Original Articles

Innovation of Calibrated Dk Drape for Quantitative Measurement of Blood Loss During and Immediately After Vaginal Delivery

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Abstract

Background: Postpartum Hemorrhage (PPH), a major cause of maternal mortality, is often diagnosed late. For early and proper diagnosis of PPH, blood loss has to be measured quantitatively during & after vaginal delivery.

Objective: To prepare a low-cost, easy to make and easy to use transparent calibrated drape innovatively which may be used for quantitative measurement of blood loss; to explore its safety, efficacy and usability; and to find out satisfaction of mothers and service providers.

Method: The study was done in three phases in Ashulia Women & Children Hospital and Institute of Women & Children Health (IWCH). First: an innovative approach was undertaken to develop a simple low-cost calibrated drape to measure blood loss during third stage of labour and immediately after delivery. A cross-sectional study was carried out on 40 mothers from 1st November 2023 to 30th April 2024 who delivered normally to find out the safety, efficacy and applicability of the drape in the second phase. To find out the level of satisfaction on using this newly innovated drape, a qualitative study was conducted on 40 mothers and 20 service providers in the third phase. Ethical clearance was obtained from IWCH.

Results: A calibrated drape Dhaka (Dk) drape is made with thin transparent polythene shopping bags available in the market (capacity 12-15kg). One of the lateral sides of the bag is split open and refolded to give it a conical shape. It is calibrated at 300, 500 and 1000ml using simple technique first and then with marked scale. The device has a cone, a shorter and a longer side. The longer and wider side is spread under the buttock of the women (who is lying on the delivery table in a dorsal position with her buttock at the edge of the table), after the delivery of the baby and before the delivery of the placenta and kept there till the amount of bleeding is controlled/reasonably low or for one hour. The swabs/gauze pieces used for any other bleeding such as repair of tear or episiotomy wound are to be weighed and added to the total blood loss. The drape is disposed of like other contaminated medical waste. Initially, the Dk drape is successfully used on 40 mothers during their vaginal delivery. The calculated cost of making the drape is only around Bangladesh Taka six (USD 0.05). According to the opinion of the patient and service providers the Dk drape is effective (correctly measuring blood loss), safe (no side effect or inconvenience), feasible (ease and willingness to use), accessible for regular use (availability).

Conclusion: The Dk drape found to be an effective, low cost, safe, easy to make device to measure blood loss accurately during and immediately after vaginal delivery and early identification of and action for PPH, without the need for manufacturing and supply. It is easy to be used by the health service providers and acceptable to women and is safe.

Recommendation: Due to its efficacy, low cost, safety, ease to make and use; and satisfaction of the patients and service providers; the calibrated Dk drape is recommended to be used after every vaginal delivery for quantitative measurement of blood loss accurately and easily.

Key word: Calibrated drape, Postpartum Hemorrhage, Qualification of blood loss, Vaginal delivery, Facility Readiness for MNH, Quantitative measurement of blood loss after vaginal delivery.

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Introduction:

Postpartum Hemorrhage is defined conventionally as blood loss of 500 ml after vaginal delivery¹. A certain amount of blood loss occurs during the process of separation of placenta. Excessive blood loss during third stage and after delivery are usually caused by atony of uterus, trauma of genital tract, retained placenta / placental bits and coagulation disorders. Globally about 70,000 women die a tragic and mostly preventable death due to post-partum hemorrhage². The latest maternal mortality survey (2016) of Bangladesh shows maternal mortality rate of 196/ 1,00,000 live births (LB) and hemorrhage causes about 33% of maternal deaths; mostly due to postpartum hemorrhage³. Suddenness of the emergency situation related to postpartum hemorrhage, lack of adequate preparation to manage PPH and lack of devices/methods to measure actual blood loss leads to late diagnosis resulting in late diagnosis & late initiation of treatment and late referral leading to severe maternal morbidity and mortality⁴. Many different qualitative and quantitative, direct and indirect methods are used to measure blood loss during and after delivery^{5,6}.

Commonly used method of estimation of postpartum blood loss is visual estimation of actual blood loss and volume of soaked clothing/bed sheets or size of the clot⁶. All these methods have risk of underestimation by 30-50% and calibrated drapes are found to improve blood loss estimation⁷.

Sustainable development goals-3 is ratified by all countries of the world, targets to achieve a maternal mortality rate to be reduced by two third by the year 2030 (70/100,000 LB for developing countries)⁸. The interventions and their effects are not yet visible to meet the target. To achieve the sustainable development goal target of reduction of maternal mortality is a major challenge to the health service providers, policy makers and managers. Most of the deaths due to PPH are preventable. Identifying pregnant mothers who are at high risk for PPH, preventing PPH by reduction of anemia, mandatory hospital delivery and active management of third stage of labour are the proven interventions.

An evidence-based intervention to improve the situation is to early diagnosis of PPH by measurement of blood loss: which can provide early warning signs to the health service provider, early detection of PPH and immediate and proper management of PPH⁴. Recent

studies including E-MOTIVE trial⁹ strongly recommends direct measurement of amount of blood loss using calibrated drapes which can warn and detect blood loss after vaginal delivery accurately. E-motive trial has successfully used quantitative method to estimate blood loss with transparent, cone shaped, calibrated drapes (manufactured for the study purpose). Different kinds of calibrated drape are available in a number of countries¹⁰⁻¹⁶.

As the national coordinator of leadership development initiative [LDI; REACH] project of International Federation of Gynecology and Obstetrics (FIGO)¹⁷, where findings of E-MOTIVE trial⁹ are focused, we were looking for a low cost, affordable, locally producible, transparent/translucent cone shaped calibrated drape to measure the blood loss during and immediately after vaginal delivery. Direct quantitative measurement of blood loss during and after delivery is mandatory to declare the facility ready for management of PPH under LDI-REACH project¹⁷. An Extensive literature search was undertaken. Locally transparent polythene sheets and sealing machine were bought and drape similar to the ones used in E-MOTIVE trial were made⁹. But the seals broke down and the liquid content leaked in most of the cases. We tried to approach industries for preparing the drape, but they were not interested to prepare a small number of drapes. The other factors for consideration were: the manufacturing/procuring and supplying the drape countywide by the Govt. is an expensive and cumbersome job.

Obstetrical and Gynaecological Society of Bangladesh (OGSB) has implemented "PPH Emergency Response using Bundle Approach" for management of PPH by first response and refractory PPH bundle for clinical management and also non-clinical bundles ^{18,19}. Scaling up of the previous interventions and also implementing Leadership Development Initiative among young gynaecologist by finding out the barriers and proper management of clinical conditions (barrier analysis) and removing those barriers ¹⁷ are ongoing.

The present study is conducted to prepare a low-cost, easy to make and easy to use transparent calibrated drape innovatively which may be used for quantitative measurement of blood loss; to explore its safety, efficacy and usability and find out satisfaction of mothers and service providers.

Methods

The study has three parts. First: an innovative approach was taken to prepare a simple low cost calibrated drape to measure blood loss during third stage of labour and immediately after delivery. After repeated trial and error, a suitable drape was prepared with locally available low cost transparent material. In the second phase a cross-sectional study was carried out on 40 mothers who delivered normally to find out the safety, efficacy and applicability of the drape. In the third phase a qualitative study was conducted on 40 mothers and 20 service providers on the level of satisfaction on using this newly innovated drape through in-depth interview (IDD) and key informers interview (KII). The study was carried out from 1st November 2023 to 30th April 2024.

Ethical clearance was obtained from Ethical review committee of Institute of women & children health (IWCH) and Ashulia women & Children Hospital (AWCH). Results were expressed in frequency, occurrence, mean and standard deviation. Students' 't' test and chi squared test were performed as required.

Results

It was really a challenge for OGSB to organize calibrated drape for the six institutes where LDI-REACH protocol is ongoing. The fact is, no such calibrated drape is available in Bangladesh. First, we have explored to make transparent calibrated drape with thick transparent plastic sheet and sealing machine in the market. And tried to make several ones. But all seals failed finally. It was evident that more powerful sealing machines are needed which are only available in commercial factories. We have explored and communicated but seeing the complicated procedure and need for small number of drapes, no one showed any interest. On the quest of a conical transparent drape this Dk drape has been innovated by the author.

Innovation of a simple, conical easy to make and use, low-cost calibrated drape of quantity blood loss after vaginal delivery:

Technique: Commercially available thin polythene transparent shopping bags are used to make instant drapes. The process of making the innovative drape

to collect blood during and after vaginal delivery is described below. The materials used are-

- Thin transparent /translucent polythene shopping bags of 12-15 kg capacity
- 2. One pair of sharp medium size scissors
- 3. One calibrated mug for measuring water
- 4. One red maker pen, permanent ink
- 5. One scale

The shopping bag has four sides (Figure I): three sides are sealed and one side is open. Step1: With a pair of scissors one of the two lateral sides is slit open (A). Step 2. The bag is refolded to give it a cone shape (B). The bag now has (i) a cone, (ii) a smaller/short end and (iii) a bigger/longer end (B). Step 3: Initial Calibration: Measured water (300 ml), using a calibrated mug, is poured into the cone and upper limit is marked with black permanent marker pen and the water has been poured out (C). Next, 500 ml of measured water is poured in and upper limit marked as 500 ml with red marker pen. Another 500 ml of water may be poured and a third mark at 1000 ml drawn with red marker. (C). Step 4: Replication of Calibration: Now all the water is poured out and a scale is placed on these marks and with red and black marker pens colored lines are drawn on the drape and also on the scale with permanent marker at 300 ml (Black), 500 ml (Red) and 1000 ml (Red) (D). This scale, which is marked similarly, may be used to reproduce as many drapes as required using same size transparent bags.

Further up two extra black lines were drawn on both the sides of the empty cone (both front and black sides of the cone) at the same place [This extra line was given to make the measurement of content of the cone accurately: when the bag contains blood, it sags; and may make quantification inaccurate].

Unique features of this cone are: it is easy to make and through simple training it can be instantly made. To replicate the drape, shopping bags can be bought from local shops/markets and may be made locally (by nurses in the institution / department and marked with the scale according to the mark). And also, bags



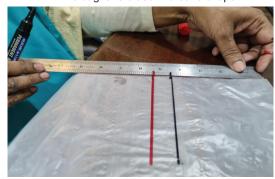
A. With scissors one of the two lateral sides is slit open



B. The bag is refolded in a cone shape



C. Initial Calibration



D. Replication of Calibration

Figure 1: Preparing the DK Drape

Legend: The shopping bag has four sides (Figure I): three sides are sealed and one side is open. Step1: With scissors one of the two lateral sides is slit open (A). Step2. The bag is refolded to give it a cone shape (B). The bag now has (i) a cone, (ii) a smaller/short end and (iii) a bigger/longer end (B). Step 3: Initial Calibration- Measured water (300 ml) is poured into the cone and upper limit was marked with black permanent marker pen and the water has been poured out (C). Next, 500 ml of measured water was poured in and upper limit was marked as 500 ml with red marker pen (C). Step 4: Replication of Calibration: Now all the water was poured out and a scale is placed of this marked end and is marked with a red and black marker and lines were drawn on the scale with permanent marker at 300 ml (Black), 500 ml (Red) [and 1000 ml (Red)]. For replication: calibrate new bags with this marked scale (D).

are found everywhere in Bangladesh for packaging purpose in general population. To make the process simpler for measuring water to mark the red and black line at 300, 500 and 1000ml: commercially available ready bottles of drinking water can be used and the water can be poured in the cone and calibration can be done easily.

For the practical use the wider end of the cone is spread on the labour table under the buttock of the women (after the delivery of the baby and before delivery of the placenta). If necessary, the wider end can be pasted with the plastic sheet on the labour table with few inches of micropore. The open short end of the cone (the front part) will hang from the table for collection of blood and measurement under direct observation through the transparent bag. And warning of readiness to PPH management can be triggered when 300 ml mark is reached and diagnosis and management by PPH first response bundle as soon as the 500 ml/red mark is reached. This easy to make, less expensive accessible affordable and safe device can be instantly made by anyone,

anywhere; and can be effectively used for accurate and direct detection of postpartum blood loss after vaginal delivery easily.

To find out the efficacy, safety and applicability, the Dk drape was used for quantification of blood loss after vaginal delivery among 40 gravid women with term pregnancy and all deliveries were conducted by competent doctors. The mean age was 24.83+5.77 years, majority were multi para (57.5%), mean BMI was 26.81+3.85, mean gestational age was 37.98+1.85 and mean birth weight was 2.66+.4kg (table I).

Mean blood loss was 133.25+53.45 ml (range 50-300ml). There was no PPH. Mean hemoglobin before delivery was 11.06+1.18gm/dl and after delivery was 10.41+1.14gm/dl, pulse rate before delivery was 90.91+09.0 versus 83.50+06.22 beats per minute after delivery. Mean systolic blood pressure before and after delivery was 110.75+45.59 versus 109.15+5.40 mmHg respectively. Diastolic blood pressure before and after delivery were 77.25+09.60 and 76.26+4.59 mmHg respectively. None was statistically significant. Time required to spread the drape was 1-2 minutes (table I).

Table-IClinical Parameters of Mothers where DK-Drape has been used for Quantitative Estimation of Blood Loss
During and after Vaginal Delivery

| Variables | | Danasatana | | CD | Danas | Ciamificance |
|--|----------------|---------------------------------------|--------|-------|--------------|--------------|
| Variables | Frequency | Percentage | Mean | SD | Range | Significance |
| Age (Years) Less than or Equal 19 20 to 35 Greater than 35 | 9 30 1 | 22.5% 75% 2.5% | 24.83 | 5.777 | 17 - 36 | |
| Parity (no.) Primi - 17 Multi - 23 | 42.5% 57.5% | | | | | |
| BMI Less than 23 23 to 25 Greater than 25 | 8 6 26 | 20% 15% 65% | 26.81 | 3.88 | | |
| Gestational Age(Weeks) Less than 37 37 to 42 Greater than 42 | 17 23 0 | 42.5% 57.5% | 37.98 | 1.85 | 34 - 41 | |
| Blood Loss (ml) Less than 300 300 to 500 Greater than 500 | 40 0 0 | 100% 0% 0% | 133.25 | 53.46 | 55 - 300 | |
| Birth Weight (Kg) Less than 2 kg 2 kg to 3 kg Greater than 3 kg | 4 29 7 | 10% 72% 18% | 2.66 | .40 | 1.96 - 3.40 | |
| (Infection of Newborn) Yes No | 0 40 | 0% 100% | | | | |
| (Any Others complication, Newborn) Yes No | 0 40 | 0% 100% | | | | |
| (Infection of Mother) Yes No | 0 40 | 0% 100% | | | | |
| Hb(gm/dl) | | | | | | |
| Before Delivery | | | 11.06 | 01.18 | 8.60 - 13.00 | NS* |
| Hb After Delivery | | | 10.41 | 01.14 | 8.00 - 12.09 | |
| Mean Change in Hb(gm/dl) | | | 0.65 | 0.22 | | |
| Pulse rate/ Min | | | | | | |
| Before Delivery | | | 90.90 | 09.0 | 78 - 120 | NS* |
| After Delivery | | | 83.50 | 06.22 | 76 - 110 | |
| Systolic BP mm Hg | | · · · · · · · · · · · · · · · · · · · | | | | |
| Before Delivery | | | 116.75 | 15.59 | 100 - 170 | NS* |
| After Delivery | | | 105.15 | 05.54 | 70 - 140 | |
| Diastolic BP mm Hg | | · · · · · · · · · · · · · · · · · · · | | | | |
| Before Delivery | | | 77.25 | 09.60 | 60 - 90 | NS* |
| After Delivery | | | 76.26 | 05.54 | 70 - 90 | |
| Time required to spread the drape | | 1-2 minutes | | | | |
| Are the service provider satisfied | | Yes 100% | | | | |
| Adverse effect | | | | | | |
| *Student's t-test | | | | | | |

For study purpose the drape was kept for 60 minutes. There was no side effect or discomfort of mothers (In Depth Interview). All mothers who delivered said that their delivery process was smooth without any difficulty especially for the drape. Ten doctors and ten nurses in the labour room expressed their full satisfaction about the drape regarding the material, spreading time and comfort of use (Key Informers Interview). Interview with nurses were undertaken regarding preparing/making, using, storing, supplying, measuring blood loss and disposing off the drapes: all commented that there was no difficulty. Rather they expressed their satisfaction and comfort that now they can measure the blood loss actually and with confidence.

It is to be mentioned here that, for direct and accurate measurement of amount of blood loss, additional blood volume was measured by weighing the blood-soaked gauze and pads (all pre & post weighed) and added to the amount collected in the drape. AMTSL was done for each and every case. PPH would be diagnosed if 500 ml blood loss and immediate

management to be started using bundle approach. At 300 ml all the services providers would be alerted.

The drape was found safe, efficient and effective: it can be spread quickly, there was not a single incidence of leaking, women did not feel any discomfort or side effect. There was no slippage. They did not feel any discomfort.

The cost is Bangladesh take (BDT) six (6) per drape: equivalent to USD 0.05 (5 pence). One kg bag consists of 60 pieces; which cost about taka 300. The cost of scale, marker and mug are recurrent and BDT 1 has been added to the price of each drape.

The bags are totally water tight and no chance to fail the seal. The time for sealing was also saved. Real time measurement of blood is possible. The drape may be removed only after the health service provided who is delivering the women is confident enough that the blood loss is minimum. The drape may be decontaminated with chlorhexidine /alcohol. These drapes were disposed of like other contaminated wastes e.g. gloves.

Table-IIComparison of different calibrated drapes

| Author | Yr | Sample Size | Place | Maternal | Comparison | Study Design | Cost |
|-----------|------|-------------------------|---|--|--------------------------------------|---|----------|
| Ambedekar | 2014 | 900 | KEM Hospital Pune, India with Gynuitty Health Project | BRASS-V Drape | Indirect Gravimetric Technique | RCT | ?? |
| Bomberg C | 2016 | 809 | Charite University Hospital, Berlin, Germany | Calibrated Transparent Drape | | Prospective observational study | ?? |
| Misra N | 2019 | Case report 32 cases | GMC Hospital Ambikapur, Chhattisgarh, India | G-Drape Sealed clear plastic Apron Supplied inside delivery Kit | Direct blood collection | Case report | \$ 3 |
| Sigh | 2020 | 500 | Umaid Hospitals Dr. SN Medical College, Jodhpur Rajasthan, India | BRASS-V Drape | Visual Estimation | Comparative study | ?? |
| Wong | 2021 | 60 | Women's Hospital School of Medicine Zhejiang University China | Two set liquid Collection Bag | | Prospective Randomized control Study | ?? |
| Gallos I | 2023 | 210, 132 | 4 countries in Africa | Calibrated Blood Collection Drape | Direct blood collection | International cluster randomized trial | \$ 5 |
| Begum F | 2024 | 40 | AWCH/ IWCH Dhaka, Bangladesh | Simple drape - modified easily available shopping bags | Direct blood collection | Innovative Prospective Cross sectional & Qualitative | USD 0.05 |

 Table-III

 Availability, Reproducibility, Efficacy & Cost of Trial Calibrated Drape & Dk Drape

| Factors | Trial Drape similar to one used in EMOTIVE trial | Dk Drape | | |
|--|---|---|--|--|
| Availability | The plastic sheet & sealing machine were bought from the market. | Ordinary shopping bag brought from the market which are readily available. No need to seal. | | |
| Seal | Easily broke away and leaves after away. | The seal is secured no chance of leakages | | |
| Material | Thick transparent plastic sheet | Thin transparent shopping bags | | |
| Making | Difficult to make | Easy to make | | |
| Cost per piece | \$ 5 | \$.05 | | |
| Effort | Needs much effort | Minimum effort | | |
| No Drape is commercially available in Bangladesh | Cutting the plastic sheet as per specification. Sealing the drape with electricity/battery operated sealing device (which needs money) and then calibrating | Just splitting one side and calibrating | | |
| Effectiveness | The seal was leaking. Not effective. Tough material, difficult to spread and dispose. | 100% leak proof. Effective. Soft material Easy to make and dispose off. | | |

Discussion:

The Dk (Dhaka) Drape is a novel device designed for quantification of blood loss during and after vaginal delivery. It can be made from locally and easily available material, easy to make, easy and safe to use, low-cost calibrated drape. It is efficient to diagnose PPH properly by real time measurement of blood loss. Though no direct comparison to Dk drape was done with other calibrated drapes but its use was easy, safe and effective.

Some recommendation for improved version: The industries who make simple medical devices may be approached for standardization, making the product commercially available and packaging, but that may increase the cost. Sterilization by gamma radiation may increase the cost further, but it will increase safety and reduce chance of infection. Disposal is also a concern.

In Bangladesh, recently Sonali bag, made of jute, is invented. These are bio-degradable. So, Bangladesh Agricultural Department/Science and Technology Department can be approached to make an environment friendly drape²⁰. Similar bags are produced in Rajshahi district of Bangladesh which are produced from corn / maize grain powder²¹.

There are a number of calibrated drapes published in literature; but none is so easy to make and price are

comparatively high. Availability, simplicity of making the drape by service providers, lack of side effect / complication, ease and satisfaction of using – made the drape unique. It is useful and indirectly lifesaving by its ability of early detection and thereby early intervention.

Similar calibrated available are Drape used in E-MOTIVE trial⁹, Brass-V drapes by Ambardekar ¹⁰, two set liquid collecting bag¹¹, collector bags to measure PP blood loss¹², C-G drape¹⁵ (Table II). Brass-V drape is Calibrated Conical Pouch (funneled and calibrated collecting pouch attached to a plastic sheet that is placed under women's buttock) used in SN Medical College Rajasthan, India and in KEM Hospital Pune, India¹⁶. Anew two-set Liquid Collecting bag (TSLCB) in Women's Hospital, Zhejiang University School of Medicine, Peoples Republic of China¹¹ which was used to collect blood and amniotic fluid separately.

In E-MOTIVE trial a calibrated blood collection drape was used to collect postpartum blood loss during delivery. The drape was applied after the delivery of the baby and before delivery of placenta and kept there for one hour for all women who had vaginal birth. For Women with excessive bleeding, the drape was kept in place for a further two hours from the point of detection of excessive bleeding. On Economic

evaluation of the E-MOTIVE trial used US\$1.5 (2023 price) for every Calibrated drape (table II). But when we tried to replicate it's cost was about \$5 and could not use as seal was not water tight. It would need a formally prepared drape, manufactured in industries and supplied to each institution. Though feasible in research setting, manufacturing it at country level, and its supply all over the country would be difficult and take time.

CG (Chhattisgarh) drape is a single use drape prepared on the spot from a clean plastic apron supplied inside the delivery kit provided by the Govt. of India¹⁵, which cost about 1 US\$. The lower edge of the folded apron (plastic apron supplied in the delivery kit) was sealed together using a plastic sealing device. And was calibrated using a standardized and marked plastic scale¹⁵. It also needs sealing and an apron from a delivery kit has to be used: which is a wastage of the kit and not available everywhere.

Conclusion and Recommendation:

Direct quantitative estimation of blood loss during and immediately after delivery is important to detect and treat PPH early and efficiently. This low cost, safe, innovative, easy to make and use, Dk drape found to be a feasible, accessible, effective device to measure blood loss during and immediately after vaginal delivery and early diagnosis of PPH. As these can be prepared by the health workers in their own institution there is no need for manufacturing and supply. It is easy to use by the health service providers and acceptable to women and is safe.

So, it is recommended that the calibrated Dk drape may be used after every vaginal delivery for quantitative measurement of blood loss accurately and easily. Its efficacy, low cost, safety, ease to prepare and use and providers satisfaction made it a novel and unique device.

An elaborate study on its effectiveness, safety, feasibility may be done. Its production with biodegradable product may be explored.

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