Incidence and Pregnancy Outcomes of Primary Postpartum Hemorrhage Following Implementation of Postpartum Drape with a Calibrated Bag after Normal Vaginal Delivery

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ABSTRACT

Objective: To evaluate the incidence, risk factors, and pregnancy outcomes of primary postpartum hemorrhage (PPH) after the implementation of postpartum drape with a calibrated bag (PDCB) after normal vaginal delivery.

Methods: This retrospective chart review compared patients who had normal vaginal delivery in June 2012 prior to PDCB implementation with patients who had normal vaginal delivery in June 2014 after PDCB implementation at Siriraj Hospital.

Results: In total, 856 patients were included in this study, with 458 and 398 patients delivered in June 2012 and June 2014, respectively. Baseline characteristics were comparable between the two groups. The incidence of primary PPH increased significantly after the implementation of PDCB (2.8% in 2012 vs. 8.5% in 2014; $p < 0.01$). The incidence of severe PPH was also significantly increased (0.4% in 2012 vs. 2.3% in 2014; $p = 0.02$). Uterine atony was the most common cause and the diagnosis increased after PCDB implementation. The use of additional uterotonic drugs was also significantly increased after PDCB implementation (30.8% in 2012 vs. 85.3% in 2014; $p < 0.01$). The blood transfusion rate was comparable between the two groups. No peripartum hysterectomy or ICU admission was observed in this study. After PDCB implementation, pregnancy-induced hypertension was found to be a significant risk factor for primary PPH ($p < 0.01$).

Conclusion: The incidence of primary and severe PPH, and the rate of the use of additional uterotonic drugs were all significantly increased after the implementation of PDCB. Pregnancy-induced hypertension was found to be a significant risk factor for primary PPH.

Keywords: Thailand; incidence; pregnancy outcomes; primary postpartum hemorrhage; postpartum drape; calibrated bag; normal vaginal delivery (Siriraj Med J 2020; 72: 219-225)

INTRODUCTION

Primary postpartum hemorrhage (PPH) is defined as a blood loss of greater than or equal to 500 mL within 24 hours postpartum.[1] PPH is a leading cause of maternal death worldwide, accounting for 27.1% of all maternal mortality.[2] After childbirth, physiologic ligation caused by uterine myometrial contraction is the vital mechanism for the prevention of massive bleeding from

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the placental bed, and failure of this mechanism causes uterine atony—the most common cause of primary PPH.[3] To reduce maternal morbidity and mortality, active management of the third stage of labor involving the use of uterotonic agents, controlled cord traction, and uterine massage is widely recommended for the prevention of atonic PPH.[4] However, the main pitfall of the PPH prevention strategy in routine obstetrics practice is an underestimation of postpartum blood loss. Objective measurement of postpartum blood loss is the essential factor that alerts the obstetrician to initiate PPH management. There are many tools for the measurement of postpartum blood loss, including photospectometry, gravimetric method (weighed soaked swabs), collector drape, and visual estimation.[5] Photospectometry is the most accurate method, but its use was found and reported to be impractical in a routine clinical setting.[5,6] Visual estimation was reported to be the least accurate and reliable method of blood loss measurement, as it was found to consistently underestimate blood loss when compared with objective methods.[6-8] Two studies found the visual estimation method to be associated with an error rate of 30% when compared with the gravimetric method or collector drape.[6,8] A study conducted by our team in 2013, which evaluated postpartum blood loss measured in 100 mL discreet categories, confirmed the inaccuracy and underestimation of the visual estimation method when compared with objective measurement using a sterile under-buttock drape (low correspondence and poor agreement, with a Cohen's kappa coefficient of 0.07; $p < 0.05$).[9]

In 2014, our center implemented a new protocol to evaluate postpartum hemorrhage by an objective measurement of postpartum blood loss using a postpartum drape with a calibrated bag (PDCB). In this protocol, postpartum blood loss ≥ 350 mL is considered to be an early warning sign for PPH. The purpose of this study was to evaluate the incidence and risk factors of primary PPH as well as pregnancy outcomes after the implementation of PDCB in 2014 compared with the same following the traditional subjective measurement of blood loss that was performed in 2012 before the implementation of PDCB.

MATERIALS AND METHODS

Study design and population

This retrospective chart review compared patients who had term normal vaginal delivery in June 2012 prior to PDCB implementation with patients who had term normal vaginal delivery in June 2014 after PDCB implementation at Siriraj Hospital-Thailand's largest national tertiary referral center. Cases with fetal anomalies, stillbirth, multifetal pregnancy, and maternal hematologic diseases that involve clotting mechanisms were excluded. Demographic data, clinical characteristics, pregnancy outcomes, and treatment information were recorded and analyzed. The protocol for this study was approved by the Siriraj Institutional Review Board (SIRB), Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand (Si 599/2015).

Sample size calculation and statistical analysis

The sample size for this study was calculated using the incidence of PPH from our previous study, which found an increase in postpartum hemorrhage from 3.5% to 9.1% when comparing the subjective visual estimation method with the objective sterile under-buttock drape method, respectively.[9] We used a type 1 error of 0.05 and a type 2 error of 0.2, and the ratio between the groups was 1:1. The calculation plus a 10% increase to compensate for errors of any type yielded a minimum sample size of at least 396 patients per group.

PASW statistics version 18.0 for Windows (SPSS, Inc., Chicago, IL, USA) was used for data analysis. Descriptive data are presented as a number and percentage or the mean ± standard deviation. Comparisons between the groups were performed using the independent t-test for continuous data, and the chi-square test or Fisher's exact test for categorical data. The second and third stages of labor were analyzed using a nonparametric test. Linear regression analysis was used for evaluation of the PPH risk factors. A p-value of less than 0.05 was considered statistically significant.

RESULTS

In total, 856 patients were enrolled in this study, with 458 patients delivered in the 2012 group and 398 patients delivered in the 2014 group. Demographic data, clinical characteristics, and pregnancy outcomes were comparable between the two groups (Table 1). Table 2 shows the incidence, cause, and treatment relative to primary PPH. It can be seen that postpartum hemorrhage increased significantly after the implementation of PDCB (2.8% in 2012 vs. 8.5% in 2014; $p < 0.01$). The incidence of severe PPH, which is defined as a blood loss greater than 1,000 mL, was also significantly increased after PDCB implementation (0.4% in 2012 vs. 2.3% in 2014; $p = 0.02$). In 2014, the most common cause of PPH was uterine atony, followed with birth passage injury, and retained placenta, respectively (47.1%, 32.4%, and 14.7%). In addition, both atonic and non-atonic PPH had more diagnoses after PDCB implementation and the percentage

TABLE 1. Demographic data, clinical characteristics, and pregnancy outcomes in 856 vaginal delivery patients.

	2012 deliveries (n=458) Mean±SD	2014 deliveries (n=398) Mean±SD	*p*-value
Age (years)	27.0±6.3	27.7±6.4	0.11
Gestational age (weeks gestation)	38.1±1.8	38.2±1.7	0.22
Baseline hematocrit (%)	34.9±3.3	35.2±3.1	0.24
Fetal birth weight (grams)	2,964.5±434.9	2,982.5±396.0	0.53
	n (%)	**n (%)**	***p*-value**
Nulliparous	212 (46.3%)	176 (44.2%)	0.54
Maternal anemia (Hct <30%)	34 (7.4%)	20 (5.0%)	0.15
Gestational diabetes	22 (4.8%)	20 (5.0%)	0.88
Pregnancy-induced hypertension (PIH)	15 (3.3%)	24 (6.0%)	0.05
Infant birth weight			0.24
AGA (10^{th} - 90^{th} percentile)	359 (78.4%)	329 (82.7%)	
SGA (<10^{th} percentile)	41 (9.0%)	32 (8.0%)	
LGA (>90^{th} percentile)	58 (12.7%)	37 (9.3%)	
Perinatal asphyxia (Apgar score at 1 min ≤7)	17 (3.7%)	13 (3.3%)	0.72
	Median (IQR)	**Median (IQR)**	***p*-value**
Second stage of labor (minutes)	18 (11, 28)	17 (11, 29)	0.66
Third stage of labor (minutes)	6 (4, 9)	6 (5, 9)	0.09

A *p*-value <0.05 indicates statistical significance

Abbreviations: SD, standard deviation; Hct, hematocrit; AGA, appropriate for gestational age; SGA, small for gestational age; LGA, large for gestational age; IQR, interquartile range

of unidentified causes was reduced (46.1% in 2012 vs. 5.8% in 2014). The use of additional uterotonic drugs was also significantly increased after PDCB implementation (30.8% in 2012 vs. 85.3% in 2014; $p < 0.01$). The blood transfusion rate was comparable between groups (7.7 % in 2012 vs. 11.8% in 2014; $p > 0.05$). There were no cases of massive blood transfusion, peripartum hysterectomy, ICU admission, or maternal death in this study. Tables 3 and 4 show the risk factors associated with primary PPH in the PDCB group, pregnancy-induced hypertension was found to be the only significant risk factor for the development of primary PPH ($p < 0.01$).

DISCUSSION

In this study, the incidence of primary PPH and severe PPH both increased after the implementation of PDCB. It is known and accepted that the correct measurement of postpartum blood loss can lead to an early diagnosis and management of postpartum hemorrhage. The gravimetric method involving weighing a blood-soaked material has been proved to be more accurate than a visual estimation of postpartum blood loss.[8] However, Ambardekar S, *et al.* performed a randomized trial to compare the efficacy of two different methods for postpartum blood loss measurement (direct method or

TABLE 2. Incidence of, cause of, and treatment for PPH between groups (N=856).

	2012 deliveries (n=458) n (%)	2014 deliveries (n=398) n (%)	*p*-value
Incidence			
Primary PPH (EBL ≥500 mL)	13 (2.8%)	34 (8.5%)	*<0.01*
Severe PPH (EBL ≥1,000 mL)	2 (0.4%)	9 (2.3%)	*0.02*
	2012 (n=13) n (%)	**2014 (n=34) n (%)**	***p*-value**
Cause			0.19
Uterine atony	3 (23.1%)	16 (47.1%)	
Non-uterine atony	4 (30.8%)	16 (47.1%)	
Birth passage injury	1 (7.7%)	11 (32.4%)	
Retained placenta	3 (23.1%)	5 (14.7%)	
Unspecified causes	6 (46.1%)	2 (5.8%)	
Treatment			
Use of additional uterotonic agents	4 (30.8%)	29 (85.3%)	*<0.01*
Blood transfusion	1 (7.7%)	4 (11.8%)	1.00

A *p*-value<0.05 indicates statistical significance

Abbreviations: PPH, postpartum hemorrhage; EBL, estimated blood loss

TABLE 3. Risk factors associated with primary PPH after implementation of PDCB (N=398).

Risk factors	**Postpartum hemorrhage n (%) Yes (n=34)**	**No (n=364)**	***p*-value**
Parity ≥3 1 (2.9%)	14(3.9%)	1.00	
Poor ANC (<4 visits)	1 (2.9%)	36 (9.9%)	0.35
Maternal anemia (Hct <30%)	0 (0.0%)	16 (4.4%)	0.38
Gestational diabetes	3 (8.8 %)	16 (4.4%)	0.22
Pregnancy-induced hypertension	5 (14.7%)	15 (4.1%)	0.02
BMI on admission ≥25 kg/m^2	26 (76.5%)	235 (64.6%)	0.19
Prolonged 3rd stage of labor (>30 min)	4 (11.8%)	59(16.21%)	0.63
Operator (medical/nursing students)	1 (2.9%)	36 (9.9%)	0.35
Infant birth weight			0.26
AGA (10th - 90th percentile)	25 (73.5%)	304 (83.5%)	
SGA (<10th percentile)	5 (14.7%)	27 (7.4%)	
LGA (>90th percentile)	4 (11.8%)	33 (9.1%)	

A *p*-value <0.05 indicates statistical significance

Abbreviations: PPH, postpartum hemorrhage; PDCB, postpartum drape with calibrated bag; ANC, antenatal care; Hct, hematocrit; AGA, appropriate for gestational age; SGA, small for gestational age; LGA, large for gestational age

TABLE 4. Linear regression analysis of factors associated with primary PPH after implementation of PDCB.

	Beta	SE	*p*-value	95% CI
Pregnancy-induced hypertension	1.306	0.555	0.02	1.24-10.97
Prolonged 3rd stage of labor (>30 min)	-0.359	0.556	0.518	0.24-2.08
BMI on admission ≥25 kg/m^2	0.530	0.423	0.210	0.74-3.89

A *p*-value <0.05 indicates statistical significance

Abbreviations: PPH, postpartum hemorrhage; PDCB, postpartum drape with calibrated bag; SE, standard error; CI, confidence interval

blood collecting drape *vs*. indirect method or weighed blood-soaked material) among 1,195 patients. They found that the direct method had a higher efficacy for postpartum blood loss measurement, given that the direct method had a greater mean blood loss and double the incidence of PPH.[10] Previous studies confirmed that objective measurements using a collection bag or drape are appropriate for the measurement of postpartum blood loss.[6,11] In 2016, Bamberg *et al*. conducted a prospective cohort study on the use of a collection bag after vaginal delivery in 809 patients. They found similar results, with an increasing incidence of both PPH and severe PPH. They also recommended this method as a tool for the diagnosis of PPH.[12] In December 2016, the Royal College of Obstetricians and Gynaecologists (RCOG) released a new guideline relative to the prevention and management of PPH. They also confirmed the underestimation of postpartum hemorrhage by the visual estimation method and suggested the use of more reliable methods, including blood collecting drapes or the weighing of soaked swabs after vaginal delivery.[13] Abbaspoor Z, *et al*. reaffirmed the effectiveness of a collection bag in the diagnosis of >500 mL postpartum blood loss (sensitivity of 80%, Specificity = 95. 7%, PPV = 88.9%, and NPV= 91.8%).[14] Accordingly, it is clear that the objective measurement of postpartum blood is superior to the subjective measurement of postpartum blood, especially via the use of PDCB, and consequently, it is presently recommended in routine obstetrics practice, where it is approved as a precise tool for the early diagnosis of primary postpartum hemorrhage.

In this study, the use of 350 mL of postpartum blood loss as an early warning sign for PPH had the effect of increasing the rate of the use of uterotonic agents after the implementation of PDCB. Although uterotonic agents are the main medication for the prevention of postpartum hemorrhage, they all have adverse effects. For example, oxytocin may cause hemodynamic instability or water intoxication, while methylergonovine can cause vasoconstriction leading to hypertension.[15] The risk of these potential adverse effects should be considered and weighed up on a case-by-case basis when using uterotonic agents based on blood loss findings from using the PDCB method. Evaluation of the clinical signs and symptoms, especially the pulse and blood pressure, rather than the blood loss volume alone should be considered as standard practice for the prevention of PPH before prescribing additional uterotonic agents.[13]

Pregnancy-induced hypertension was found to be the only independent risk factor for the development of primary PPH in this study. Many risk factors associated with primary PPH have been reported in the literature, including previous PPH, grand multiparity, macrosomia, prolonged used of oxytocin, and prolonged third stage of labor.[16,17] Shortening the duration of the third stage of labor showed benefit for PPH prevention, which was consistent with the recommended process of active management of the third stage of labor (AMTS).[1,4] Pregnancy-induced hypertension was also included in a review by Sebghati and Wetta *et al*. in 2013, and in a guideline from the Royal College of Obstetricians and Gynaecologists (RCOG), as it causes PPH by disturbing maternal coagulation.[13,17,18] All pregnant women with pregnancy-induced hypertension in our setting, both with or without severe features, were treated with magnesium sulfate for the prevention of seizures that might raise concerns of a tocolytic effect.[17,19] Our previous 2010 study explored the risk factors for PPH by comparing the characteristics of 222 patients between those with and without PPH. We found the duration of the third stage of labor and pregnancy-induced hypertension to be the risk factors for primary PPH, and uterine atony to be the most common cause of PPH-all of which are similar to the findings of this study.[20] However, this study found only pregnancy-induced hypertension to be a significant

risk factor for PPH after the implementation of PDCB. A possible explanation for this may be that PDCB had not yet been introduced in 2010, and consequently, our postpartum blood loss data at that time may have been inaccurate. The incidence of PPH that we reported in 2010 was only 2.4%, which may have been inaccurately low. It is, therefore, possible that the risk factor analysis that we performed in that study may have been based on a rate that was lower than it should have been.

The strength of this study is that our analysis was based on data derived from a real-life clinical setting, using adequate statistical power, and from two different groups: one delivering before and the other after the implementation of PDCB. Therefore, our findings in the present study reflect and support the value and application of PDCB. It is possible that differences in the study population, the healthcare providers, and patient management practices between 2012 and 2014 could have affected the outcomes of this study. However, the demographic and clinical characteristics between the groups were similar, and our study population also covered the period representing the beginning of residency training (June 2012 and June 2014). As such, doctors would have given the same level of care, and patients would have received the same level of care. This, therefore, lowers the opportunity for study bias. Although the size of our study satisfied the sample size calculation-required minimum, our sample size may not have been large enough to identify statistically significant differences between methods for major complications of primary PPH, including massive transfusion, peripartum hysterectomy, ICU admission, and maternal death. A larger sample size or multi-center trial, especially in primary or community settings, should be considered to further elucidate the benefit of PDCB. However, a 2010 cluster randomized controlled trial performed by Zhang *et al.* compared effectiveness between a collection bag and visual estimation for reducing severe PPH in 25,381 patients from 13 European countries after vaginal delivery. They found no significant difference regarding the incidence of severe PPH between groups. They hypothesized that their results suggested a common improper use of the collection bag. Their hypothesis resulted in an increased awareness of the proper use of the collection bag and more vigilant PPH management, with a resulting associated increase in the rate of medical intervention.[21] A systemic review of 36 studies (both quantitative and qualitative) by Hancock *et al.* in 2015 reported similar findings. They found that the use of a collection bag or drape improved the accuracy of blood loss measurement over other methods, but that they did not reduce the rate of severe PPH. They recommended that there are many factors in addition to blood volume that influence outcomes, including and especially the speed of blood flow, nature of blood loss, and patient condition.[22] Taken together, these findings suggest that an early diagnosis of PPH by an objective measurement of postpartum blood loss using PDCB is not the only factor that affects the outcomes of PPH. In fact, multiple factors influence the outcomes of PPH, and all of these factors need to be considered in the decision-making by healthcare providers, including when establishing organizational policy and when designing a local protocol for effective PPH management.

In conclusion, in the present study, it was found that the incidence of primary and severe PPH and the rate of use of additional uterotonic drugs all significantly increased after the implementation of PDCB. Pregnancy-induced hypertension was found to be a significant risk factor for the development of primary PPH. Further study in a larger, multi-center study population is needed to evaluate major complications, especially massive blood transfusion, peripartum hysterectomy, ICU admission, and maternal mortality.

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