การศึกษาเปรียบเทียบปริมาณการเสียเลือดหลังคลอด ระหว่างการประเมินด้วยสายตาและการใช้ถุงตวงเลือดในสตรีตั้งครรภ์ที่คลอดทางช่องคลอดในโรงพยาบาลสรรพสิทธิประสงค์: การศึกษาทดลองแบบสุ่มปกปิดสองทางมีกลุ่มควบคุม

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บทคัดย่อ

วัตถุประสงค์: เพื่อเปรียบเทียบปริมาณการเสียเลือดหลังคลอด ระหว่างวิธีการประเมินด้วยถุงตวงเลือดและการประเมินด้วยสายตาในสตรีตั้งครรภ์ที่คลอดบุตรทางช่องคลอด

วัสดุและวิธีการ: การศึกษาทดลองแบบสุ่มทำในสตรีตั้งครรภ์ที่มาคลอดบุตรทางช่องคลอดที่โรงพยาบาลสรรพสิทธิประสงค์ช่วงระหว่างเดือนพฤศจิกายน 2559 ถึงเดือนเมษายน 2560 อาสาสมัครจำนวน 320 คนที่เข้ามาในการศึกษาถูกแบ่งออกเป็นกลุ่มคู่ขนาน 2 กลุ่ม คือกลุ่มที่ 1 ประเมินโดยใช้ถุงตวงเลือด และกลุ่มที่ 2 กลุ่มประเมินด้วยสายตา โดยกลุ่มที่ 1 นั้นจะถูกประเมินปริมาณการเสียเลือดโดยวิธีถุงตวงเลือดเท่านั้น ส่วนกลุ่มที่ 2 นั้นจะประเมินปริมาณการเสียเลือดด้วยสายตาร่วมกับวิธีถุงตวงเลือด ทำการเก็บข้อมูลทางคลินิกของอาสาสมัคร ประวัติการคลอดและภาวะแทรกซ้อนของทารกแรกเกิดและภาวะแทรกซ้อนหลังคลอด

ผลการศึกษา: ในอาสาสมัคร 312 คนที่เข้ามาในการศึกษา พบอาสาสมัคร 4 คนในกลุ่มใช้ถุงตวงเลือด และ 7 คนในกลุ่มประเมินด้วยสายตา ที่ถูกคัดออกเนื่องจากคลอดโดยการผ่าตัดคลอดและข้อมูลไม่ครบ เหลืออาสาสมัคร 301 คนในการวิเคราะห์ ค่ามัธยฐานปริมาณเสียเลือดหลังคลอดแตกต่างกันอย่างมีนัยสำคัญระหว่างกลุ่ม โดยที่กลุ่มถุงตวงเลือดได้ 349.1 มิลลิลิตรและกลุ่มการประเมินด้วยสายตาได้ 320 มิลลิลิตร (P=0.01) เมื่อพิจารณาเปรียบเทียบในกลุ่มที่ได้รับการประเมินด้วยทั้งสองวิธี พบว่ามัธยฐานปริมาณเลือดที่ประเมินประเมินด้วยสายตาได้ 320 มิลลิลิตร แตกต่างกับปริมาณเลือดที่เสียจริงหลังคลอดจากการใช้ถุงตวงเลือด 377.1 มิลลิลิตร อย่างมีนัยสำคัญ (P< 0.001) ภาวะตกเลือดหลังคลอดไม่แตกต่างกันระหว่างกลุ่ม โดยในกลุ่มประเมินด้วยถุงตวงเลือดพบร้อยละ 17.1 ขณะที่กลุ่มที่การประเมินด้วยสายตาพบร้อยละ 25.5 ส่วนการเปลี่ยนแปลงค่าของฮีโมโกลบิน ความเข้มข้นของเลือด ก้อนเลือดคั่งบริเวณฝีเย็บ การได้รับเลือด ทั้งสองกลุ่มไม่แตกต่างกันอย่างมีนัยสำคัญ

สรุป: การประเมินปริมาณการเสียเลือดหลังคลอดโดยใช้ถุงตวงเลือดมีความแม่นยำมากกว่าการประเมินด้วยสายตาในสตรีตั้งครรภ์ที่คลอดบุตรทางช่องคลอด

คำสำคัญ: การประเมินการเสียเลือดหลังคลอด ถุงตวงเลือด ภาวะตกเลือดหลังคลอด

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Introduction

Postpartum hemorrhage (PPH) was the leading cause of the maternal mortality which account for 19.7%[1] worldwide. This is an important obstetric emergency causing postpartum maternal death in several countries. More than half of mothers in postpartum period were died within 24 hours due largely to abnormal uterine bleeding.[2] According to the data of the year 2012 from the World Health Organization (WHO 2012), PPH affects approximately 2% of all women who give birth. It is associated not only with nearly one quarter of all maternal deaths globally but is also the leading cause of maternal mortality in most low-income countries[3]. The overall aspects of maternal deaths in Thailand during the year 2007- 2011, the statistic showed the annual dead rate of mother at 12.2, 11.3, 10.2 and 8.9 per 100,000 live births. The major cause of deaths came from PPH.[4] From study in Srinagarind Hospital, Faculty of Medicine, Khon Kaen University, prevalence of PPH in 2001-2010 was approximately 1- 2 % of the parturients who had vaginal delivery.[5]

The study in Tha Uthen Hospital, Nakhon Phanom, compared difference of blood loss and proportion of pregnant women who had significant blood loss of 300-500 ml recorded using collecting bag VS visual estimation. This study in 121 women who attended antenatal care and delivered vaginally without any complications during February to July 2014 revealed significant different blood loss of 218 ml and 314 ml, in plastic film collecting bag and visual estimation group, respectively, ($P<0.001$).[6]

The average number of pregnant women who delivered vaginally in Sanpasitthiprasong, the referral center in northeastern region of Thailand, was 4500 per year during 2013-2015. The prevalence of PPH for vaginal delivery was at the average of 3.9%. In the year 2016, collecting bag was used for women undergoing vaginal delivery, prevalence of PPH was markedly increased to 13.8%. The primary purpose of this study was to compare postpartum blood loss volume between using plastic collecting bag (CB) compared with visual estimation (VE) in pregnant women who delivered vaginally in Sunpasitthiprasong Hospital, Ubonratchathani.

Materials and Methods

This randomized controlled trial conducted after an approval from the Ethics Committees, Sunpasitthiprasong Hospital. All pregnant women who delivered vaginally in Sunpasitthiprasong Hospital during November 2016 to April 2017 were eligible. All participants were informed about the study and signed the informed consent before enrollment. The inclusion criteria were viable singleton pregnant women after 24 weeks of gestation (estimated from the last menstrual period, validated by antenatal record review and ultrasonographic confirmation). The exclusion criteria were dead fetus in utero, maternal history of bleeding tendency, those who refused to participate, and those who just received blood transfusion (less than 7 days).

A total of 312 pregnant women were randomly allocated into two groups: collecting bag (CB) and visual estimation (VE). Computer-generated randomization was used to create

randomization number. Allocation concealment was assigned by sequentially opaque, sealed envelopes. An envelope was picked up and opened by the attending physician or nurse in the delivery room before the participants delivered vaginally. The participants, attending physician and nurse were blinded to the assignment. When the participants reached the stage of pushing and the force of contraction, the collecting bags were placed in all cases. The blood loss in CB group was estimated by collecting bag plus actual loss on gauze, while participants in VE group would use both CB and VE methods to estimate blood loss. The collecting bag was put under the buttocks in lithotomy position, and immediately opened after the baby had been delivered and the amniotic fluid had been cleaned off. After neonatal umbilical cord clamping, the placenta was delivered and the blood was flown into CB. The total amount of blood loss was calculated including blood volume in CB and all gauze, and pad used by assistant nurse when finishing suturing. Measuring blood loss volume 1 ml. was equally 1.06 gram.[7]

Baseline characteristics included age, race, referral status, parity, prepregnant body mass index (BMI [kg/m^2]), gestational age (GA) were recorded. The clinical data relating to PPH such as previous history of PPH, precipitate labor, prolonged second stage of labor, using tocolytics, induction of labor or augmentation more than 8 hours, neonatal birthweight and sex were recorded. The primary outcome of postpartum blood loss volume in CB group were recorded in ml from exact calculation, while in VE group blood loss was assess by both CB and VE techniques. The secondary outcomes such as prevalence of PPH, cause of PPH, perineal hematoma, blood component transfusion, postpartum change of hematocrit (Hct), hemoglobin (Hb) at admission and 24 hours after delivery. Blood pressure, pulse rate, and oxygen saturation using non-invasive monitor were evaluated every 15 minutes since fully cervical dilatation to 2 hours after delivery. PPH was defined as blood loss 500 ml or more. Postpartum complications, defined as the changes in hemoglobin and hematocrit, perineal hematoma, blood transfusion, pulse rate of over 100 beats per minute, oxygen saturation less than 95%, and blood pressure decreased less than SBP < 90 mmHg or DBP < 60 mmHg.

The sample size was calculated according to the study by Kadri HM[8] which reported of 30% underestimation of calculated blood volume loss during postpartum using VE compared with CB. With 80% power and a two-sided type I error at 5% and expected loss follow-up of 5%, the sample size of 312 participants were required to evaluate the primary outcome between groups.

The results were analyzed by SPSS version 16.0 (SPSS Inc., Chicago, IL, USA). Descriptive statistics were carried out using mean, standard deviation (SD), median, interquartile range (IQR). Categorical variables were tested for statistical significance with the Chi-square test. Continuous variables were evaluated for distribution using Kolmogorov–Smirnov test. Student t test and Mann-Whitney U test were used for normally-distributed and non-normally distributed data, respectively. Wilcoxon Signed Ranks Test was applied for significant testing in the same group. A P value of < 0.05 was considered statistically significant.

Results

Of the total 925 pregnant women at gestational age (GA) of 24 weeks or more, who admitted for delivery at labor room, Sunpasitthiprasong Hospital, during November 2016 to April 2017, 612 women were excluded from the study. These include 538 cases under private care, 50 cases refused to take part of the study, 4 cases of intrauterine fetal death and 10 cases recently receiving blood transfusion within one week of delivery. Consequently, 312 pregnant women were enrolled and divided into two equal groups of 156. After randomization, 11 participants (7 in VE group and 4 in CB group) dropped out due to incomplete data and underwent cesarean section as shown in Figure 1.

The clinical characteristics between groups were not significantly different in terms of age, race, GA, referred status, parity, prepregnant BMI, and underlying diseases such as presence of hypertension prior to or after 20 weeks of gestation. The risk factors of PPH such as previous history of PPH, induction/ augmentation of labor, tocolytics use, prolonged second stage of labor, precipitate labor, perineal laceration and causes of PPH were not significantly different as shown in Table 1.

Figure1. Enrollment and randomization the study participants

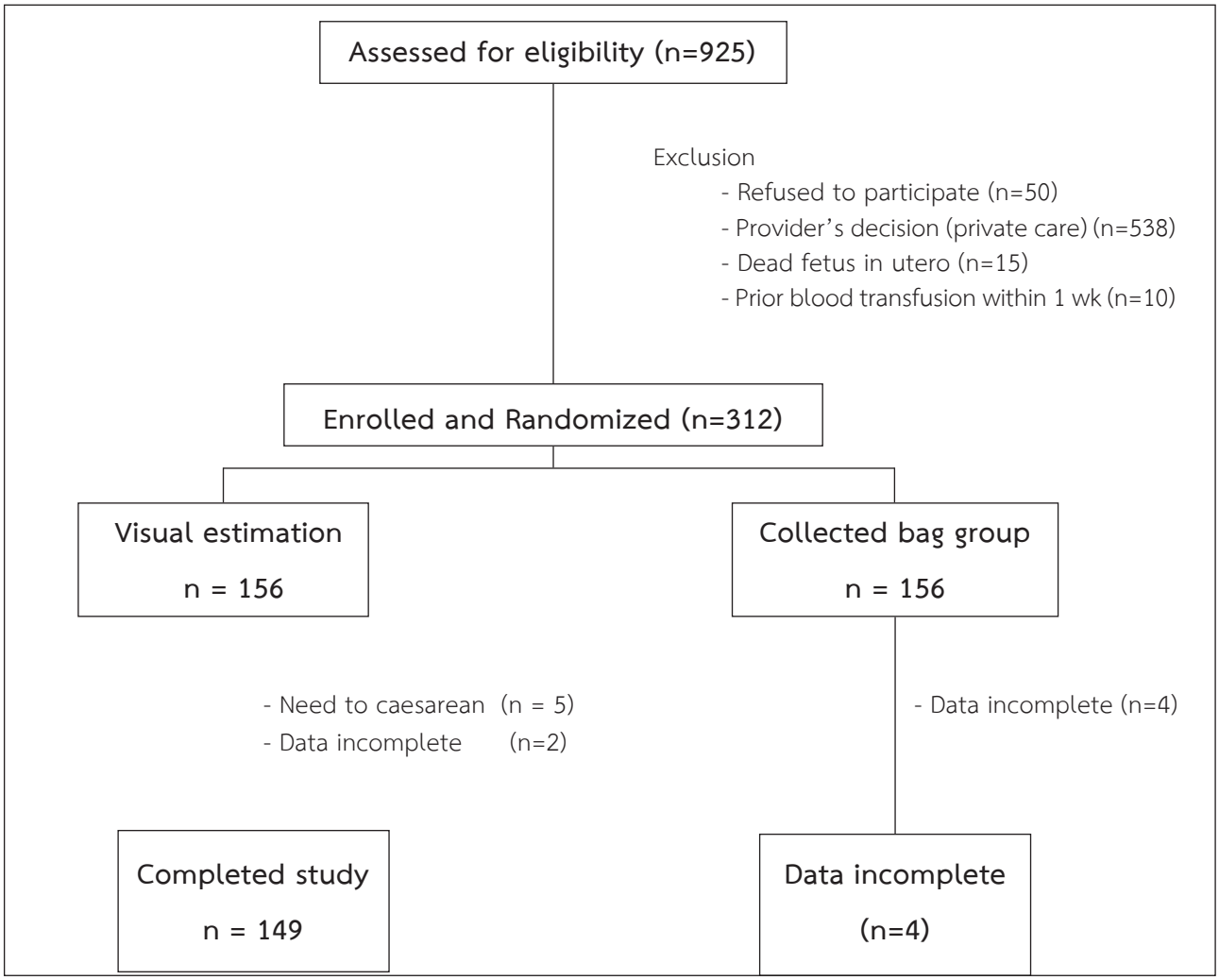

Table 1. Baseline characteristics of the participants (n= 301)

Characteristics	Collected bag group (n=152)	Visual estimated group (n=149)	p-value*
Age (year), mean (SD)	24.1 (5.7)	24.5 (6.3)	0.80[a]
Teenage (<20)	103 (67.8%)	102 (68.5%)	0.18[b]
Normal age (20-34)	42 (27.6%)	33 (22.1%)	
Advanced age (≥35)	7 (4.6%)	14 (9.4%)	
Race, n(%)			0.13[b]
Thai	144 (94.7)	146 (98.0)	
Other races (Loa, Myanmar)	8 (5.3)	3 (2.0)	
Refer in, n(%)			0.54[b]
No	104 (68.4)	97 (65.1)	
Yes	48 (31.6)	52 (34.9)	
Prepregnant BMI (kg/m2), n(%)			0.32[b]
Under weight (<20.0)	48 (32.6)	39 (26.2)	
Normal weight (20.0-24.9)	70 (46.1)	64 (43.0)	
Over weight (≥25.0-29.9)	25 (16.4)	37 (24.8)	
Obesity (≥30.0)	9 (5.9)	9 (6.0)	
Gestational age, weeks, n(%)			0.85[b]
< 37 weeks	23 (15.1)	20 (13.4)	
$37\text{-}40^{+6}$ weeks	125 (82.2)	126 (84.6)	
≥41 weeks	4 (2.7)	3 (2.0)	
Parity, n(%)			0.87[b]
Nullipara	79 (52.0)	76 (51.0)	
Multipara	73 (48.0)	73 (49.0)	
Chronic hypertension/PIH, n(%)	9 (5.9)	10 (6.7)	0.78[b]
Previous PPH, n(%)	0	1 (0.7)	0.49[c]
Induction/Augmentation >8hrs, n(%)	8 (5.3)	9 (6.0)	0.77[b]
Tocolytic drugs, n(%)			0.60[b]
Magnesium sulfate	0	1 (0.7)	
Terbutaline	1 (0.7)	1 (0.7)	
Prolong second stage of labor, n(%)	1 (0.7)	2 (1.3)	0.55[b]
Precipitate labor, n(%)	8 (5.3)	10 (6.7%)	0.60[b]
Tear perineum, n(%)			0.89[b]
No tear	3 (2.0)	3 (2.0)	
First degree	3 (2.0)	3 (2.0)	
Second degree	141 (92.8)	140 (94.0)	

Table 1. Baseline characteristics of the participants (n= 301) (ต่อ)

Characteristics	Collected bag group (n=152)	Visual estimated group (n=149)	p-value*
Third degree	4 (2.6)	3 (2.0)	
Fourth degree tear	1 (0.7)	0	
Neonatal sex, n(%)			0.77
Male	76 (50.0)	77 (51.7)	
Female	76 (50.0)	72 (48.3)	
Neonatal birthweight (grams), mean (SD)	3015.6 (432.7)	2959.8(435.1)	0.27[a]
Low birth weight (<2,500), n(%)	21(13.8%)	14(9.4%)	
Normal weight (2,500-3,999), n(%)	130 (85.5%)	134(89.9%)	
Macrosomia (≥4,000), n(%)	1 (0.7%)	1 (0.7%)	

PIH, Pregnancy Induce Hypertension; IV, intravenous route; BMI, Body Mass Index

[a] p-value from comparison of mean using independent- student t test

[b] p-value from chi-square test,

[c] p-value from Fisher's Exact test

Regarding the primary outcome, the median (IQR) volume of postpartum blood loss, was significantly different between group [349.1 ml (268.5, 429.2) in CB group VS 320 ml (180,450) in VE group, P=0.01]. The incidence of PPH was not significantly different (17.1 % CB group VS 25.5 % in the VE group, P=0.08). (Table 2) Changes in hemoglobin (Hb) and hematocrit (Hct) level evaluated before vaginal delivery and at 24 hours postpartum were not significantly different between groups [median (IQR) Hb of -1.7 (-2.4,-1.1)] in CB group VS -1.7 (-2.5,-1.1) in VE group, P=0.612 and median (IQR) Hct of -5.0 (-7.2,-3.1) in CB group VS -5.1 (-7.9,-3.1) in VE group, P=0.685]. Postpartum complications related to PPH were not significantly different (17.1% in CB group VS 25.5% in VE group, P=0.075). There was no difference in perineal hematoma (p=0.63) and blood transfusion following labor (p=1.00) between groups.

Table 2. Comparison postpartum blood loss and treatment (collected bag group vs visual estimated group) n= 301

Characteristics	Collected bag group(n=152)	Visual estimated group (n=149)	p-value*
Estimated postpartum blood loss (ml), median (IQR)	349.1 (268.5,429.2)	320 (180 ,450)	0.01c
< 500 ml, n(%)	125 (82.9)	111 (74.5)	0.10a
≥ 500 ml, n(%)	27 (17.1)	38 (25.5)	
Causes of PPH, n(%)			0.31a
Uterine atony	21 (32.8)	28 (43.8)	
Episiotomy	4 (6.1)	7 (10.9)	
Retained placenta	0	2 (3.2)	
Perineal laceration	1 (1.6)	1 (1.6)	
Perineal hematoma, n(%)	3 (2.0)	1 (0.7)	0.63b
Blood transfusion, n(%)	4 (2.6)	4 (2.7)	1.00b
Change in Hb, mg/dl, median (IQR)	-1.7(-2.4,-1.1)	-1.7 (-2.5,-1.1)	0.61c
Change in Hct, %, median (IQR)	-5.0 (-7.2,-3.1)	-5.1(-7.9,-3.1)	0.68c

Hct, Hematocrit; Hb, Hemoglobin; PPH, Postpartum hemorrhage

a P-value from chi-square test

b P-value from Fisher's Exact test

c P-value from comparison of median using Mann-Whitney U Test,

Subgroup analysis in VE group, the median (IQR) volume of blood loss after delivery was 320 ml (180, 450) by visual estimation while the actual median (IQR) volume of blood loss by exact calculation from CB and gauze was 377.1 ml (275, 514.1). This blood loss estimation was different (P<0.001) as described in Table 3.

Table 3. Blood losses assessed by both visual estimation and exact calculation in visual estimation (VE) group (n=149)

Visual estimation group	Median (IQR)	Min -Max	P-value*
Visual estimated blood loss (ml)	320.0 (180, 450)	50-1050	<0.001
True estimated blood loss (ml)	377.1 (275.9, 514.1)	61.3-1188.7	

Median (interquartile range, IQR),
*P-value from Wilcoxon Signed Ranks Test

PR of over 100 beats per minute at 1 hour of second stage labor was observed in 38.2% in the CB group and 36.9% in the VE group. This was not significantly different (P=0.08). Oxygen saturation of less than 95% at 1 hour of second stage of labor was observed in 1.3% in the CB group and 0.7% in the VE group. This difference was not significantly different. At 2 hours of second stage of labor, pulse rate (PR) of over 100 beats per minute was recorded in 26.3% in the CB group and 24.2% in the VE group. This difference between both groups was not significantly different (P=0.66). Oxygen saturation of less than 95% at 2 hours of second stage of labor was observed in 1.32% in the CB group and 2.0% in the VE group. This was not significantly different (P=0.63). Systolic blood pressure (SBP) of less than 90 mmHg at 1 hour of second stage of labor was observed in 0.9% (P=0.248) and 0.3 at 2 hours of second stage of labor in both groups (P=1.00) while diastolic blood pressure (DBP) of less than 60 mmHg was found in 98.7% at 1 hour of second stage of labor (P=0.98) and 99.0 % at 2 hours of second stage of labor (P=0.57). The differences for SBP and DBP were not significantly different between groups.

Discussion

This study has shown that the estimated volume of blood loss after delivery in pregnant women who had vaginal delivery is significantly different between the use of the CB and the VE. Besides, the group that uses both VE with CB to evaluate the volume of postpartum blood loss also shows that the VE and actual blood lost volume are significantly different.

This finding is consistent with the previous studies which investigated the estimation of blood lost volume after delivery using the CB and the VE. The difference of these 2 methods was significantly different.[7] This underestimated volume of blood loss caused by most of blood lost into the blood-soaked materials and clothes during labor. Most of the PPH is related to the underestimation of blood volume, as well as the ability of the healthcare personnel to estimate the volume of blood loss by VE. Thus, the blood measurement device should be used to get more accurate assessment than visual estimation. The result in this study showed that the prevalence of PPH increased from 3.9% during pre-study period to 21.6% in this study.

Age, nationality, GA, number of child birth, pre-pregnant BMI, as well as the general

clinical information either high blood pressure before the 20 weeks of gestation or after 20 weeks of gestation, receiving a labor inducing drugs for more than 8 hours, receiving tocolytics, prolonged second stage of labor, precipitate labor and perineal laceration are risk factors for PPH in the pregnant women who had vaginal delivery.[2] In this study, there was no difference in these factors between groups. Therefore, the additional study investigating which risk factors promoting postpartum hemorrhage from vaginal delivery may require.

The changes of Hct and the changes of Hb measured before the delivery and 24 hours after the delivery in this study has shown that the more volume of blood lost after delivery, the more reduction of Hct and Hb value. This finding is consistent with the study of Ambardekr S, et al.[9] which measured Hb value before the delivery and 24 hours after the delivery. However this study is inconsistent with the study of Gharoro EP, et al.,[10] Wangwe PJ, et al.(11) in which the changes of Hct value is opposite to the volume of the postpartum blood loss. This might be because of different time of measurement Hct after delivery at 48 hours and 12 hours, respectively. The percentage of PPH in current study was not significantly different between groups (17.1% in CB group vs 25.5% in VE group, P=0.075). From current study, the group using the VE in combination with the use of CB to evaluate the postpartum blood volume helps provide additional confirmation that the volume of the actual blood loss obtained from the same person. Thus, the result of the estimated blood loss between two methods of assessment emphasized more accurate diagnosis of PPH.

The strength of this study is the use of RCT and double-blind study design, which helps reduce the bias of the estimation of the volume of blood loss after vaginal delivery of the pregnant women. Because the CB is used in both groups, therefore the pregnant women would not know which group they were in. In addition, for the VE group, there was another assistant who helped weigh the CB, counted the gauze, and informed the nurse to record. Therefore, this would help reduce the bias and the study result can be applied to use in general population who have vaginal delivery. In this study, there are 100 out of 301 pregnant women (33.2%) who were referred from the community hospital. This method of postpartum blood loss measurement would be set as the standard helped accurately diagnosed PPH and easily transfered the data in the same perception Sunprasitthipasong Hospital and community hospitals within Ubonratchathani.

The limitation of this study is that the estimated blood volume using CB barely avoid contaminated amniotic fluid flown into the bag, since the CB was placed from placental delivery until finishing repair of the perineal laceration or episiotomy wound. This might increase the volume of fluid collected, and lead to false overestimated postpartum blood loss. The future study is recommended to use the CB starting from episiotomy until completion of the repair of the perineal laceration in order to evaluate the PPH, as well as to use PR value and oxygen saturation for taking care of the pregnant women having vaginal delivery. The measurement should be done every 15 minutes for initial 2 hours postpartum. Both PR and oxygen saturation have not yet been used in any study to assist in estimation of postpartum

blood volume and help in early detection of PPH. This study, hence, started measuring these values from entering the second stage of a vaginal delivery. However, each pregnant woman had different delivery duration, in some cases, the 8 values had already been measured, but the delivery was still not completed. Thus, the data obtained does not represent the reality. Some participants had the pulse rate more than 100 beat per minute at the beginning, and the pulse rate was remained higher than 100 bpm after delivery. This makes the value obtained higher than the actual value. Besides, the baseline blood pressure in most participants started at SBP < 90 mmHg or DBP < 60 mmHg. This causes the data obtained not reflect the reality. There is a study of Bellad MB, et al.(12) found the different of pulse rate changes by measuring at 30 minutes, 60 minutes and 24 hours after the vaginal delivery with and without postpartum hemorrhage. It was found that there is no statistical significantly different.

Conclusion.

The estimation of postpartum blood volume using CB was more accurate measurement than VE in women delivered vaginally. Health care providers working in delivery rooms need to be trained how to estimate blood loss using simulated methods to increase the accuracy in diagnosis of PPH, hence provision of immediate intervention.

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Comparison of postpartum blood loss volume between visual estimation and collected bags in women delivered vaginally at Sunpasitthiprasong Hospital: Randomized double-blinded controlled trial

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Abstract

Objective: To compare volume of postpartum blood loss between collecting bag and visual estimation in pregnant women delivered vaginally

Material & Methods: A randomized controlled trial was conducted from November 2016 to April 2017 in pregnant women undergoing vaginal delivery at Sunpasitthiprasong Hospital. All 320 pregnant women were recruited and allocated into 2 parallel groups: collecting bag (CB) group and visual estimation (VE) group. Blood volume of postpartum loss was assessed only by collecting bag in CB group and was assessed by both techniques in VE group. The clinical characteristics, delivery, and neonatal outcomes, including postpartum complications were recorded.

Results: Among 312 participants enrolled, there are 4 participants in CB group and 7 participants in VE group who delivered by cesarean section, or incomplete data collection, leaving overall 301 participants completed analysis. The median volume of postpartum blood loss was significantly different between the CB and VE group (349.1 ml VS 320 ml, respectively, P=0.01). Subgroup analysis in VE group which both techniques were used, median blood loss was significantly different by standard visual estimation (VE) VS actual values measured by collecting bag (CB) (320 ml VS 377.1 ml, respectively, P<0.001). Postpartum hemorrhage was not significantly different between groups (17.1% in CB group VS 25.5% in VE group). There was no significant difference between groups in term of changes in hemoglobin, hematocrit, perineal hematoma, and blood transfusion.

Conclusions: The assessment of postpartum blood loss volume using CB was more accurate measurement than VE in women delivered vaginally.

Keywords: Postpartum blood loss assessment, blood collecting bag, postpartum hemorrhage

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