear exemption from fasting is permitted for pregnant women, then must make up the missed days later	Fasted	464(86.1%)	75 (13.9%)	0.252
	Nonfasted	65(81.3%)	15(18.7%)	
3. If you are worried that fasting may increase the risk of malnutrition, you can exempt from Ramadan fasting.	Fasted	317 (58.8%)	222 (41.2%)	0.137
	Nonfasted	40 (50.0%)	40 (50.0%)	
4. If you are worried that fasting may increase the risk of fetal low weight gain, you can exempt from Ramadan fasting.	Fasted	288 (53.4%)	251 (46.6%)	0.063
	Nonfasted	33 (41.3%)	47 (58.7%)	
5. An eating of the leftover food or spicy food has a negative effect on your health.	Fasted	245 (45.5%)	294(54.5%)	0.348
	Nonfasted	41 (51.3%)	39 (48.7%)	
6.If you abstinence from the predawn meal, it will make you tired due to a longer period of fasting	Fasted	368 (68.3%)	171 (31.7%)	0.419
	Nonfasted	51 (63.8%)	29 (36.2%)	
7. If the fetal movement decreases, you should stop your fast, and see the doctor.	Fasted	426 (79.0%)	113 (21.0%)	0.284
	Nonfasted	59 (73.7%)	21 (26.3%)	

Summary of participants' attitudes about Ramadan fasting during pregnancy are shown in Table 3. The attitudes of participants in the fasting group did not differ from the non-fasting group with respect to all attitude's statement, except in their believe that fasting during pregnancy did no harm for maternal health, there were significant higher in the fasting group than in the non-fasting group (73.8% vs. 56.3%, p = 0.004). Most pregnant women had positive attitude about Ramadan fasting especially in the spiritual system. However, some pregnant women thought that fasting during pregnancy had effect for the fetus and maternal health.

Table 3. Pregnant Thai-Muslim's attitudes about Ramadan fasting during pregnancy.

Statement	Pregnant women fasting group	Agree (%)	Disagree (%)	p value
1. The fasting in Ramadan month, you will get better merit than another month.	Fasted	483 (89.6%)	56 (10.4%)	0.876
	Nonfasted	72 (90.0%)	8 (10.0%)	
2. I want to fast with my family, because I do not want to make up the fasting later alone.	Fasted	411 (76.3%)	128 (23.7%)	0.091
	Nonfasted	54 (67.5%)	26 (32.5%)	
3. Ramadan fasting gives you peace of mind.	Fasted	474 (87.9%)	65 (12.1%)	0.594
	Nonfasted	72 (90.0%)	8 (10.0%)	
4. Ramadan fasting during pregnancy is not harmful	Fasted	398 (73.8%)	141 (26.2%)	0.001*
	Nonfasted	45 (56.3%)	35 (43.7%)	
5. The fasting during pregnancy, make cause of fetal low birth weight	Fasted	161 (29.9%)	378 (70.1%)	0.261
	Nonfasted	19 (23.8%)	61 (76.2%)	
6. I feel weak and fatigue from the fast during pregnancy	Fasted	314 (58.3%)	225 (41.7%)	0.447
	Nonfasted	43 (53.8%)	37 (46.3%)	

* p-value < 0.05 is considered significant

Summary of the predictive factors related with fasting during pregnancy in a univariate and multivariate logistic regression analysis are shown in Table 4. A univariable analysis demonstrated that their age > 35 years, Islamic education, multigravida, the third trimester of gestational age during Ramadan

and attitude respect to the Ramadan fasting during pregnancy is not harmful were significant variables for increased the fasting during pregnancy. After adjustment for potential confounding factors, these three variables included their age > 35 years, Islamic education and attitude respect to the Ramadan fasting during pregnancy is not harmful were identified as independent factors for increased the fasting during pregnancy (Adjusted OR 2.478, 95%CI 1.174–5.230, p = 0.017, 2.244, 95%CI 1.236–3.988, p = 0.006 and 2.042, 95%CI 1.244-3.352, p = 0.005 respectively).

Table 4. Variables correlated with their relationship of fasting during pregnancy from the univariate and multivariate logistic regression analysis.

Variable	Crude OR (95%CI)	p value	Adjusted OR (95%CI)	p value
Characteristics Age (year)				
< 35	1		1	
≥ 35	2.457 (1.194-5.054)	0.015*	2.478 (1.174-5.230)	0.017*
Islamic education				
No education	1		1	
Education	2.311 (1.337-3.995)	0.003*	2.244 (1.263-3.988)	0.006*
Gravida				
Primigravida	1		1	
Multigravida	1.795 (1.104-2.917)	0.017*	1.363 (0.816-2.277)	0.237
Gestational age				
First trimester	1		1	
Second trimester	1.019 (0.580-1.790)	0.948	0.624 (0.309-1.260)	0.188
Third trimester	2.110 (1.077-4.134)	0.030*	1.157 (0.641-2.091)	0.628
Ramadan fasting during pregnancy is not harmful				
Disagree	1		1	
Agree	2.217 (1.369-3.589)	0.001*	2.042 (1.244-3.352)	0.005*

* p-value < 0.05 is considered significant

Summary of participants' practices about Ramadan fasting during pregnancy are shown in Table 5. A majority of pregnant women (80.0%) broke a fast immediately after hearing an Azan sound regularly. Some pregnant women often broke a fast with sweet foods (29.1%) and delicatessen foods (13.4%). Overall, 315 (58.4%) of pregnant women had to eat the leftover foods sometimes. Regarding cycle of sleep during Ramadan fasting, 338 (62.7%) slept less at night time sometimes, 375 (69.6%) slept more at daytime sometimes. Overall, 118 (21.9%) of pregnant women missed antenatal care appointments because they felt weak sometimes. Most pregnant women (71.2%) forgot to take iron-supplement drug sometimes. In Ramadan month, 230 (42.7%) of pregnant women still made religious activity regularly.

The results of participants' adversities encountered from Ramadan fasting during pregnancy are shown in Table 6. The most common complications were the weakness and fatigue.

Table 5. Practices of pregnant Thai-Muslim women during Ramadan fasting.

Statement	Frequency		
	Frequently (%)	Sometime (%)	Never (%)
Characteristics of fasting			
- You are fasting during pregnancy	343 (63.6%)	195(36.2%)	1 (0.2%)
- You have to eat during a predawn meal	363 (67.4%)	157 (29.1%)	19 (3.5%)
- You break a fast immediately after hearing an Azan sound hearing an Azan sound	431 (80.0%)	103(19.1%)	5 (0.9%)
- You break a fast was late because of work	21 (3.9%)	141(26.2%)	377 (69.9%)
- You break a fast because you feel weak, hungry and thirsty	36 (6.7%)	275 (51.0%)	228 (42.3%)
Eating pattern			
- You break a fast with a sweet foods	157 (29.1%)	325 (60.3%)	57 (10.6%)
- You break a fast with a delicatessen foods	72 (13.4%)	359 (66.6%)	108 (20.0%)
- You eat leftover foods	48 (8.9%)	315 (58.4%)	176 (32.7%)
- You have overeating at breaking a fast time	147 (27.3%)	329 (61.0%)	63 (11.7%)
- You drink at least 6-8 glasses of water per day	326 (60.5%)	205 (38.0%)	8 (1.5%)
Sleep cycle			
- You sleep less at night time	56 (10.4%)	338 (62.7%)	145 (26.9%)
- You sleep more during daytime	81 (15.0%)	375 (69.6%)	83 (15.4%)
Other behaviors			
- You forget to take an iron-supplement drugs	32 (6.0%)	384(71.2%)	123(22.8%)
- You miss antenatal care appointments because feel weak	31 (5.7%)	118 (21.9%)	390 (72.4%)
- You stop working because your body is exhausted	56 (10.4%)	324 (60.1%)	159 (29.5%)
- You make religious activity	230 (42.7%)	304(56.4%)	5 (0.9%)

n = 539 (pregnant women in fasting group)

Table 6. Adversities encountered mentioned by participant during Ramadan fasting.

Adversities	Frequency		
	Frequently (%)	Sometime (%)	Never (%)
Weakness, Fatigue	130 (24.1%)	374 (69.4%)	35 (6.5%)
Dizziness	57 (10.6%)	324 (60.1%)	158 (29.3%)
Abdominal pain/ Nausea/ Vomiting	59 (10.9%)	284 (52.7%)	196 (36.4%)
Diarrhea	7 (1.3%)	198 (36.7%)	334 (62.0%)
Abnormal vaginal bleeding	6 (1.1%)	32 (5.9%)	501 (93.0%)
Decreased fetal movement	10 (1.9%)	43 (8.0%)	486 (90.1%)
Fever	0 (0%)	6 (1.1%)	533 (98.9%)

n = 539 (pregnant women in fasting group)

Discussion

Most pregnant Thai-Muslim women in the three southernmost provinces of Thailand (87.1%) preferred fasting during pregnancy and more than half (63.0%) successfully observed fasting between 21-30 days. These results were similar to previous studies[3,5,7] which indicated that most Muslim women fasted during pregnancy.

Our finding showed that women who were ≥ 35 years were more likely to fast during pregnancy. The higher rate of fasting adherence in their group could partly be explained by some elderly pregnant women were higher a spiritual reason than in the younger age pregnant women, a sense of religious duty, positive attitude of fasting, cultural reasons and familial support.

In our study, women who had Islamic education were more likely to fast during pregnancy. This might because we recruited most participants from religious area and their Islamic education level appeared to strongly influence their beliefs regarding fasting obligation during pregnancy, such as faith in God and the fear on the day of Judgment[2]. There were some pregnant Muslim women who did not fast during pregnancy for worrying about their fetal health and feel guilty because of their religious beliefs[19].

In our study, multigravida women tended to fast more than primigravida women, but the difference was not statistically significant when a multivariate logistics regression model was used to adjust for other variables. However, many studies found that multigravida women observed fast more than primigravida women[3,23], and assumed that primigravida women, experiencing pregnancy for the first time, might be more apprehensive and cautious about fasting[3].

The present study showed that pregnant women in their third trimester were more likely to fast. When a multivariate logistics regression model was used to adjust for other variables, the third trimester of gestational age during Ramadan was not associated with fasting during pregnancy. However, it was different from several other studies which reported higher adherence to Ramadan fasting among women who were in the first trimester, as compared to those in the second or third trimester[24,25]. The higher rate of fasting adherence in women in third trimester of gestational age could partly be explained by the fact that morning sickness had already been improved and pregnant women felt sure that their babies' healths were good from fetal movement.

Approximately half of pregnant women in our study still gained weight albeit fasting, which was similar to the previous study[26]. Our finding showed that pregnant women in their all trimester of gestational age had increasing total weight gain during Ramadan fasting. Weight gain after Ramadan could be explained by increase in food consumption, types of foods being rich in carbohydrates, fatty and sugary and lack of physical exercise during Ramadan[26].

Most participants (83.2%) knew that Ramadan fasting was a religious obligation for the healthy pregnant women and 85.5% reported to knew the Islamic law clear exemption from fasting for pregnant women who were worry about their health. However, this was different from previous study[3] which showed that only 67.0% of them correctly understood the Islamic law on fasting during pregnancy. Pregnant women who misunderstood the Islamic law believed that fasting in pregnancy was optional[3].

Most participants in the present study believed the fasting during pregnancy did no harm to maternal health which was similar to several previous studies[3,5,7]. The beliefs seem to be an important role in decisions to fast during pregnancy.

The main adversities from Ramadan fasting during pregnancy were weakness and fatigue, while dizziness, abdominal pain, nausea and/or vomiting and diarrhea could found sometimes in participants who fasted during pregnancy. These results were similar of the previous studies[3,7,16,23].

Ramadan fasting during pregnancy is a religious event and the choice of whether to fast or not is also motivated by religious beliefs, familial support, societal pressure, and the proper information of fasting during pregnancy. Empowering healthcare providers through generating standard guideline would be an important step. The guideline should specify on certain conditions

which a pregnant woman can fast or keep on fasting, by discussing and counseling her in regard to safety, risk of fasting, delineating the best way of monitoring, and managing lifestyle changes during Ramadan fasting.

Strengths and limitations

This study investigated knowledge, attitude and practice of pregnant Thai-Muslim women's adherence to Ramadan fasting. The study population comprised pregnant women living in the three southernmost provinces of Thailand which are one of the largest Muslim populations in Thailand. This made it an ideal location to study religiously influenced knowledge, attitude and practice of Ramadan fasting.

The data collection were performed shortly after Ramadan, when the women were still be pregnant, thereby allowing the accurate data and avoiding possible recall bias. This study focused on the Islamic law clear exemption from fasting for pregnant women and understanding its religious reason which many studies did not take into the understanding of the reasons. Multiple behaviors were evaluated, including the days and characteristics of fasting, type and amount of food about the practice of Ramadan fasting during pregnancy, sleeping, medication, religious activity, and the antenatal care appointment.

The limitation of the present study was samples were taken from only at antenatal care clinic in the hospitals, which might recruit specific population who were educated. Thus, it could be less generalized and excluded pregnant women who did not attend antenatal care clinic. Another limitation of our study was that we had a large proportion of multigravida women and small proportion of primigravida women. Experience of practicing Ramadan fasting during pregnancy among multigravida might confound the results.

Conclusion

Ramadan fasting is a religious obligation for healthy adult Muslims. Islamic law clearly exempts fasting for pregnant Muslim women who are worried about their health and/or fetal health. This study found that their age ≥ 35 years, Islamic education, influenced women's adherence to Ramadan fasting. Most pregnant women had appropriate knowledge of Islamic law regarding fasting during pregnancy, and many of them preferred fasting during Ramadan. They believed the fasting during pregnancy did no harm for maternal health. Although, the study on health effects of Ramadan fasting in pregnancy outcomes are still unclear, it is important for healthcare providers to be aware of potential risks that may be associated with Ramadan fasting during pregnancy.

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Potential conflicts of interest

The authors declare no conflict of interest.

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OBSTETRICS

Outcome of Nipple Puller Use during Antenatal Care in Short Nipple Pregnant Women: A randomized controlled trial

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ABSTRACT

Objectives: The aim of this study was to compare the nipple length of the short nipple pregnant women who used nipple puller or not during antenatal care.

Materials and Methods: A randomized controlled trial was conducted. The pregnant women who were classified as low risk pregnancy and the nipple length less than 7 millimeters at the first antenatal visit were randomized into two groups; 125 cases of nipple puller use group and 125 cases of routine follow-up group. The first group, the mothers were taught by nurse and practiced nipple puller use twice a day until delivery. The second group or comparison group, the mothers had routine follow-up during antenatal care. When the mothers delivered, the nipple length was measured again at the first day postpartum and compared with the previous measurement. The demographic data and nipple length between both groups were compared using chi-square test and student t-test.

Results: The mean nipple length of the nipple puller use and routine follow-up group was not significantly different at first antenatal visit. In routine follow-up group, the mean right nipple length was 5.3 ± 1.4 millimeters at antenatal care clinic and 5.6 ± 1.4 millimeters at postpartum. The mean left nipple length was 5.0 ± 1.2 millimeters at antenatal care clinic and 5.4 ± 1.2 millimeters at postpartum. In nipple puller use group, the mean right nipple length was 4.7 ± 1.5 millimeters at antenatal care clinic and 9.5 ± 1.7 millimeters at postpartum. The mean left nipple length was 5.1 ± 1.6 millimeters at antenatal care clinic and 9.4 ± 1.7 millimeters at postpartum. The nipple length differences between routine follow-up and nipple puller use groups were statistically significant at postpartum ($p<0.001$).

Conclusion: The nipple puller use during antenatal period could increase nipple length.

Keywords: nipple puller, nipple length, short nipple, antenatal care.

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ผลลัพธ์ของการใช้อุปกรณ์ดึงหัวนมในระยะฝากครรภ์ของมารดาที่มีหัวนมสั้น

นงเยาว์ ใบยา, สุขวดี เกษสุวรรณ, สุชาสินี ธนะ, ภาวิน พัวพรพงษ์

บทคัดย่อ

วัตถุประสงค์: *เพื่อเปรียบเทียบความยาวหัวนมของมารดาที่ใช้อุปกรณ์ดึงหัวนม (nipple puller) ในระยะฝากครรภ์กับมารดาติดตามดูแลครรภ์ตามปกติ*

วัสดุและวิธีการ: *ศึกษาวิจัยทดลองควบคุมแบบสุ่ม (randomized controlled trial) ในสตรีตั้งครรภ์ความเสี่ยงต่ำที่มีความยาวหัวนมสั้นกว่า 7 มิลลิเมตร ที่มาฝากครรภ์ที่แผนกฝากครรภ์ โดยวัดความยาวหัวนมขณะมาฝากครรภ์ครั้งแรก โดยทำการแบ่งมารดาเป็นสองกลุ่มโดยวิธีการสุ่ม กลุ่มแรกมารดาใช้อุปกรณ์ดึงหัวนมแก้ไขความยาวหัวนมจำนวน 125 ราย กลุ่มนี้มารดาจะได้รับการสอนโดยพยาบาลและให้ใช้อุปกรณ์ดึงหัวนม ดึงหัวนมวันละสองครั้งจนกระทั่งคลอด ส่วนกลุ่มที่สองเป็นกลุ่มเปรียบเทียบคือ กลุ่มที่ดูแลครรภ์ตามปกติ โดยหลังการคลอดบุตร มารดาทั้งสองกลุ่มจะได้รับการตรวจวัดความยาวหัวนมในวันแรกหลังคลอด จากนั้นรวบรวมข้อมูลพื้นฐานของมารดาและความยาวหัวนมมาวิเคราะห์ผลโดยใช้สถิติ chi square และ student t-test*

ผลการศึกษา: *ความยาวหัวนมเฉลี่ยเริ่มต้นที่วัดที่คลินิกฝากครรภ์ของมารดากลุ่มที่ใช้อุปกรณ์ดึงหัวนม และกลุ่มที่ดูแลครรภ์ตามปกติไม่แตกต่างกัน ในกลุ่มที่ดูแลครรภ์ตามปกติ ความยาวหัวนมเฉลี่ยข้างขวาจากการตรวจที่คลินิกฝากครรภ์เท่ากับ 5.3 ± 1.4 มิลลิเมตร และเท่ากับ 5.6 ± 1.4 มิลลิเมตรที่หลังคลอด ความยาวหัวนมเฉลี่ยข้างซ้ายจากการตรวจที่คลินิกฝากครรภ์เท่ากับ 5.0 ± 1.2 มิลลิเมตรที่หลังคลอด ในกลุ่มที่ใช้อุปกรณ์ดึงหัวนมแก้ไข ความยาวหัวนมเฉลี่ยข้างขวาจากการตรวจที่คลินิกฝากครรภ์เท่ากับ 4.7 ± 1.5 มิลลิเมตร และเท่ากับ 9.5 ± 1.7 มิลลิเมตรที่หลังคลอด ความยาวหัวนมเฉลี่ยข้างซ้ายจากการตรวจที่คลินิกฝากครรภ์เท่ากับ 5.1 ± 1.6 มิลลิเมตรที่หลังคลอด และเท่ากับ 9.4 ± 1.7 มิลลิเมตรที่หลังคลอด ความแตกต่างของความยาวหัวนมระหว่างกลุ่มที่ดูแลครรภ์ตามปกติกับกลุ่มที่ใช้อุปกรณ์ดึงหัวนมแก้ไขที่หลังคลอดมีความแตกต่างอย่างมีนัยสำคัญ ($p<0.001$)*

สรุป: *การใช้อุปกรณ์ดึงหัวนมสามารถเพิ่มความยาวหัวนมได้*

คำสำคัญ: *อุปกรณ์ดึงหัวนม, ความยาวหัวนม, หัวนมสั้น, การดูแลระหว่างฝากครรภ์*

Introduction

Breast problem is one of important breastfeeding problem to cause breastfeeding cessation[1]. In Thailand, health professional concerns with nipple length and its length is sometimes measured during antenatal care. The nipple length and its relation to success in breastfeeding were studied. The cut-off point for nipple length that facilitates successful breastfeeding was 7 millimeters[2]. The researcher suggested health professional to use 7 millimeters of nipple length as a criteria for a successful breastfeeding screening test and give close breastfeeding support if postpartum women had less than 7 millimeters in nipple length.

Although the definition of short nipple is not clear and the short nipple diagnosis may make mother worried, but many health professionals still correct short nipple by nipple puller or syringe nipple puller without evidence-based support. We were interested to investigate the outcome of nipple puller use in the mothers with nipple length less than 7 millimeters and the routine follow-up mothers in this study. Besides, the associated factors affecting breastfeeding including body mass index, route of delivery and birth weight were collected for bias control[3-8].

Materials and Methods

Setting

The study was performed in Nakhon Nayok province, a rural area in the central part of Thailand. The data was collected during the period from September, 2013 to January, 2014 at the HRH Princess Maha Chakri Sirindhorn Medical Center. Breast examination and nipple length measurement had been routinely performed for pregnant woman who attended antenatal clinic for the first time.

Design

This study was a single-blinded randomized controlled trial. The postpartum-ward nurses who measured nipple length at postpartum did not know about antenatal care history of both groups.

Inclusion criteria

The pregnant women attended antenatal care clinic without complication including diabetes mellitus, hypertension, hyperthyroid, hypothyroid, cardiac disease, sexual transmitted disease, systemic lupus erythematosus, other autoimmune disease and had at least one short nipple. The criterion for short nipple diagnosis was nipple length less than 7 millimeters.

Exclusion criteria

Pregnant women had inverted or flat nipple, previous nipple or breast surgery, multiple pregnancies and previous preterm birth would be excluded.

Sample size

The sample size was based on 0.05 of α error, 0.95 of power and 0.47 of effect size (the mean difference between two groups was 23.5% from the pilot study of 20 cases). The calculated sample size was 119 in each group. The subjects were summed up with 5% added for data loss. The total samples collected were 250.

Nipple length measurement

Nipple length was measured by the tool that was made of a cut off syringe with a millimeter scale[2]. Two nurses at antenatal care clinic and two nurses at postpartum ward were trained by researchers for nipple length measurement. The correct steps for nipple measurement of the nurses were assessed before research beginning. The measurement was done after nipple stimulation to an erection state while pregnant woman was in sitting position, placing the nipple length measurement tool over the nipple, adjusting the inner lip of the tool so that it just contacted the tip of nipple, and reading and recording the length of the nipple in millimeters. Nipple length was measured in both breasts. After birth, the nipple length was measured again in the same way at the first day postpartum.

Procedure and collection of material

Randomization was done using a computer-

generated list with block of five methods. Sequential number would be kept in sealed envelopes. Participants who met the inclusion criteria would be allocated to either nipple puller use group or routine follow-up group. In the first group, the mothers were taught and practiced nipple puller use. The method of nipple puller use was compressing the bulb of nipple puller for negative pressure formation, placing the nipple puller on areola area, releasing pressure out of the bulb compression, waiting for 10 minutes. After that, the nipple puller was off by opening and allowing air pass into the contact area. The nipple puller was lost of negative pressure and came out of the breast. The mothers had to use nipple puller for short nipple twice a day until delivery. The data of nipple puller use was daily recorded and the mothers had to use nipple puller more than 80% of all recorded days. The preterm labor complication was followed and recorded. In the second group, the mothers had no intervention during antenatal care. Both groups would get the same routine antenatal care. When the mothers delivered, the nipple length was measured and compared with the previous measurement on the first day postpartum. Demographic data, factors affecting breastfeeding including body mass index, route of delivery, birth weight and nipple length were analyzed.

Ethical considerations

This study was approved by the Ethics committee of Srinakharinwirot University, Faculty of Medicine and registered with Thai Clinical Trials Registry (registration number TCTR20170509002)

Statistical analysis

Demographic data was reported in means and percentages. We used the student t-test to compare the means of maternal age, gestational age, body mass index, birth weight and nipple length between the nipple puller use and routine follow-up groups. The data of parity and route of delivery was analyzed by chi-square test. We used intention to treat method for analysis. Nipple puller use group must practice 80% of the recorded days or more. If the mothers used nipple puller less than 80%, subgroup analysis was done for this data. A p-value less than 0.05 was considered statistically significant. Statistical analysis was performed using SPSS version 19.0 IBM Singapore Pte. Ltd (Registration No.1975-01566-C).

Results

The total number of short nipple pregnant women who enrolled in our research project was 250. A flow chart of the number of participants was shown in Fig. 1. The mean mother's age was 24.8 ± 6.2 years. The mean gestational age of nipple length measurement at antenatal care clinic was 25.1 ± 1.9 weeks. The percentage of primipara was 74.0. The mean body mass index was 24.7 ± 5.0 kg/m^2. The demographic data of nipple puller use group was similar to the routine follow-up group. There were no statistically significant differences of the mother's age, gestational age, parity, body mass index, route of delivery, birth weight and nipple length between the nipple puller use and routine follow-up groups. Demographic data were shown in Table 1. There was no mother who used nipple puller less than 80% of all recorded days.

In both routine follow-up and nipple puller use groups, the nipple length differences between antenatal care clinic and postpartum measurement were statistically significant. The comparison of nipple length between antenatal care clinic and postpartum measurement was shown in Table 2.

At postpartum, there were statistically significant nipple length differences between the nipple puller use and routine follow-up groups. The comparison of the nipple length between nipple puller use and routine follow-up groups at postpartum were shown in Table 3. The mean difference between antenatal care clinic and postpartum nipple length measurement was 3.8 ± 0.2 and 4.0 ± 0.2 millimeters in the right and left nipple.

There was no complication of nipple puller use including abrasion, cracked nipple and preterm labor which was reported during antenatal care follow-up.

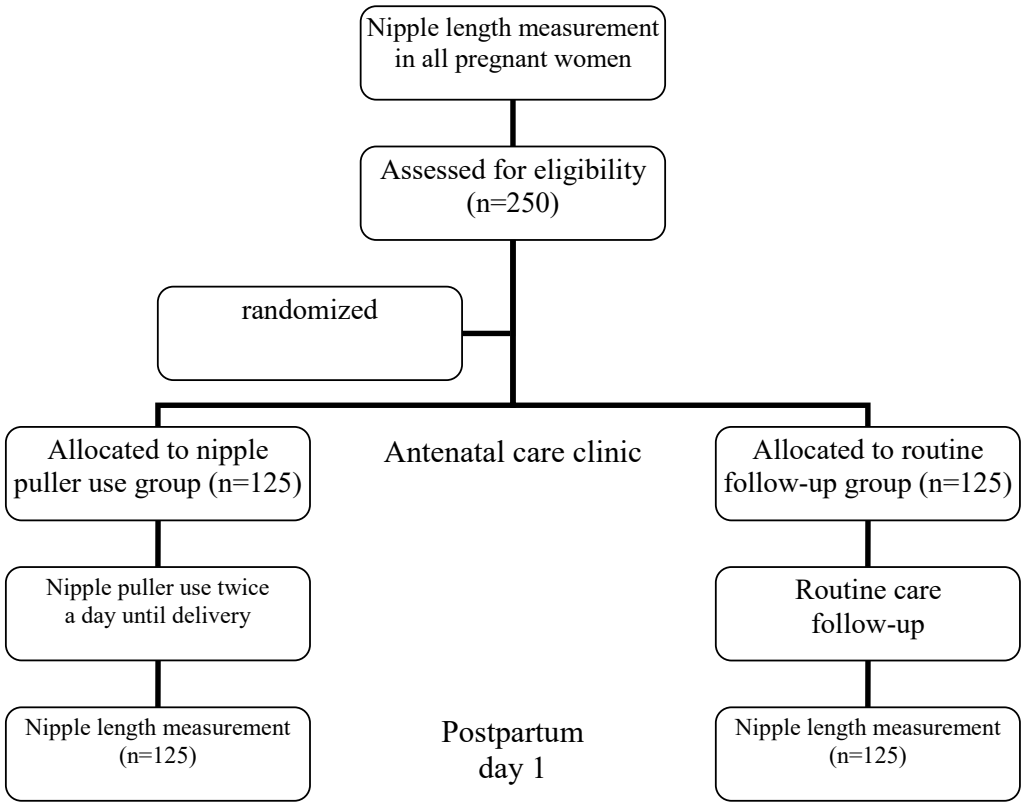

Fig. 1. Flow diagram of participants through the study.

Table 1. Demographic data of the nipple puller use and routine follow-up groups.

Mother's and newborn's data	Nipple puller use group (n=125)	Routine follow-up group (n=125)	p value
Mother's age (years)	24.5 ± 6.0	25.1 ± 6.3	0.406
Gestational age at the first antenatal visit (weeks)	27.9 ± 2.6	24.6 ± 1.2	0.148
Primipara n (%)	99 (79.2)	86 (68.8)	0.064
BMI (kg/m^2)	25.2 ± 6.9	25.1 ± 5.1	0.933
Route of delivery n (%)			
Vaginal delivery	63 (50.4)	68 (54.4)	0.810
Cesarean section	62 (49.6)	57 (45.6)	0.810
Birth weight (grams)	3,070.0 ± 450.8	3,141.6 ± 415.8	0.280
Gestational age at delivery (weeks)	38.2 ± 1.0	38.0 ± 0.9	0.165
Nipple length (mm.)			
Right nipple	4.7 ± 1.5	5.3 ± 1.4	0.060
Left nipple	5.1 ± 1.6	5.0 ± 1.2	0.224

Table 2. Comparison of the nipple length between antenatal care clinic and postpartum measurement in routine follow-up and nipple puller use groups.

Group	Antenatal care clinic measurement (n=125)	Postpartum measurement (n=125)	p value
Routine follow-up			
right nipple (millimeters)	5.3 ± 1.4	5.6 ± 1.4	< 0.001
left nipple (millimeters)	5.0 ± 1.2	5.4 ± 1.2	< 0.001
Nipple puller use			
right nipple (millimeters)	4.7 ± 1.5	9.5 ± 1.7	< 0.001
Left nipple (millimeters)	5.1 ± 1.6	9.4 ± 1.7	< 0.001

Table 3. Comparison of the nipple length between nipple puller use and routine follow-up groups at postpartum.

Nipple length at postpartum	Nipple puller use group (n=125)	Routine follow-up group (n=125)	p value
right nipple (millimeters)	9.5 ± 1.7	5.6 ± 1.4	< 0.001
left nipple (millimeters)	9.4 ± 1.7	5.4 ± 1.2	< 0.001

Discussion

The nipple length between nipple puller use and routine follow-up group had statistically significant difference. The nipple puller could make nipple elongate about 3.8-4.0 millimeters if the nipple puller use was started at the second trimester in this study. In Thailand, an alternative method for nipple elongation is breast cup use which can soften areola concurrently. The breast cup can elongate nipple about 2.4 millimeters during antenatal care use whereas the nipple length can increase automatically 1.8 millimeters by no intervention[9]. The nipple length associated with breastfeeding success is more than 7 millimeter at postpartum evaluation[2]. For the pregnant women at antenatal care clinic who have nipple length about 3-5 millimeters, the nipple puller may be an effective method for nipple elongation. However, the mothers with nipple length about 4.5-5 millimeters and firm areola consistency may have more benefit from nipple cup.

In this study, the routine follow-up group had only 0.3-0.4 millimeters of nipple length elongation. It was different from previous study which had more nipple elongation. We had a hypothesis; the short nipple may elongate less than normal length nipple because the different data was collected from the pregnant women who had nipple length more than 7 millimeters in the study of Thanaboonyawat, et al[10]. However, it needs further research for more investigation.

The complication of nipple puller use might be concerned. In this study, no preterm labor, nipple abrasion and cracked nipple were detected. However, the pregnant women who choose the nipple puller should be low risk for preterm labor.

The nipple puller is used routinely but no evidence-based support for nipple elongation and no answer of the question "How many millimeters of nipple length does the nipple puller use effectively" were reported. The strength of this study was the answer of this research question. In addition, our method of nipple length measurement was simple and health professional in community hospital can use plastic syringe to produce this tool. The cost of nipple puller is 120-250 baht. The application of nipple measurement tool and nipple puller is possibly accessible.

We determined only the nipple length in this study but not other nipple factors including nipple width, areola size and consistency which might affect breastfeeding. This was the limitation of this study. So we suggest that nipple and areola should be evaluated during breast examination of pregnant women at antenatal clinic. If only the nipple length was suspected as breastfeeding problem, the nipple puller is the alternative method to elongate nipple length.

Conclusion

The nipple puller use in low risk pregnant women could increase nipple length without preterm labor complication.

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Potential conflicts of interest

The authors declare no conflict of interest.

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OBSTETRICS

Rate and Predictors of Infant Abandonment among Unmarried Mothers at a Public Hospital in Kedah, Malaysia: A cross-sectional study

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ABSTRACT

Objectives: This study aimed to determine the rate of unmarried mothers who decided to abandon their infants at the Hospital Sultan Abdul Halim, Kedah, Malaysia and the predictors that influenced such decisions.

Materials and Methods: A retrospective study was conducted on unmarried mothers who gave birth at the hospital between January 2011 and December 2013. Information about their sociodemographic and clinical characteristics and their decisions on whether to abandon their infants was obtained from medical records. Furthermore, the predictors of infant abandonment were identified through binary logistic regression analysis.

Results: Of the 266 unmarried mothers included in this study, nearly half were aged less than 20. Most of them were Malay, unemployed and first-time mothers with a generally low educational level and income. Fifty (18.8%) of them decided to abandon their children, and the predictors of making such decisions included being aged 30 or above (adjusted odds ratio [aOR] 3.33 [95% confidence interval {CI} 1.21–9.15]), having rape-related pregnancy (aOR 5.89 [95% CI 2.10–16.53]) and having unemployed male partners (aOR 3.10 [95% CI 1.50–6.39]).

Conclusion: This study revealed that infant abandonment was common in the studied area, particularly among unmarried mothers with complex social factors. The factors that can be used to predict decisions on infant abandonment included the mother's age, rape-related pregnancy and employment status of the male partner.

Keywords: abandonment, infant, Malaysia, unmarried mother.

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Introduction

Premarital pregnancy is deemed socially unacceptable, particularly in eastern countries[1,2]. Young women are taught to protect their virginity before marriage, and any deviation from sexual norms may result in embarrassment to their families and social stigma[3,4]. Consequently, women with premarital pregnancies tend to give up their infants for adoption after giving birth[5,6] or, in a worst-case scenario, infants are abandoned to die[7,8]. In general, the issue of infant abandonment by unmarried mothers is not a focus in the literature. An early study by Ventura found that the proportion of premarital pregnancy increased from 10% in the 7th century to nearly 30% in the late 18th century[9]. Another analysis showed that in 2013, more than 1.6 million births were recorded among unmarried women[10].

Various factors are considered potential risk factors for unmarried mothers who abandon their infants. The association between the mother's age and her decision to abandon her child has been frequently studied. However, findings have been inconsistent[11-13]. Other factors that forced the single mother to abandon the infants were low incomes[12], high educational level[13], brought up in intact families, and influences from the male partners[14]. Women who were raped commonly abandon their newborns[6,15]. Furthermore, parity, initiation of prenatal care and gender of the children, which are pregnancy-related factors, influence mothers' decisions on infant abandonment[11,13].

Malaysia is known for its diverse cultures and traditions. The Malaysian population consists of the ethnic groups Malay-Bumiputra (68.6% of the population), Chinese (23.4%), Indian (7.0%) and others (1.0%)[16,17]. Despite firm religious beliefs and traditional values, the number of unmarried mothers is rising in Malaysia. The National Obstetrics Registry, a clinical database that compiles nationwide obstetrics data, indicated that between 2011 and 2012, approximately 5,200 cases of premarital pregnancies were recorded in 14 government-funded tertiary hospitals[18]. Of these cases, the highest incidence was reported among women aged 21–30, followed by those aged 10–20 and 31–40. This pressing issue is also reflected by the increasing numbers of illegitimate children born in the country. For the period 2005–2015, the National Registration Department (NRD) reported that 532,158 children were born out of wedlock in Malaysia[19].

The fear of being religiously and socially stigmatised, coupled with uncertainty about raising children without familial and financial support, may cause unmarried mothers to abandon their children[20]. Poor knowledge and the lack of awareness about adoption may also be contributing factors to such a decision. Although premarital pregnancy and infant abandonment have been substantially discussed, local studies on these topics are limited. In addition, most of the published research has focused on obstetrics and neonatal aspects[18,21,22]. In some studies, only teenagers with premarital pregnancies were included[19,23]. Hence, studying this issue using local data is imperative. Identifying factors that may affect unmarried mothers' decision to abandon their infants is beneficial to addressing this alarming issue. The authors hypothesised that an association exists between maternal factors, male partner characteristics, obstetrics variable and unmarried mothers' decision to abandon their infants. Thus, the objectives of this study were to determine the rate and predictors of infant abandonment among unmarried mothers in a major public hospital in Kedah State, Malaysia.

Materials and Methods

Participants and study design

This retrospective study was conducted at the Hospital Sultan Abdul Halim. This government-funded tertiary hospital registers 7,000–9,000 newborns annually, equivalent to 25–40 per day. Additionally, this site is a referral birthing centre that caters to the needs of the mixed urban–rural population in the southern part of Kedah state. For this study, the designation of 'unmarried mother' was determined by the women's marital status at the time of giving birth. The designation for a Muslim mother

was defined as one giving birth without having performed the akad nikah (marriage solemnisation) or when the child was born less than six qamariah months after the solemnisation[24]. For non-Muslims, the designation was defined as a woman giving birth without a formal marriage registration certificate, regardless of whether she lived with her partner or not. All unmarried mothers who gave birth at this centre were included in data analysis. Unmarried mothers who were not Malaysian citizens or delivered stillborns were excluded.

All unmarried mothers giving birth at this centre received standard obstetrics and neonatal care, similar to that provided to other mothers. Before being discharged from the postnatal ward, they were referred to the hospital's Social Welfare Unit, where their plans for themselves and the infants were assessed. One of the questions asked was regarding the mothers' decision of raising the children (unmarried motherhood) or abandoning them (for either adoption or foster care). Information about family background and male partners was also collected and recorded in the patient medical records for future reference. The patients' medical records were kept at the Medical Record Unit upon patient discharge.

Data collection

According to the list provided by the hospital's Social Welfare Unit, 306 unmarried mothers gave birth at this hospital between January 2011 and December 2013. Thirty-one mothers were excluded because they were not Malaysian citizens, and nine were excluded because they delivered stillborns. Accordingly, data analysis was performed among 266 mothers with premarital births. The data of each mother were extracted from their medical records, including age, ethnicity (Malay/non-Malay), educational level (primary/secondary/tertiary), employment status (employed/unemployed), family background (whether parents were divorced or not) and average monthly income. Incomes were presented in Malaysian ringgit (MYR 1 is approximately equal to USD 0.24) and categorised on the basis of the Household Income Survey of the Department of Statistics, Malaysia[25].

Obstetrics information, namely, parity, initiation of antenatal visit (early/delayed), child's gender and mode of delivery (vaginal/instrumental/caesarean delivery) were also obtained. Early antenatal visit was defined as the first visit made to the health clinic within the first trimester of pregnancy[26]. In addition, we gathered information about the characteristics of the male partners, including age and employment status. We also determined whether the premarital pregnancy resulted from rape. All information was cross-checked with the hospital birth registration records to minimise incomplete data.

Sample size and statistical analysis

Sample size was estimated using the population proportion formulae[27]. A study by Bachrach et al[13], indicated that 2% of children born to unmarried mothers were abandoned. If the Type I error probability and precision were 0.05 and 0.05, respectively, and an additional 20% dropout rate was considered, then the sample size needed was 39 samples.

The data was analysed by using IBM SPSS version 20.0 (IBM Corp., Armonk, NY, USA). All the categorical data were presented as frequencies and percentages. Univariable analysis was performed using binary logistic regression, and the decision to abandon the infants was considered the outcome variable. The results were presented as crude odds ratios (ORs) and 95% confidence intervals (CIs). Variables with p value less than 0.25 from the univariable analysis were chosen for multivariable logistic regression analysis[28]. To identify independent predictors for infant abandonment, we removed the selected variables in a stepwise method at several steps, until only those factors significant at the 0.05 level remained in the final model.

Ethical approval

The study was conducted in compliance with the ethical principles outlined in the Declaration of Helsinki and the Malaysian Good Clinical Practice

Guidelines. No personal information of the participants was disclosed or could be identified in any part of the study. The Medical Research and Ethics Committee of the Ministry of Health, Malaysia, approved this work (NMRR-13-1360-18553).

Results

During the three-year study period, 28, 527 deliveries were recorded, 306 (0.13%) of which were by unmarried mothers. Only 266 medical records were included in the data analysis. Nearly half of the 266 unmarried mothers included were aged less than 20; the youngest and oldest mothers were aged 14 and 44, respectively. Most of the unmarried mothers were Malay and unemployed, had secondary educational level and an average monthly income of less than MYR 1,000. More than 80% of these women were first-time mothers, and 75.6% attended their first antenatal visit during the first trimester. The infants were equally distributed by gender. Other demographic characteristics are summarised in Table 1.

Table 1. Demographic characteristics of unmarried mothers who gave birth at Hospital Sultan Abdul Halim, Kedah, Malaysia.

Variables	n	(%)
Maternal characteristics		
Age group (years)		
< 20	129	(48.5)
20 – 29	108	(40.6)
≥ 30	29	(10.9)
Ethnicity		
Malay	207	(77.8)
Non-Malay	59	(22.2)
Highest educational attainment*		
Primary	18	(6.8)
Secondary	220	(83.7)
Tertiary	25	(9.5)
Employment status**		
Employed	77	(29.6)
Unemployed	183	(70.4)
Estimated household income (in RM)		
< 1000	151	(56.8)
1000 – 2999	98	(36.8)
≥ 3000	17	(6.4)
Parents[a] divorced		
Yes	17	(6.4)
No	249	(93.6)
Rape-related pregnancy		
Yes	21	(7.9)
No	245	(92.1)

Table 1. Demographic characteristics of unmarried mothers who gave birth at Hospital Sultan Abdul Halim, Kedah, Malaysia. (Cont.)

Variables	n	(%)
Male partner characteristics		
Age group (years)		
< 20	29	(10.9)
20 – 29	180	(67.7)
≥ 30	57	(21.4)
Employment status		
Employed	200	(75.2)
Unemployed	66	(24.8)
Obstetrics information		
Parity		
1	215	(80.8)
2 or more	51	(19.2)
Timing for first antenatal visit		
Early (within 1st trimester)	201	(75.6)
None / Delayed	65	(24.4)
Mode of delivery		
Vaginal	191	(71.8)
Instrumental	12	(4.5)
Caesarean	63	(23.7)
Gender of infant		
Male	131	(49.2)
Female	135	(50.8)

* data missing for 3 cases, ** data missing for 6 cases
n = frequency; % = percent; RM = ringgit Malaysia; a = parent of unmarried mother

Of all the unmarried mothers, 50 (18.8%) decided to abandon their children. Table 2 shows the percentage of unmarried mothers who decided to abandon their infant on the basis of the demographic characteristics. In the univariable analysis, the factors that were found to affect the mothers' decisions included being aged 30 or above and having rape-related pregnancies (Table 3). By contrast, the mothers' ethnicity, educational level, employment status, income level and family background were not associated with their decisions. Unemployed male partners were linked to the abandonment decision. Additionally, although majority was a first-time mother, it was not a predictor in the women's decision making. In the multivariate analysis (Table 3), the following factors were shown to independently affect the mothers' decisions to abandon their infants: being aged 30 or above (adjusted odds ratio [aOR] 3.33 [95% CI 1.21–9.15), having rape-related pregnancy (aOR 5.89 [95% CI 2.10–16.53]) and having unemployed male partners (aOR 3.10 [95% CI 1.50–6.39]). Moreover, the influences of having an income of less than MYR 1,000 and more than MYR 3,000 on the mothers' decisions were marginally significant.

Table 2. Percentage of unmarried mothers with decision to abandon their infants at Hospital Sultan Abdul Halim, Kedah, Malaysia.

Variables	Decision to abandon the infant	
	Yes, n (%)	No, n (%)
Maternal characteristics		
Age group (years)		
< 20	23 (17.8)	106 (82.2)
20 – 29	17 (15.7)	91 (84.3)
≥ 30	10 (34.5)	19 (65.5)
Ethnicity		
Malay	40 (19.3)	167 (80.7)
Non-Malay	10 (16.9)	49 (83.1)
Highest educational attainment*		
Primary	4 (22.2)	14 (77.8)
Secondary	40 (18.2)	180 (81.8)
Tertiary	6 (24.0)	19 (76.0)
Employment status**		
Employed	13 (16.9)	64 (83.1)
Unemployed	37 (20.2)	146 (79.8)
Estimated household income (MYR)		
< 1,000	32 (21.2)	119 (78.8)
1,000 – 2,999	13 (13.3)	85 (86.7)
≥ 3,000	5 (29.4)	12 (70.6)
Parents[a] divorced		
Yes	2 (11.8)	15 (88.2)
No	48 (19.3)	201 (80.7)
Rape-related pregnancy		
Yes	9 (42.9)	12 (57.1)
No	41 (16.7)	204 (83.3)
Male partner characteristics		
Age group (years)		
< 20	6 (20.7)	23 (79.3)
20 – 29	31 (17.2)	149 (82.8)
≥ 30	13 (22.8)	44 (77.2)
Employment status		
Employed	30 (15.0)	170 (85.0)
Unemployed	20 (30.3)	46 (69.7)

Table 2. Percentage of unmarried mothers with decision to abandon their infants at Hospital Sultan Abdul Halim, Kedah, Malaysia. (Cont.)

Variables	Decision to abandon the infant	
	Yes, n (%)	No, n (%)
Obstetrics information		
Parity		
1	40 (18.6)	175 (81.4)
2 or more	10 (19.6)	41 (80.4)
Timing for first antenatal visit		
Early (within 1st trimester)	33 (16.4)	168 (83.6)
None / Delayed	17 (26.2)	48 (73.8)
Mode of delivery		
Vaginal	32 (16.8)	159 (83.2)
Instrumental	4 (33.3)	8 (66.7)
Caesarean	14 (22.2)	49 (77.8)
Gender of infant		
Male	24 (18.3)	107 (81.7)
Female	26 (19.3)	109 (80.7)

* data missing for 3 cases, ** data missing for 6 cases
n = frequency; % = percent; RM = ringgit Malaysia; a = parent of unmarried mother

Table 3. Univariable and multivariable analysis of unmarried mothers with decision to abandon their infants at Hospital Sultan Abdul Halim, Kedah, Malaysia.

Variables	Crude OR (95% CI)	p value	Adjusted OR (95% CI)[b]	p value
Maternal characteristics				
Age group (years)				
< 20	1.16 (0.59, 2.31)	0.669	0.93 (0.44, 1.99)	0.859
20 – 29	1.00 (ref.)		1.00 (ref.)	
≥ 30	2.82 (1.12, 7.10)	0.028	3.33 (1.21, 9.15)	0.020
Ethnicity				
Malay	1.17 (0.55, 2.52)	0.681		
Non-Malay	1.00 (ref.)			
Highest educational attainment*				
Primary	1.27 (0.40, 4.11)	0.672		
Secondary	1.00 (ref.)			
Tertiary	1.23 (0.47, 3.22)	0.678		

Table 3. Univariable and multivariable analysis of unmarried mothers with decision to abandon their infants at Hospital Sultan Abdul Halim, Kedah, Malaysia. (Cont.)

Variables	Crude OR (95% CI)	p value	Adjusted OR (95% CI)[b]	p value
Employment status**				
Employed	1.00 (ref.)			
Unemployed	1.20 (0.59, 2.40)	0.610		
Estimated household income (MYR)				
< 1,000	1.76 (0.87, 3.55)	0.115	2.03 (0.93, 4.42)	0.076
1,000 – 2,999	1.00 (ref.)		1.00 (ref.)	
≥ 3000	2.72 (0.82, 9.00)	0.100	3.57 (0.96, 13.24)	0.057
Parents[a] divorced				
Yes	1.00 (ref.)			
No	1.79 (0.40, 8.10)	0.449		
Rape-related pregnancy				
Yes	3.73 (1.48, 9.43)	0.005	5.89 (2.10, 16.53)	0.001
No	1.00 (ref.)		1.00 (ref.)	
Male partner characteristics				
Age group (years)				
< 20	1.25 (0.47, 3.34)	0.650		
20 – 29	1.00 (ref.)			
≥ 30	1.42 (0.69, 2.95)	0.346		
Employment status				
Employed	1.00 (ref.)		1.00 (ref.)	
Unemployed	2.46 (1.28, 4.73)	0.007	3.10 (1.50, 6.39)	0.002
Obstetrics information				
Parity				
1	0.94 (0.43, 2.03)	0.869		
2 or more	1.00 (ref.)			
Timing for first antenatal visit				
Early (within 1st trimester)	1.00 (ref.)		1.00 (ref.)	
None / Delayed	1.80 (0.93, 3.51)	0.083	1.86 (0.89, 3.90)	0.101
Mode of delivery				
Vaginal	1.00 (ref.)		1.00 (ref.)	
Instrumental	2.48 (0.71, 8.75)	0.157	3.40 (0.88, 13.08)	0.075
Caesarean	1.42 (0.70, 2.87)	0.330	2.03 (0.92, 4.48)	0.081
Gender of infant				
Male	1.00 (ref.)			
Female	1.06 (0.58, 1.97)	0.845		

* data missing for 3 cases, ** data missing for 6 cases, n = frequency; % = percent; CI = confidence interval; OR = odds ratio; ref. = reference group; MYR = Malaysian ringgit, a = parent of unmarried mother, b = Enter method for multiple logistic regression model was applied. Adjusted for maternal age group, household income, rape-related pregnancy, male partner employment status, timing for first antenatal visit and mode of delivery.

Discussion

The rate of unmarried mothers who decided to abandon their infants found in our study was 18.8% (50/266), or nearly 1 in 5 premarital birth cases. This value was higher than that in a previous survey[13], thereby indicating that the issue of infant abandonment among unmarried mothers requires increased attention from local authorities. According to the study analysis, the pertinent variables that can be used to predict decisions on infant abandonment include the mother's age, rape-related pregnancy and employment status of the male partner. Our study revealed that women 30 years old or above were likely to abandon their children. Even after adjusting for other factors in the model, unmarried mothers in this age group were still found to be 3.3 times more likely to abandon their infants in comparison with women from other age groups. To date, existing research on the association between mother's age and the decision to abandon has yielded contradictory findings[11-13]. Old unmarried women are likely to abandon their children because they may receive less family support in childcare and financial assistance than do young unmarried mothers. The decision to abandon an illegitimate infant for adoption requires a complex evaluation process, including the consideration of the child's future needs[13,14]. Thus, old unmarried mothers who are relatively psychologically mature are more likely to opt for infant abandonment than their young counterparts.

Rape-related pregnancy influences a mother's decision to abandon her child[6,15], and our study confirms this effect. Many possible reasons exist for making such a decision. After the traumatic experience of being raped, a pregnancy and birth that are beyond a woman's control can be additionally challenging events. In a qualitative study on ten women who were raped before their first childbirth, the women cited that the rape events flashed through their minds during childbirth[29]. Besides, the newborns can remind the mothers of the rape perpetrators. Additionally, women with a history of sexual trauma are 12 times more likely to experience traumatic childbirths than those without such experiences[30]. With such a high level of stress, a child born to a mother who has experienced rape is likely to be abandoned for adoption. Fear of social stigma or rejection by their own family may also affect the mothers in choosing not to raise an illegitimate child.

The present study also found that the employment status of the male partners independently influence mothers' decision on infant abandonment. Raising a child alone requires various life adjustments for an unmarried mother, particularly with respect to financial aspects[31]. Having an unemployed partner may increase the financial burden, especially if the woman is also unemployed. Thus, unmarried mothers may see adoption as a good choice for the children's development and future needs. However, we were unable to investigate further the influences of partner-related characteristics on the mothers' decisions because of limited information provided by the mothers about their male partners, particularly educational level, family background and socioeconomic status. This gap warrants further studies in future.

The results of this study provided necessary information for healthcare providers about the characteristics of unmarried mothers who were likely to abandon their infants. As recommended by the American College of Obstetricians and Gynecologists[32], healthcare providers are responsible for educating these mothers on the options available. Although abandonment of illegitimate infants is not technically a medical matter, healthcare providers, especially those who deal with antenatal and postnatal care, must equip themselves with knowledge on infant abandonment among unmarried mothers. These mothers may need information and advice about their options from healthcare staff after giving birth. Failure to assist these women places children at risk of abandonment after the mother is discharged from the hospital. A counselling session during antenatal visit follow-ups for unmarried mothers may be particularly useful. With our findings, unmarried mothers at risk of infant abandonment can be identified early during pregnancy and thus provided support. Guidance and information at the early stage of pregnancy can help mothers make the best decisions for themselves and their children. Involvement of professionals with relevant expertise, including the NRD and the Department of Social

Welfare, is also essential to supporting mothers with the difficult decision of infant abandonment beyond hospital care.

Several limitations were identified in this study. First, the data collected were sampled from a single hospital, thereby limiting the generalisation of the study findings. Unmarried mothers may have delivered at nearby private hospitals; hence, their birth information was not obtained by this study. Nevertheless, the large study sample size and the mixed urban–rural population made our data analyses useful to providing insights into this topic. A population-based study would be an appropriate future research approach to generating an improved overview of infant abandonment. Second, the information retrieved was limited only to the period before the mother was discharged from the hospital. No data were available to confirm whether these mothers implemented their decision to abandon their infants after being discharged from the hospital. Following discharge, the influences of close relatives, the mother's mental health and societal perception may change a woman's decision. How these external factors influence mothers' decisions about infant abandonment is an essential area to be explored in future research.

Conclusion

In conclusion, a high proportion of unmarried mothers choose to abandon their infants. This group of mothers requires significant attention from healthcare providers and other local authorities. Maternal age of 30 or above, rape-related pregnancy and having an unemployed male partner were the significant predictors for an unmarried mother to opt for infant abandonment. A multidisciplinary team must assist the mother with decisions not only during hospital care but also for continuous follow-up when she is discharged.

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Potential conflicts of interest

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Accuracy of Preoperative Sonographic Adnexal Fixation for Prediction of Pelvic Adhesion in Gynecologic Surgery

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ABSTRACT

Objectives: To assess the accuracy of preoperative sonographic adnexal fixation for prediction of pelvic adhesion in gynecologic surgery.

Materials and Methods: This was a descriptive study of 106 gynecologic patients who were scheduled for elective abdominal surgery. Preoperative sonographic adnexal fixation was done. The accuracy of transvaginal ultrasonographic findings suspecting pelvic adhesion, including at least one side of adnexal fixation, in predicting intraoperative adnexal adhesion was calculated. Pelvic adhesion risk factors were also collected.

Results: Sonographic adnexal fixation was found in 81 adnexa. Ipsilateral adnexal adhesion was found intraoperatively in 78 adnexa of this study. Overall, pelvic adhesion prediction based on ultrasonographic finding had an accuracy, sensitivity, specificity, positive and negative predictive values of 74.4, 69.2, 77.7, 66.7 and 79.7 percent respectively. History of pelvic infection and dysmenorrhea were positively correlated with pelvic adhesion (Adjusted OR, 3.50; 95%CI, 1.26-9.75; p = 0.016 and adjusted OR, 2.47; 95%CI, 1.37-4.46; p = 0.003 respectively). However, combined a history of pelvic infection and dysmenorrhea with an ultrasonographic finding showed the most correlation with pelvic adhesion.

Conclusion: Preoperative adnexal fixation on transvaginal ultrasonography accurately identified patients with pelvic adhesions. Furthermore, history of pelvic infection and dysmenorrhea could increase the ability to predict pelvic adhesion.

Keywords: pelvic adhesion, transvaginal ultrasound, prediction, accuracy.

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การศึกษาความแม่นยำของการตรวจคลื่นเสียงความถี่สูงผ่านทางช่องคลอดโดยประเมินการยึดตรึงที่ปีกมดลูกก่อนการผ่าตัด เพื่อทำนายภาวะพังผืดในอุ้งเชิงกรานในการผ่าตัดทางนรีเวช

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บทคัดย่อ

วัตถุประสงค์: *เพื่อศึกษาความแม่นยำของการตรวจคลื่นเสียงความถี่สูงผ่านทางช่องคลอด โดยประเมินการยึดตรึงที่ปีกมดลูกก่อนการผ่าตัด เพื่อทำนายภาวะพังผืดในอุ้งเชิงกรานในการผ่าตัดทางนรีเวช*

รูปแบบการวิจัย: *การศึกษาเชิงพรรณนาเพื่อศึกษาความแม่นยำของการตรวจคลื่นเสียงความถี่สูงผ่านทางช่องคลอด เพื่อทำนายภาวะพังผืดในอุ้งเชิงกราน โดยการตรวจการเคลื่อนที่ของปีกมดลูก กับภาวะพังผืดที่ปีกมดลูกที่พบระหว่างการผ่าตัดในผู้ป่วยทางนรีเวชที่จำเป็นต้องได้รับการผ่าตัดทางหน้าท้อง จำนวน 106 ราย รวมทั้งศึกษาปัจจัยเสี่ยงที่มีผลต่อการเกิดภาวะพังผืดในอุ้งเชิงกราน*

ผลการวิจัย: *จากการศึกษาพบการยึดตรึงที่ปีกมดลูกจากการตรวจคลื่นเสียงความถี่สูงผ่านทางช่องคลอดจำนวน 81 ข้าง มีจำนวน 78 ข้างที่พบภาวะพังผืดที่ปีกมดลูกจริงระหว่างการผ่าตัด และพบว่าการตรวจคลื่นเสียงความถี่สูงผ่านทางช่องคลอดสามารถคาดการณ์ภาวะพังผืดที่พบระหว่างการผ่าตัดจริง โดยมีความแม่นยำ ความไว ความจำเพาะ ค่าทำนายเมื่อผลเป็นบวกและลบ ได้ร้อยละ 74.4, 69.2, 77.7, 66.7 และ 79.7 ตามลำดับ เมื่อผู้เข้าร่วมการวิจัยมีปัจจัยอื่น ได้แก่ ประวัติการติดเชื้อในอุ้งเชิงกราน หรือประวัติการปวดท้องประจำเดือน จะสัมพันธ์กับการคาดการณ์ภาวะพังผืดในอุ้งเชิงกรานด้วย (Adjusted OR, 3.50; 95%CI, 1.26-9.75; p= 0.016 and adjusted OR, 2.47; 95%CI, 1.37-4.46; p= 0.003 ตามลำดับ) อย่างไรก็ตามเมื่อพิจารณาปัจจัยดังกล่าวรวมกับการพบภาวะพังผืดที่ปีกมดลูก จากการตรวจคลื่นเสียงความถี่สูงผ่านทางช่องคลอดจะสัมพันธ์กับการคาดการณ์ภาวะพังผืดในอุ้งเชิงกรานเพิ่มมากขึ้น*

สรุป: *การตรวจคลื่นเสียงความถี่สูงผ่านทางช่องคลอด โดยประเมินการยึดตรึงที่ปีกมดลูกก่อนการผ่าตัดสามารถทำนายภาวะพังผืดในอุ้งเชิงกรานในการผ่าตัดทางนรีเวช และความน่าจะเป็นของภาวะพังผืดในอุ้งเชิงกรานหลังทราบผลการตรวจคลื่นเสียงความถี่สูงผ่านทางช่องคลอดเพิ่มขึ้นเมื่อวิเคราะห์ร่วมกับประวัติการติดเชื้อในอุ้งเชิงกรานและประวัติการปวดท้องประจำเดือน*

คำสำคัญ: *ภาวะพังผืดในอุ้งเชิงกราน, การตรวจคลื่นเสียงความถี่สูงผ่านทางช่องคลอด, ความแม่นยำ, การทำนายผลการตรวจ*

Introduction

General gynecologic surgery, especially hysterectomy, is associated with 6 percent of major complications, including major hemorrhage, bladder injury, and bowel injury[1].

Pelvic adhesion is a significant cause of major complications in gynecologic surgery. Previous study showed arising complication incidence during gynecologic laparoscopic surgery among patients who have undergone previous abdominal surgeries[2]. These comprised of 38.8 percent with intrapelvic adhesions. Pelvic adhesion can cause short term complications such as bowel damage, urinary system damage, conversion to laparotomy, prolonged operative time and hospitalization at 13.4 percent[3-5]. On the other hand, long term complication adhesion formation can affected the patient to postoperative bowel obstruction, chronic pelvic pain and dyspareunia[3-6].

Currently, preoperative assessments play a major role in reducing comorbidity and complication associated with pelvic adhesion. Preoperative imaging such as ultrasonography[7-12], computed tomography scan[13], and magnetic resonance imaging[14,15] were used for adhesion mapping before surgery.

Initially in 1940, ultrasonography was applied in medical technology and has been developed to high efficiency and become widespread[7,8,16]. The resolution of images obtained by vaginal probes enables identification of pelvic pathology, evaluation of mass in pelvic cavity, adnexa, and uterus. Transvaginal ultrasound can be broadly applied to diagnose gynecologic condition with ease. Prediction of pelvic adhesion on transvaginal ultrasonography was used any technique (poor definition of pelvic structure, blurring of ovarian margins, distance of ovary from probe, fixation from the ovary to the uterus)[11,12]. Although, in 2010, Guerriero et al[7] used adnexal fixation on transvaginal ultrasound to predict pelvic adhesion in endometrioma with high sensitivity and specitivity in diagnosis, they could not apply this information to the general population.

The research objective of study was to assess the accuracy of preoperative sonographic adnexal fixation for prediction of pelvic adhesion in general gynecologic surgery. The secondary objective was to find out the other risk factors for prediction of pelvic adhesion.

Materials and Methods

Subjects

This study was conducted from April 2016 to January 2017. A total of 106 gynecologic patients who were scheduled for elective abdominal surgery in Her Royal Highness Princess Maha Chakri Sirindhorn Medical Center (MSMC) were eligible and signed written informed consent. All patients undergone transvaginal ultrasound on the day before surgery by a physician trained by an experienced ultrasonographer. The physician was also blinded about the history or diagnosis of each patient.

The inclusion criteria were as follows: patient who were scheduled for elective abdominal surgery (laparotomy or laparoscopy) with gynecological indication, non-pregnant, had uterus and at least one ovary. The exclusion criteria were as follows: patient who had unstable condition, inadequate ultrasound imaging (enlarged uterus more than 12 week-size), ascites, and patients who had complications after vaginal probe insertion (contact bleeding at cervical mass, virgin).

Data collection

The data collection included baseline characteristics; age, body mass index (BMI), underlying diseases, previous surgery, chronic pelvic pain, menstruation pattern, dysmenorrhea, and previous pelvic infection. All patients underwent transvaginal ultrasonography 1 day before of surgery, using a Samsung Medison,

ultra-compact SonoAce R7, real-time scan with 7 MHz endo-cavity transducers (EVN4-9, field of view: 148°). Vaginal transducer was applied in vaginal canal until semi-coronal view of left or right of adnexa were obtained after the bladder was emptied. The presence of adnexal fixation between ovary and uterus, after gentle probe pressure at vaginal fornix with gentle suprapubic pressure, was considered to have pelvic adhesion. Result of ultrasonography scanning was blinded from surgeon.

On the next day, all patients underwent abdominal surgery in which peritoneum, ovaries and uterus were carefully observed. Pelvic adhesion was classified as either right/ left adnexa. The classification was applies from modified of revised American Fertility Society Classification system (AFS, 1985). The extent and site of pelvic adhesion were recorded by camera during operation.

Statistical analysis

The sample size was calculated with simple formula[17]. Sample size of study based on results of an earlier study by Guerriero et al[7], with 89 percent of sensitivity. The number of 93 patients was required and additional 10% for losing to follow-up. Approximately 103 patients were required.

Demographic data was described with descriptive statistics. Age and BMI were described with mean ± SD. History of pelvic surgery, chronic pelvic pain, dysmenorrhea, pelvic infection and principle diagnosis for surgery were described with percentage.

Risk factors and ultrasonographic findings suspecting adhesion were then compared with intraoperative findings. Chi-square test was used to compare categorical variables with p value of < 0.05 was considered significantly different. To analyze the predictive value of transvaginal ultrasound result in differentiating intraoperative result at same site, sensitivity, specificity, positive and negative predictive values were used.

Then the probability of pelvic adhesions according to the significant variables was calculated by:

Probability of pelvic adhesions = (Posttest odds of disease) / (1+Posttest odds of disease)

Posttest odds of disease = Pretest odds of disease x LR1 x LR2 x ….

Pretest odds of disease = Pretest probability / (1 - Pretest probability)

The calculation of post-test odds of disease depended on the patient's risk factor. If the patient had a history of risk factors, the positive likelihood ratio (LR) was used. However, if the patient had no history of any risk factors, the negative likelihood ratio (LR) was used.

Results

Among 106 patients, 13 patients had one ovary, and remaining 93 patients had both ovaries. Sonographic adnexal fixation was found in 81 adnexa. Adnexal adhesion was found intraoperatively in 78 adnexa. Baseline characteristics were presented in Table 1. The risk factors of pelvic adhesion were presented with percentage. The most common principle diagnosis for surgery was a myoma uteri.

Preoperative adnexal fixation on transvaginal ultrasound could predict pelvic adhesion that showed sensitivity, specificity, positive and predictive value in Table 2. We compared transvaginal ultrasonographic findings, risk factors associated with adhesion and intraoperative finding. History of pelvic infection and dysmenorrhea were positively high correlated with pelvic adhesion (Table 3). The sonographic adnexal adhesion were positively correlated with pelvic adhesion (OR, 7.833; 95%CI, 4.12-14.91; $p < 0.001$). Prevalence of pelvic adhesion was 39.2 percent and the accuracy was 74.4 percent respectively. Probability of pelvic adhesions according to significant variables was calculated and shown in Table 4.

Table 1. Baseline characteristics (n = 106 patients).

Characteristics	
Age (mean ± SD; year)	44.44±10.85
BMI (mean ± SD; kg/m²)	24.33±4.82
Risk factors of pelvic adhesion	
- History of dysmenorrhea (%)	56 (52.8)
- History of pelvic surgery (%)	31 (29.2)
- History of chronic pelvic pain (%)	15 (14.2)
- History of pelvic infection (%)	10 (10.4)
Principle diagnosis	
- Myoma uteri (%)	34 (32.1)
- Malignancy* (%)	27 (25.4)
- Endometriosis (%)	25 (23.6)
- Ovarian cyst (%)	11 (10.4)
- Pre-malignancy** (%)	7 (6.6)
- Chronic pelvic pain (%)	2 (1.9)

* Malignancy: Cervical cancer[11], Endometrial cancer[11] and Ovarian cancer[5]
** Pre-malignancy: CIN3[3], AIS[2] and Endometrial hyperplasia[2]

Table 2. Validity and efficacy of factor to diagnosis pelvic adhesion (n=199 sites).

Factor predict adhesion		Surgical adhesion finding		Sensitivity	Specificity	PPV*	NPV**
		Yes	No				
Sonographic adnexal	Yes (%)	54 (66.7)	27 (33.3)	69.2	77.7	66.7	79.7
fixation	No (%)	24 (20.3)	94 (79.7)				
History of pelvic infection	Yes (%)	14 (70.0)	6 (30.0)	17.3	95.4	70.0	65.1
	No (%)	67 (34.9)	125 (65.1)				
History of dysmenorrhea	Yes (%)	55 (49.1)	57 (50.9)	67.9	56.5	49.1	74.0
	No (%)	26 (26.0)	74 (74.0)				

* Positive predictive value, ** Negative predictive value

Table 3. Risk factors to predict intra-operative pelvic adhesion finding by logistic regression (n =199 site).

Risk factor		Crude OR	95%CI	p value	Adjusted OR*	95%CI**	p value
History of pelvic infection	Yes	4.35	1.59-11.85	0.004	3.50	1.26-9.75	0.016
	No	1	-	-	1	-	-
History of dysmenorrhea	Yes	2.75	1.54-4.91	0.001	2.47	1.37-4.46	0.003
	No	1	-	-	1	-	-

* Adjusted with Chronic pelvic pain, Pelvic infection and Dysmenorrhea
** Confidence interval

Table 4. Ultrasound finding and history of risk factors predict probability of adhesion (n=199 sites).

Factor predict adhesion	Result						
Sonographic adnexal fixation	Yes	Yes	Yes	No	Yes	No	No
History of pelvic infection	Yes	Yes	No	Yes	No	Yes	No
History of dysmenorrhea	Yes	No	Yes	Yes	No	No	Yes
Probability of adhesion (%)	91.8	80.4	72.2	60	48.6	35.5	25.7

Discussion

In general, pelvic adhesion during gynecologic surgery has significant effect on surgical complication, operative duration and intra-operative blood loss. This study showed that preoperative adnexal fixation on transvaginal ultrasonography accurately identified patients with pelvic adhesions. Furthermore, history of pelvic infection and dysmenorrhea could increase the ability to predict pelvic adhesion. So, transvaginal ultrasound was very good predictor of pelvic adhesion when combined with ultrasonographic adnexal fixation and clinical risk factors.

Previous descriptive studies[11,12] on transvaginal ultrasonography reported pelvic adhesion prediction among infertility premenopausal women with a sensitivity between 61.1-64 percent and high specificity between 86-98.2 percent. Our study had a sensitivity of 69.2 percent which was comparable to previous studies. Our study showed less specificity, at 77.7 percent, comparing with previous studies. This might be due to a high incidence of myoma among our population, which could interfere with anatomical location or adnexal movement.

Previous studies have found an association between surgical trauma in causing adnexal adhesion[7, 12]. However, this study did not depict the same association because most patients in the study who had a history of pelvic surgery underwent a cesarean section which may cause minor trauma to the adnexal area.

Pelvic infection in earlier studies was not a strong evidence to predict pelvic adhesion[7]. In this study, however, pelvic infection showed a statistically significant association with pelvic adhesion. This was primarily because pelvic infection in this study was diagnosed by a physician

with a medical record. In contrast, pelvic infection in the previous study was diagnosed only by history taking.

The strength of our study was the double-blinded study. The ultrasonographer was blinded to the history associated with adhesion and the surgeon was blinded to the ultrasonographic result which may decreases selection bias. In addition, our study focused on general gynecologic patients which was different from previous studies which focused on patients who underwent endometritic surgery[7] or those who were categorized as subfertile[8, 11, 12].

This study also had some limitations. There was no data on adhesion grading or scoring. If this information were obtained, it may lead to a better prediction of intra-operative dense adhesion which may lead to various surgical complications. Second, the physicians who assess the adhesion received the same standardized instruction by revised American Fertility Society Classification system, however, this classification was used in endometriosis more than in general patients. The data in this study was a time consuming; it may be temporal effect on intra-observer reliability. Because this study had one ultrasonographer, the skills of ultrasound may increase over time.

Conclusion

In conclusion, preoperative sonographic adnexal fixation accurately identified patients with pelvic adhesions. With additional risk factors such as history of pelvic infection or dysmenorrhea and fixation upon transvaginal ultrasound examinations, pelvic adhesion prediction increased in general gynecologic surgery population. The authors expect this prediction to benefit in forthcoming surgery and reduce intra-operative complications associated with pelvic adhesion. Reduction of surgical complications could be done by appropriate bowel preparation, preparing blood product for resuscitation and timely multidisciplinary intra-operative consultation.

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Potential conflicts of interest

The authors declare no conflict of interest.

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Application of a Rod USB Digital Microscope for Pelvic Examination Demonstration for Fourth Year Medical Students: An assessor-blinded randomized trial

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ABSTRACT

Objectives: To evaluate the students' satisfaction of the fourth year medical students learning the pelvic examination and the benefits of the rod USB digital microscope compared with the traditional method.

Materials and Methods: The fourth year medical students were recruited after commencing gynecologic rotation and were randomly assigned to receive the traditional method and the rod USB digital microscope assisted method on pelvic examination demonstration. There was only one trainer performing all demonstration session and all participants were not informed to which group they were assigned. The validated 5-question students' satisfaction questionnaire was used to evaluate the participants' satisfaction by assessor-blinded, randomized trial and the validated 5-question rod USB digital microscope questionnaire was used to evaluate its benefits. The primary outcome was students' satisfaction of pelvic examination learning with the rod USB digital microscope.

Results: There were 35 students in the study group (21 female, 14 male, aged 22.14 ± 0.36 years) and 35 students in the control group (25 female, 10 male, aged 22.12 ± 0.33 years). The overall satisfaction score of the study group was significantly higher than that of the control group (4.88 ± 0.12 vs 3.69 ± 0.69) ($p < 0.001$). Regarding the benefits of the instrument, the overall mean score was 4.75 ± 0.24, and the highest score was the use for medical student teaching (mean score 4.97 ± 0.17).

Conclusion: The rod USB digital microscope could be applied to pelvic examination demonstration with high satisfaction of the fourth year medical students.

Keywords: Rod USB digital microscope, pelvic examination demonstration, medical students.

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การประยุกต์กล้องยูเอสบีดิจิตอลขนาดเล็ก เพื่อการสอนแสดงและการตรวจภายในสำหรับนักศึกษาแพทย์ชั้นปีที่สี่: การวิจัยแบบสุ่มโดยปกปิดผู้ประเมิน

ภัสสิรา วารินศิริรักษ์, ญาดา ติงธนาธิกุล, อนุสร อดิเรกกิตติคุณ, จิตติมา มโนนัย บาร์เลตต์

บทคัดย่อ

วัตถุประสงค์: *เพื่อเปรียบเทียบความพึงพอใจในการเรียนการสอนของนักศึกษาแพทย์ชั้นปีที่สี่ คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี ที่ผ่านการเรียนการสอนวิชานรีเวชวิทยาแบบปกติ กับการเรียนการสอนโดยใช้กล้องยูเอสบีดิจิตอลขนาดเล็กในการตรวจภายในสตรี*

วัสดุและวิธีการ: *ศึกษาโดยนำกล้องยูเอสบีดิจิตอลขนาดเล็กมาประยุกต์ใช้สอนแสดงการตรวจภายในสตรีสำหรับนักศึกษาแพทย์ชั้นปีที่สี่ที่ผ่านการเรียนการสอนวิชานรีเวชวิทยา ในการพัฒนาประยุกต์สิ่งประดิษฐ์รูปแบบการวิจัยแบบสุ่ม และมีกลุ่มควบคุม โดยแบ่งกลุ่มนักศึกษาแพทย์สองกลุ่ม กลุ่มละ 35 คน โดยกลุ่มควบคุมสอนแสดงการตรวจภายในสตรีแบบปกติ และกลุ่มศึกษาสอนแสดงการตรวจภายในสตรีโดยใช้กล้องยูเอสบีดิจิตอลขนาดเล็กซึ่งเชื่อมต่อกับคอมพิวเตอร์และแสดงภาพสู่จอคอมพิวเตอร์ นักศึกษาทั้งสองกลุ่มได้ตอบแบบสอบถามความพึงพอใจหลังเรียน นำแบบสอบถามทั้งสองกลุ่มมาเปรียบเทียบความพึงพอใจหลังเรียน*

ผลการศึกษา: *นักศึกษาแพทย์กลุ่มศึกษา 35 คน (หญิง 21 คน, ชาย 14 คน, อายุ 22.14 ± 0.36 ปี) และ กลุ่มควบคุม 35 คน (หญิง 25 คน, ชาย 10 คน, อายุ 22.12 ± 0.33 ปี) นักศึกษาแพทย์กลุ่มศึกษามีคะแนนความพึงพอใจโดยรวมสูงกว่ากลุ่มควบคุมอย่างมีนัยสำคัญ (4.88 ± 0.12 และ 3.69 ± 0.69) ($p < 0.001$) ประโยชน์ของกล้องยูเอสบีดิจิตอลขนาดเล็กมีคะแนนรวม 4.75 ± 0.24 และคะแนนสูงสุดได้แก่ ทำให้การเรียนการสอนของนักศึกษาแพทย์สัมฤทธิ์ผล (คะแนนเฉลี่ย 4.97 ± 0.17)*

สรุป: *กล้องยูเอสบีดิจิตอลขนาดเล็กสามารถใช้ประยุกต์ในการเรียนการสอนการตรวจภายในและมีความพึงพอใจในระดับสูงของนักศึกษาแพทย์*

คำสำคัญ: *กล้องขยายแบบดิจิตอล ยู เอส บี ชนิดแท่ง, การสอนแสดงการตรวจภายในสตรี, นักศึกษาแพทย์*

Introduction

Pelvic examination is an essential component of women's annual health check up. This procedure typically consists of visual inspection of external genitalia, insertion of a speculum, performing of any tests of cytology and then bimanual palpation to determine the size and characteristic of uterus and ovaries[1-4].

Teaching how to perform a pelvic examination is challenging; it requires the integration of technical and communication skills. There are several teaching methods to help in introducing the pelvic examination to medical students[5,6]. Traditional lectures have some benefits such as efficient use of time for both instructors and students. The pelvic examination demonstration for medical students during their early clinical encounters has been an ideal teaching method to develop clinical and communication skills along with substantiating appropriate ethical practices with real patients. In addition, medical students could learn how to do suitable sensational examinations which would benefit their future patients to gain better standards of care[7-13].

In our institute, all of the fourth year medical students are taught the standard pelvic examination through the demonstration consisting of use of a speculum and bimanual examination, and practicing a Papanicolaou smear on an actual patient. Typically, after inserting a speculum, the students have to take turns looking through the speculum to see the cervix and observe how to perform the Papanicolaou smear. However, this approach seems to be inconvenient for the patient, the instructor and also the students. The medical students are usually unable to have a proper observation, which inevitably affects their confidence to perform subsequent pelvic examination independently.

In order to improve the teaching and demonstration of these basic techniques of pelvic examination to medical students, we designed a rod USB digital microscope as a teaching aid for pelvic examination demonstration. By applying this instrument, the tasks of pelvic examination demonstration can be displayed through the monitor connected to a laptop computer. Students can have a better look at the cervix, vaginal wall, and learn the necessary steps to perform a Papanicolaou smear in real time. The objective of this study was to evaluate the students' satisfaction among the fourth year medical students learning the female pelvic examination, as well as the added benefits of the rod USB digital microscope compared with the traditional method of learning.

Materials and Methods

An assessor-blinded, randomized control trial was conducted in a university hospital from June to December 2015. This study was approved by the Ethical Clearance Committee on Human Rights Related to Researches Involving Human Subjects of Faculty of Medicine Ramathibodi Hospital, Mahidol University.

Device

The rod USB digital microscope type 200X 2.0 MP Endoscope 6 is a new technology that has been applied as a pelvic examination teaching aid (Fig. 1). The rod USB digital microscope is a tubular imaging system consisting of an optical lens and an image sensor with a 3X zoom, an illumination mechanism, and an image transfer control circuit that can be connected to a computer on real time. The user can display the images captured by the rod USB microscope on computer screen, print them, or send them through the internet. Additionally, by applying the rod USB digital microscope for teaching medical students, the Ramathibodi vaginal sleeve for digital camera with a medical grade stainless 8 mm in diameter was invented to cover the camera to maintain sterility. To test the efficacy of the device, three gynecological staffs utilized the index of item objective congruence (IOC) to validate the rod USB digital microscope as a tool.

Participants

Participants were the fourth year medical students recruited after commencing an Obstetrics & Gynaecology rotation.

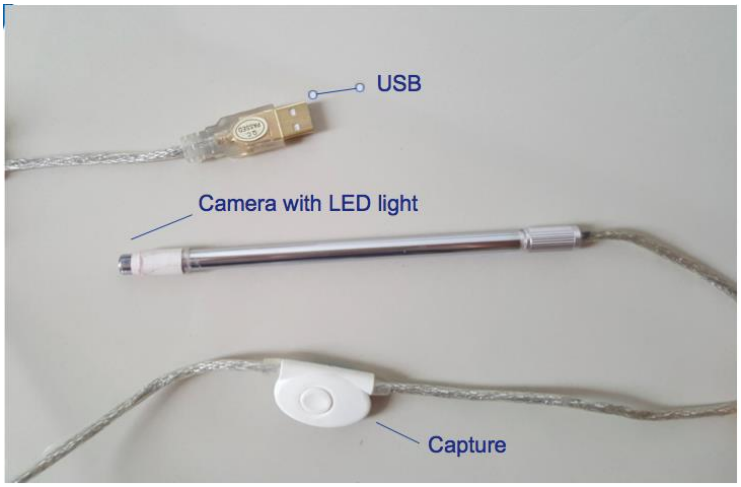

Fig. 1. Rod USB Digital Microscope.

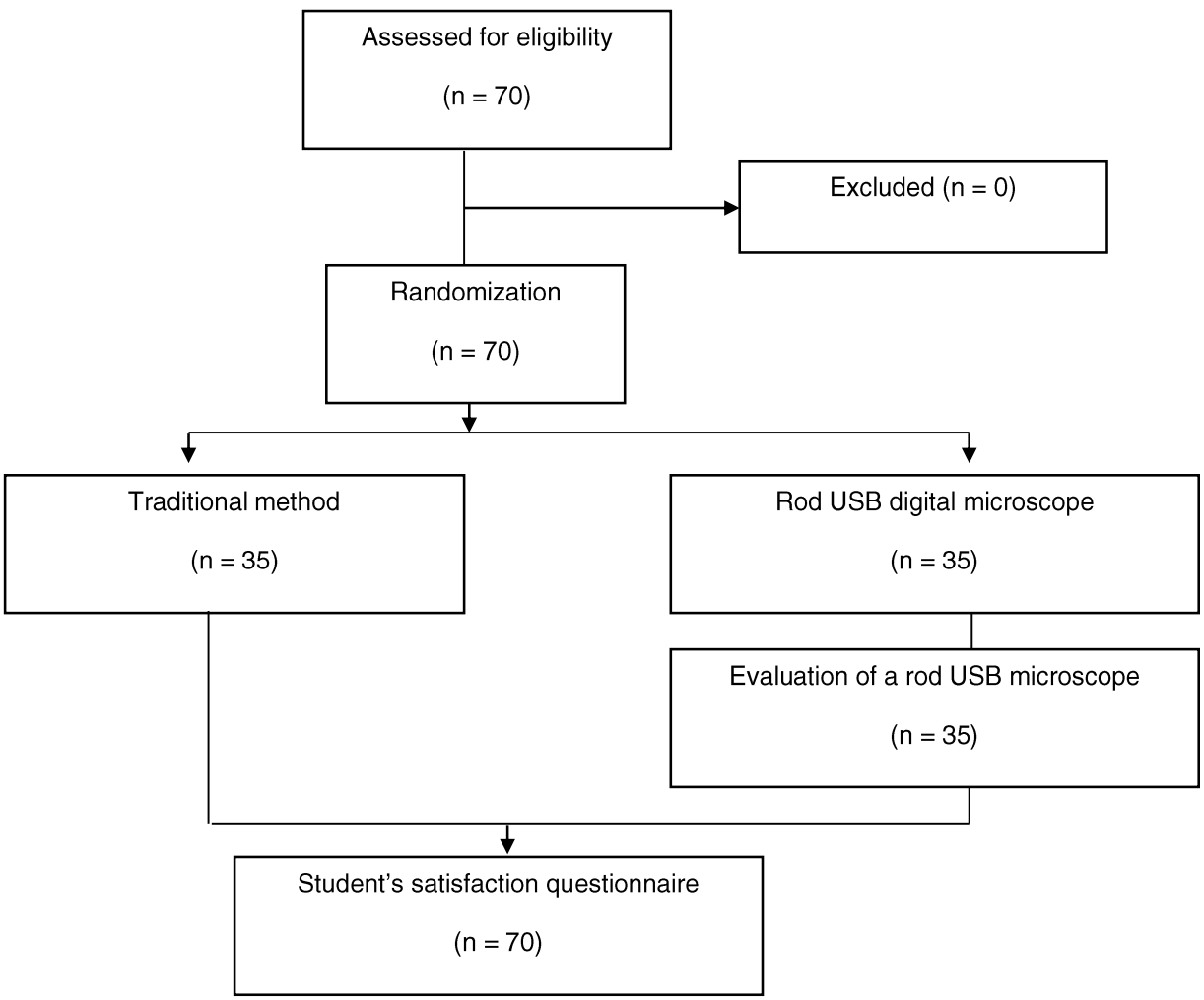

Fig. 2. Flow chart design.

Inclusion criteria

The fourth year medical students in Faculty of Medicine, Ramathibodi hospital, Mahidol University, Thailand from June to December 2015 in their fourth week of gynecologic rotation who agreed to participate in the study.

Exclusion criteria

The fourth year medical students who could not fully attend the procedure and complete the questionnaire.

All eligible participants gave written consent before entering the study. The third person performed a random number table generated independently from the investigator and put in the sealed envelop. The students were individually randomized by picking up a sealed envelope with number inside to divide them in each group they were assigned. This process was been in the fourth week of rotation class.

Intervention

During the fourth year of study, all medical students are given a lecture on the fundamental and technical skills involved with pelvic examination. Thereafter, the students participate in two learning sessions, which are a pelvic examination demonstration by an instructor and practicing a pelvic examination on a patient at the out patient clinic. Conventionally, the instructor (gynecologist) performs pelvic examination by applying speculum into a patient's vagina while teaching and discussing. All of the medical students in each group (6 medical students) observe pelvic examination by looking through the speculum one by one. To assign participants in each group, randomized assigned number were kept in sealed envelopes and opened individually. This process was been in the fourth week of rotation class.

Prior to the learning session, participants were asked about their demographic data and past experiences regarding the pelvic examination. Afterwards a standardized instructor demonstrated to the participants how to perform a pelvic examination on a real patient. This procedure consisted of speculum and bimanual examination and a Papanicolaou smear. The students in the study group were demonstrated with the rod USB digital microscope inserted through the speculum. The images were displayed on the computer screen and all of the students in study group could see them on the computer screen at the same time. For the students in control group, they could see one by one through the speculum. Promptly, after the learning session, participants in both groups were asked to fill in a students' satisfaction questionnaire. Participants in the study group also completed a questionnaire to evaluate of the rod USB digital microscope assisting in the pelvic examination learning session. The data was collected by one blinded assessor who did not know in which group the students were and was not in learning session to eliminate the bias.

Outcomes

The primary outcome was based on students' satisfaction of pelvic examination learning which was assessed immediately after applying the new methods of teaching. Participants were asked to complete the validated Thai version of students' satisfaction questionnaire. Students' satisfaction was evaluated after completed teaching session by the questionnaire: 10 questions, 5 rating scale[14].

The index of item objective congruence (IOC) was used to validate the questionnaire and the instrument by three gynecologists. The questionnaire was clear by 1.00; the standard measure was 0.50-1.00 by evaluation using the index of item objective congruence (IOC)[15].

The questionnaire was made in order to assess the students' satisfaction of traditional method and rod USB digital microscope by using Likert scaling[14]. Additionally, a blank was provided for students to give additional comments if necessary.

The secondary outcome was to develop the device. According to the contamination problem while the inserting rod USB digital microscope into vagina, we invented Ramathibodi vaginal sleeve for digital camera with 8 mm in diameter to apply a camera into vagina to maintain sterility. The device was modified according to the authors' consideration to affirm that the users' needs are met and it consistently provides the intended benefit in actual-use conditions in pelvic examination demonstration. Verification and validation were done by measurement of IOC for the clearly displayed pictures, high repeatability and patient's safety.

Sample size calculation

Pilot study was done by 50 students (25 students each group) for students' satisfaction to calculate the size of population. The students who were satisfied with the traditional method were 10 from 25 students and the rod USB digital microscope method were 24 from 25 students. The sample size was calculated from the formula for comparing proportion with $Z\alpha$ set as 1.96 and $Z\beta$ set as 1.28 with power of 90% and added with 10% of calculated number of participants who might be excluded due to data loss. Therefore, 35 students were needed in each group.

Statistical analysis

Pearson Chi-Square and Fisher Exact test, percentage were used for categorical data. Mann-Whitney U test was used for non-parametric data. Kolmogorov-Smirnov test was used to check normal distribution. Student's t-test was used to compare score in overall satisfaction and satisfaction in each teaching method. A p value of less than 0.05 was set as statistically significant. All data were analyzed using STATA version 14.0 software

Results

Firstly, the device was tested by 10 participants for its efficacy.

Then we proceeded to the clinical setting.

A total of 70 fourth year medical students in the faculty of Medicine, Ramathibodi hospital, Mahidol University, Thailand from June to December 2015 in the fourth week of gynaecologic rotation. There were 35 students in the study group (21 female, 14 male, aged 22.14 ± 0.36 years) and 35 in the control group (25 female, 10 male, aged 22.12 ± 0.33 years). The number that ever seen pelvic examination before were no significantly difference (4 (11.42%) vs 5 (14.28%) p-value = 1.00) (Table 1).

Table 1. Characteristics of students in traditional method and rod USB digital microscope groups.

	Traditional method (n = 35)	**Rod USB Digital Microscope (n = 35)**	**p value**
Age (years)[a] Mean ± SD	22.12 ± 0.33	22.14 ± 0.36	0.76
Gender[b] number (percent)	Female 25 (71.4%)	Female 21 (60%)	0.45
	Male 10 (28.57%)	Male 14 (40%)	
Number that ever seen pelvic examination before[b] number (percent)	4 (11.42%)	5 (14.28%)	1.00

[a] t-test

[b] Chi-square

Evaluation of Rod USB digital microscope

The overall for satisfaction of the rod USB digital microscope were high (4.75 ± 0.24) (Table 2). The top three highest satisfaction scores of rod USB digital microscope were 1. educational equipment, 2. adaption for diagnosis and treatment for Gynaecologic disease and 3. capturing for display.

Student's satisfaction

Most of the medical students showed high satisfaction with the rod USB digital microscope. There was significant of overall satisfaction between the rod USB digital microscope and traditional method (95%CI = 0.45-1.91, p < 0.001). Satisfaction score of the rod USB digital microscope and the traditional method are shown in Table 3. Compared with the traditional method, the rod USB digital microscope had a significant higher satisfaction score than the traditional method; appropriated technology, students' interest, appropriateness of education atmosphere, approach to point of Papanicolaou smear, however no significant difference in duration of examination of both method.

Table 2. Evaluation of the rod USB digital microscope (n = 35).

Questionnaire (Rod USB digital Microscope)	Mean	Specificity
1. Appropriated size	4.65	0.59
2. Appropriated for vaginal examination	4.37	0.81
3. Captured images to display	4.86	0.36
4. Advantage for pelvic examination teaching and learning	4.97	0.17
5. Adapted for diagnosis and treatment of Gynaecologic disease	4.91	0.28
Overall	4.75	0.24

* Normal distribution of data SD = standard deviation

Table 3. Student's satisfaction questionnaire (n = 70)

Questionnaire	Traditional method (n = 35)	Rod USB Digital Microscope (n = 35)	Mean difference (95% CI)	p value
1. Duration of examination	4.37 ± 0.81	4.69 ± 0.63	0.86 - 1.01	0.069
2. Appropriated technology	2.68 ± 0.68	4.89 ± 0.32	0.50 - 0.60	< 0.001
3. Student's interest	3.31 ± 0.90	4.83 ± 0.51	0.62 - 0.75	< 0.001
4. Appropriateness of education atmosphere	3.9 ± 1.15	4.97 ± 0.17	0.71 - 0.86	< 0.001
5. Approach to point of Pap smear	4.2 ± 0.96	5 ± 0.0	0.78 - 0.91	< 0.001
Overall	**3.69 ± 0.69**	**4.88 ± 0.12**	**0.45 - 1.91**	**< 0.001**

Comparison of student's satisfaction score according to gender

The overall of satisfaction score in both male and female medical students are higher than traditional method (Table 4). The satisfaction of male and female have no statistically significant in difference (p = 0.2529, 95%CI = -0.18 - 0.61). But there were higher score of male students' satisfaction than female in appropriated technology, appropriateness of education atmosphere, approach to point of Papanicolaou smear. However, the satisfaction of duration of examination and students' interest in female student are significantly higher than male students (p < 0.001).

Table 4. Comparison of student's satisfaction scores according to gender (n = 70).

Questionnaire	Mean ± SD		p value	95%CI
	Female	Male		
Traditional method (n = 35) Female = 25 male = 10				
1. Duration of examination	4.40 ± 0.82	4.10 ± 0.74	0.264	-0.27 - 0.95
2. Appropriated technology	2.84 ± 0.55	2.30 ± 0.82	0.031	0.05 -1.03
3. Student's interest	3.56 ± 0.92	2.70 ± 0.48	0.009	0.23 -1.49
4. Appropriateness of education atmosphere	3.80 ± 1.22	4.40 ± 0.84	0.167	-1.46 - 0.26
5. Approach to point of Pap smear	4.32 ± 0.80	3.90 ± 1.29	0.250	-0.31 - 1.15
Overall	**3.78 ± 0.63**	**3.48 ± 0.92**	**0.607**	**-0.85 - 1.45**
Rod USB Digital Microscope (n = 35) Female = 21 Male = 14				
1. Duration of examination	5.00 ± 0.00	4.21 ± 0.80	< 0.001	0.43 - 1.14
2. Appropriated technology	4.81± 0.40	5.00 ± 0.00	0.087	-0.4 - 0.03
3. Student's interest	5.00 ± 0.00	4.43 ± 0.76	0.001	0.24 - 0.90
4. Appropriateness of education atmosphere	4.95 ± 0.22	5.00 ± 0.00	0.422	-0.7 - 0.07
5. Approach to point of Pap smear	4.95 ± 0.22	5.0 ± 0.0	0.422	-0.7 - 0.07
Overall	**4.94 ± 0.07**	**4.72 ± 0.38**	**0.253**	**-0.18 - 0.61**

Discussion

The aim of this study was to evaluation medical students' satisfaction in learning pelvic examination with rod USB digital microscope. Teaching aid is one of the tools to satisfy the students in learning and teaching process[16]. Rod USB digital microscope is a teaching aid to motivate and satisfy the students in learning. The highest satisfaction in the questionnaire were the advantage of rod USB digital microscope for pelvic examination learning and teaching in a clear point of Papanicolaou smear, real time during learning and capturing images for display.

In this study, we found that the students as a whole significantly prefer learning with the rod USB digital microscope to the traditional method, especially understanding the point of Papanicolaou smear while practicing training from monitor display effecting learning and teaching achievement.

From the study, male and female students preferred learning by the rod USB digital microscope to

the traditional method. However the satisfactions of female students were significantly higher in appropriation of examination duration and interest in the rod USB digital microscope than male students. Nevertheless, male students were interested in adapting technology for a teaching aid to make them understand the point of Papanicolaou smear from computer screen connected to the rod USB digital microscope as a real time. The results among male and female students were compared in order to investigate the relationship between new technology and identity categories. Regarding the use of rod USB digital microscope connected to the computer in teaching pelvic examination, this study found that male had more preference than female on the point of appropriated technology. The earlier studies of Chen, Collis and Shashaani, found that male students, compared with their female peers, had more access to computers, felt more confident with their computer skills, and showed more positive attitude toward computers[17-19]. As the result of positive attitude toward computers, male preferred learning using computer as a teaching aid to female. Moreover, male students felt more comfortable to look in the vagina through monitor than through the speculum.

According to findings of duration in pelvic examination, the rod USB digital microscope and the traditional method were not significantly different.

From the additional free comment, most students commented that the rod USB digital microscope was very useful not only in education but also for diagnosis cervical abnormality. In addition, they can capture the images and make recording for self-study. The rod USB digital microscope is a cheap instrument for any hospital all over the country. The rod USB digital microscope doesn't cause pain to the patients because of its small size.

The strength of this study was that the medical education studies were rarely found and this study would benefit the further study to use the simple technology in teaching pelvic examination to help the medical students understand point of Papanicolaou smear clearly. Rod USB digital microscope could be helpful to diagnosis gynecologic disease. Moreover, the questionnaire and the device were validated by three gynecological staffs by using IOC (Index of item objective congruence).

There were some limitations in this study. Due to clinical performance evaluations were not performed. Further studies should be performed with clinical performance evaluation and larger population.

Conclusion

In conclusion, the rod USB digital microscope could be applied for pelvic examination demonstration with high satisfaction score of the fourth year medical students. The findings of this study suggested that the rod USB digital microscope should be applied to pelvic examination demonstration class. In addition, low price innovation may be used in further diagnosis of the gynecological disease and study.

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Potential conflicts of interest

The authors declare no conflict of interest.

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Factors Associated with Long-Acting Reversible Contraception (LARC) use in Postpartum Women at Srinagarind Hospital

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ABSTRACT

Objectives: To determine the associated factors those predict the use of long-acting reversible contraception (LARC) among postpartum women at Srinagarind Hospital.

Materials and Methods: A cohort study of postpartum women was conducted at Srinagarind Hospital from May to October 2016. LARC methods were defined as progestogen-only injectable contraceptives, intrauterine devices, and contraceptive implants. The participants were interviewed during admission to the postpartum ward in order to ascertain baseline information, as well as information regarding their intention to use or not to use LARC. The participants were interviewed again after their six week postpartum visit about the contraceptive method they actually used. Data of participants who did not appear for their six-week postpartum visit were obtained by telephone interview within 6-12 weeks after delivery. Logistic regression analysis was applied to determine the factors associated with LARC use.

Results: The mean age of the participants was 28.4 ± 5.7 years. One hundred twenty-six out of a total of 312 participants (40.4%) reported using LARC. The methods of LARC used were depot medroxyprogesterone acetate (DMPA) (82.5%) and contraceptive implants (17.5%). Participants who were more likely to use LARC included those who had expressed their intention to use LARC during the first interview, current students, and women whose medical expenses were covered by universal coverage scheme.

Conclusion: Rate of LARC use in this study was approximately 40%. The most common method of LARC used was DMPA. Significant independent factors affecting the use of LARC were participants' intentions, occupation, and type of health care coverage.

Keywords: contraceptive use, long-acting reversible contraception, postpartum women.

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ปัจจัยที่มีความสัมพันธ์ต่อการตัดสินใจใช้วิธีการคุมกำเนิดชนิดออกฤทธิ์นานของสตรีหลังคลอดที่โรงพยาบาลศรีนครินทร์

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บทคัดย่อ

วัตถุประสงค์: *เพื่อศึกษาปัจจัยที่มีความสัมพันธ์กับการเลือกใช้วิธีคุมกำเนิดชนิดออกฤทธิ์นานในสตรีหลังคลอดที่โรงพยาบาลศรีนครินทร์*

วิธีการวิจัย: *การศึกษาแบบไปข้างหน้าของสตรีที่คลอดบุตรที่โรงพยาบาลศรีนครินทร์ ในช่วงเดือนพฤษภาคมถึงเดือนตุลาคม พ.ศ. 2559 โดยการคุมกำเนิดชนิดออกฤทธิ์นานกล่าวรวมถึงยาฉีดคุมกำเนิด ห่วงอนามัย และยาฝังคุมกำเนิด อาสาสมัครที่เข้าร่วมงานวิจัยจะถูกสอบถามข้อมูลขณะที่พักรักษาตัวหลังคลอดอยู่ในโรงพยาบาล เกี่ยวกับปัจจัยพื้นฐานและความตั้งใจในการคุมกำเนิดชนิดออกฤทธิ์นาน และสอบถามข้อมูลเมื่อมาติดตามการรักษาหลังคลอด 6 สัปดาห์ หากสตรีหลังคลอดไม่ได้มาติดตามการรักษาจะใช้วิธีสอบถามทางโทรศัพท์เมื่อ 6-12 สัปดาห์หลังคลอด เพื่อสอบถามวิธีคุมกำเนิดที่เลือกใช้จริง หลังจากนั้นนำข้อมูลมาวิเคราะห์การถดถอยโลจิสติคพหุ*

ผลการวิจัย: *อายุเฉลี่ยของอาสาสมัครอยู่ในช่วง 28.4 ± 5.7 ปี อาสาสมัคร 126 จาก 312 คน (ร้อยละ 40.4) เลือกใช้วิธีการคุมกำเนิดชนิดออกฤทธิ์นาน โดยวิธีที่เลือกใช้ คือ ยาฉีดคุมกำเนิด (ร้อยละ 82.5) และยาฝังคุมกำเนิด (ร้อยละ 17.5) โดยปัจจัยที่ส่งผลต่อการเลือกวิธีการคุมกำเนิดชนิดออกฤทธิ์นาน ได้แก่ ความตั้งใจที่จะเลือกใช้ในการสอบถามครั้งแรก อาสาสมัครที่เป็นนักเรียน และสิทธิการรักษา*

สรุป: *การเลือกใช้วิธีการคุมกำเนิดชนิดออกฤทธิ์นานในการศึกษานี้ยังพบน้อย และชนิดที่มีการเลือกใช้มากที่สุด คือ ยาฉีดคุมกำเนิด โดยปัจจัยที่มีผลต่อการเลือกใช้ คือ ความตั้งใจของอาสาสมัคร อาชีพ และสิทธิ์การรักษา*

คำสำคัญ: *การคุมกำเนิด, วิธีคุมกำเนิดชนิดออกฤทธิ์นาน, สตรีหลังคลอด*

Introduction

Family planning is the most cost-effective intervention that can be employed in order to reduce perinatal morbidity, mortality, and the burden of childbearing[1, 2]. Appropriate pregnancy spacing improves health and survival for children[3-7]. The deleterious effects of multiparity with too close spacing include fetal death, low birth weight, preterm labor, and infants being small for their gestational age[5-7]. The goals of family planning often are not realized in cases of pregnant Thai adolescents and young women, in approximately 65% of which the pregnancies are unintended[8, 9].

According to recent guidelines proposed by the United Kingdom's National Institute for Health and Care Excellence (NICE), long-acting reversible contraception (LARC) is defined as contraceptive methods requiring administration less than once per cycle or month such as progestogen-only injectable contraceptives, intrauterine devices, and contraceptive implants[10]. However, the American College of Obstetricians and Gynecologists (ACOG) defines LARC as consisting only of intrauterine devices and contraceptive implants[11]. Both NICE and ACOG have long recommended LARC as the most effective reversible contraceptive option for most women of reproductive age[10, 11].

However, LARC use remains suboptimal in some settings. For example, a previous study conducted among 1,009 Thai postpartum women observed a notably low prevalence of intrauterine device and contraceptive implant use (0.8%). The most common reversible contraceptive method used in this study was depot medroxyprogesterone acetate (DMPA) (38.4%), a progestogen-only injectable contraceptive that is available in Thailand[12]. According to data collected among women who attended the Family Planning Clinic at Khon Kaen University's Srinagarind Hospital (Thailand) from 2013-2015, the usage rates of intrauterine devices, contraceptive implants, and DMPA were 2.7%, 4.2%, and 20.0%, respectively.

This study was conducted to determine factors associated with LARC use among postpartum women who attended the Srinagarind Hospital Family Planning Clinic. This information may be helpful in planning and implementing interventions aimed at promoting the use of LARC in our setting.

Materials and Methods

After receiving an approval from the Khon Kaen University Ethics Committee in Human Research (HE591022), a cohort of postpartum women at Khon Kaen University's Srinagarind Hospital were recruited from May to October 2016. Women who desired permanent contraception or those whose deliveries were complicated with neonatal death were excluded. Informed consent was obtained from all participants. In this study, LARC was defined according to the NICE guidelines which include progestogen-only injectable contraceptives, intrauterine devices, and contraceptive implants[10].

First, participants were interviewed during admission to the postpartum ward by trained interviewers who used a standardized questionnaire to collect information on baseline characteristics, previous contraception practices, and their intentions with regard to LARC usage. Delivery outcomes were extracted from medical and labor records. Participants were interviewed again at the Family Planning Clinic after their six-week postpartum visit about the contraceptive method that they actually used. Data of participants who did not attend the six-week postpartum visit were obtained by phone interview within 6-12 weeks after delivery following the data required in the standardized questionnaire. Participants who changed their minds about LARC use were interviewed for root cause analysis.

A sample size of 310 participants was required for multiple logistic regression analysis with 80% power of analysis. There was an expected incomplete data rate of 15% which meant that 357 participants were required for this study.

Data were analyzed using the STATA program version 10 (Stata Corp, College Station, TX, USA). Descriptive statistics including mean ± standard

deviation (SD) and number (percentage) were used to describe the baseline characteristics of the participants, rate of LARC use, and root cause analysis of participants who had originally intended to use LARC but ultimately changed their minds. Chi-square test or Fisher's exact test was applied whenever appropriate to compare between the groups. Univariate analysis was carried out to identify variables potentially associated with the LARC use. Variables with a p value of less than 0.20 according to univariate analysis were further included in a backward elimination logistic regression analysis to determine which, if any, were independently associated with LARC use.

Results

During the study period, data obtained from 312 participants were suitable for analysis. The mean age of the participants was 28.4 ± 5.7 years with most being 20-35 years old. Seventeen participants were currently students (5.4%). Of the 312 participants, 126 reported having used LARC (40.4%; 95% confidence interval [CI], 34.9% to 46.1%). The methods used were DMPA (104 participants; 82.5%) and implants (22 participants; 17.5%). Table 1 displays the baseline characteristics of the participants. Participants who used LARC were more likely to declare that the current pregnancy was unintended than those who did not use LARC (21.4% versus 14.5%, respectively). The mean ages of women who used LARC and those who did not use LARC were 27.7 ± 6.3 and 28.9 ± 5.3 years, respectively.

Table 1. Baseline characteristics.

	Non-LARC N = 186	LARC N = 126	p value*
Age			0.164
Under 20 years old	8 (4.37)	12 (9.52)	
Between 20 and 35 years old	156 (85.25)	99 (78.57)	
35 years or older	19 (10.38)	15 (11.90)	
Educational attainment			0.655
In high school	19 (10.50)	16 (13.11)	
High school graduate or equivalent	78 (43.09)	55 (45.08)	
Bachelor degree or higher	84 (46.41)	51 (41.80)	
Occupation			0.001
Housewife/ Unemployed	36 (19.64)	30 (24.00)	
Business owner	34 (18.58)	21 (16.80)	
Government officer	46 (25.41)	23 (18.40)	
Employee	65 (35.52)	36 (28.80)	
Student	2 (1.09)	15 (12.00)	
Income (Baht/month)			0.059
Less than 15,000	69 (37.10)	61 (48.41)	
15,000-30,000	81 (43.55)	51 (40.48)	
More than 30,000	36 (19.35)	14 (11.11)	
Multiparity	54 (29.03)	29 (23.02)	0.238
Unintended pregnancy	27 (14.52)	27 (21.43)	0.113
Neonatal birth weight			0.856

Table 1. Baseline characteristics. (Cont.)

	Non-LARC N = 186	LARC N = 126	p value*
Less than 2,500 grams	13 (6.99)	11 (8.73)	
2,500 – 4,000 grams	171 (91.94)	114 (90.48)	
More than 4,000 grams	2 (1.08)	1 (0.79)	
Follow-up Hospital			0.014
Clinics/ private hospital	41 (22.04)	40 (31.74)	
Primary care hospital	47 (25.26)	18 (14.28)	
Secondary care hospital	21 (11.29)	7 (5.55)	
Tertiary care hospital	77 (41.39)	61 (48.41)	

Abbreviation: LARC, long acting reversible contraception
Data are presented as number (percentage)
* p value was calculated via the Chi-square or Fisher exact test, as appropriate

Table 2 shows the results of logistic regression analysis. Three variables were independently associated with the LARC use: intention to use LARC (as declared at admission to the postpartum ward), occupation, and type of health care coverage.

Only 69 out of 114 participants (60.5%) who had expressed a desire to use LARC were actually using it at the time of their postpartum visit. However, 57 out of 198 participants (28.8%) who expressed that they did not intend to use LARC had actually ended up using it at the time of their postpartum visit. The total number of women using LARC at the time of their postpartum visit in this study was only 126 out of 312 (40.4%).

Table 2. Factors associated with LARC used at 6-12 weeks postpartum.

	Crude OR (95% CI)	p value	Adjusted OR* (95% CI)	p value
Occupation				
Housewife/ Unemployed	Reference	Reference	Reference	Reference
Business owner	0.74 (0.35-1.53)	0.420	0.82 (0.37-1.78)	0.618
Government officer	0.60 (0.29-1.20)	0.151	0.96 (0.40-2.29)	0.933
Employee	0.66 (0.35-1.25)	0.206	1.01 (0.47-2.19)	0.958
Student	9.00 (1.90-42.52)	0.006	6.90 (1.40-34.06)	0.018
Desire to use LARC	3.79 (2.33-6.16)	< 0.001	3.55 (2.12-5.96)	< 0.001
Health care coverage				
Civil Servant Medical Benefit Scheme	Reference	Reference	Reference	Reference
Social Security Scheme	1.19 (0.61-2.31)	0.598	1.34 (0.57-3.15)	0.494
Universal coverage Scheme	2.25 (1.11-4.52)	0.023	2.70 (1.07-6.80)	0.035

Abbreviation: LARC, long acting reversible contraception; OR, Odd ratio; CI, confidence interval
* Adjusted for occupation, desire to use LARC and type of health care coverage

The in-depth reasons that the 126 participants used LARC are listed in Table 3. These included convenience, lack of impact on the quantity or quality of breast milk, recommendation by a physician, and planning for a space of ≥ 3 years before their next pregnancy. Table 4 displays the reasons for participants not using LARC, despite having initially expressed their intention to do so.

Table 3. Reasons of 126 participants who finally used LARC methods.

Reasons	N = 126
Convenience	59 (46.82)
No effect on amount of breast milk	25 (19.84)
Suggestion by doctors	15 (11.90)
Desire for 3 years or more between pregnancies	11 (8.73)
Previous LARC use	2 (1.58)
Other	14 (11.10)

Abbreviation: LARC, long acting reversible contraception
Data are presented as number (percentage)

Table 4. Reasons of 45 participants who had initially expressed a desire to use LARC, but who subsequently changed their minds.

Reasons	N = 45
Never had sexual intercourse/ Never lived together	17 (37.77)
Inconvenience	7 (15.55)
Financial problem	5 (11.11)
Previous used	3 (6.66)
No affected to breast milk production	3 (6.66)
No follow up/ instruction	3 (6.66)
Amenorrhea	2 (4.44)
Adverse effects	2 (4.44)
Impropriation of the number/ gender of children	2 (4.44)
Receiving false information	1 (2.22)

Abbreviation: LARC, long acting reversible contraception
Data are presented as number (percentage)

Discussion

This study was conducted at a tertiary university hospital in Northeast Thailand. We found that 114 of the 312 participants (36.5%) enrolled expressed a desire to use LARC at the time of their admission to the postpartum ward, and that 69 (60.5%) of these participants actually ended up using LARC at the time of their six-week postpartum visit. The most common type of LARC used was DMPA (82.5%). The findings observed in this study were consistent with those of a previous study in Thailand[12]. The significant independent factors that

predicted the use of LARC were participants' initial intention to use LARC, occupation, and type of health care coverage.

This study revealed that participants who intended to use LARC were approximately 3.5 times more likely to use when compare to those who did not plan to use. This finding might indicate important considerations when promoting LARC use such as antenatal health education with regard to LARC methods. A previous randomized controlled trial found more contraceptive used among postpartum women who received antenatal counseling than who received only postpartum counselling sessions[13].

Occupation was also found to be a significant independent factor for LARC use (Table 2). Students were 6.9 times more likely to use LARC compared to participants applied as a reference level. This may be the result of an increased effort to offer LARC to students, as well as pressure from their families to use contraception, reduce the risk of contraceptive failure, and prevent unintended pregnancy[8, 9, 12].

The cost of LARC may limit its use if it is not included in woman's health care coverage[14]. The type of health care coverage was also found to be independently associated with the use of LARC in this study (Table 2). Participants whose medical expenses were covered by the universal coverage scheme were more likely to use LARC compared to those who were covered by the Civil Servant Medical Benefit Scheme which is the welfare health services for government or state enterprise officer and do not cover any contraceptive methods (OR, 2.70; 95% CI, 1.07-6.80). However, the uptake rate of LARC among participants whose medical expenses were covered by the social security scheme did not significantly differ from those under the universal coverage scheme (OR, 1.34; 95% CI, 0.57-3.15). Meticulous exploration of the underlying reasons and possible causes leading to the underuse of LARC methods among postpartum women with some types of health care coverage is warranted. This may be due to some women having to pay for LARC out of pocket.

Misconceptions regarding LARC are not uncommon[14]. There were some misconceptions about LARC methods noted in this study (Table 4). For example, some participants who had originally expressed their intention to use LARC did not end up doing so due to cost (approximately 11.1%) and inconvenience (approximately 15.5%). Additionally, some participants who had changed their minds about LARC use were concerned that LARC may affect to their milk production (approximately 6.6%) or cause adverse effects (approximately 4.4%). These findings confirm the importance of counselling and correcting misinformation about the advantages and safety of LARC among postpartum women.

Some limitations of this study were worthy of note. First, the majority of LARC methods used in this study were DMPA. Second, there was no information regarding the details of contraceptive practice among 45 participants who had initially expressed a desire to use LARC but had changed their mind later. Third, we applied face to face interview which might affect to the participants' decision. Additionally, this study was conducted at a tertiary hospital in a low-middle income country. Generalization of the results to the use of other LARC methods and different population settings may be limited.

Conclution

In conclusion, the rate of LARC use in this study was approximately 40%. Significant independent factors affecting the use of LARC were participants' initial intention, occupation, and type of health care coverage.

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Potential conflicts of interest

The authors declare no conflict of interest.

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