

Digital Postpartum Hemorrhage Management Device (DPHMD)

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Technical advance

Keywords: Postpartum Hemorrhage, Blood loss, Blood Pressure, Diagnosis, Fluid delivery, Maternal Mortality

Posted Date: October 31st, 2019

DOI: <https://doi.org/10.21203/rs.2.13489/v4>

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Version of Record: A version of this preprint was published on November 26th, 2019. See the published version at <https://doi.org/10.1186/s12884-019-2601-3>.

Abstract

Background Primary postpartum hemorrhage (PPH) is an obstetric emergency caused by excessive blood loss that occurs most commonly after the placenta is delivered. PPH can lead to volume depletion, hypovolemic shock, anemia, and it is the leading cause of maternal mortality worldwide. With 470 deaths per 100,000 live births, the maternal mortality ratio in Ethiopia is one of the highest in the world. It is estimated that 94% of births occur at home in Ethiopia and that 10% of maternal deaths are attributed to PPH. Currently, physicians use visual estimation to calculate blood loss and provide fluid during delivery. This traditional method is subjective and generally inaccurate. **Method** In this project, after delivery blood loss measurement system integrated with fluid delivery and vital sign monitoring method is proposed. The collection and measurement system collects blood loss after delivery and measures the amount of blood loss. The management system continuously monitors the mother's heart rate and blood pressure. These vital sign values are integrated with the measured blood loss to estimate the amount of IV fluid required to be delivered for the mother. The rate of IV fluid delivery is regulated by a flow rate sensor and solenoid valve. **Results** The prototype was built and undergone through different tests and iterations. The proposed device was tested for accuracy, cost effectiveness and ease to use. 91.28% accuracy has been achieved and the prototype was built with less than 210 USD. **Conclusion** The proposed design allows physicians, especially those in low resource setting, to estimate blood loss and deliver fluid accurately. This helps to reduce maternal mortality rate that may occur due to postpartum hemorrhage.

Background

Primary postpartum hemorrhage (PPH) is defined as blood loss of 500 ml after vaginal delivery and above or 1,000 ml of blood loss after caesarean section within the first 24 hours (1, 2). It is the most common cause of premature mortality of women worldwide. PPH is dangerous and life-threatening and can also lead to long-lasting health effects, including severe anemia (3). According to the 2013 World Health Statistics, the maternal mortality rate in low income countries were 410/100,000 live births (4). The majority of maternal deaths occurred mainly in Asian and African countries (5). Major causes of maternal deaths are similar across low income countries, often obstetric in origin including hemorrhage, hypertensive diseases and maternal infections (4, 6-12). 94% of births in Ethiopia are estimated to occur at home and 10% of maternal deaths are attributed to PPH (13).

Uterine atony, or lack of effective contraction of the uterus, is the most common cause of PPH (3) followed by infection, subinvolution of the placental site, and inherited coagulation deficits (14-17). The majority of these fatal obstetric complications occur during labor and immediately after birth. In the low income countries, more than three-quarters of maternal deaths due to the direct obstetric causes occur during and after birth (4, 18, 19). Organized diagnosis and management of PPH, including administration of uterotonic agents (20), controlled cord traction, and uterine massage after delivery of the placenta, are required to avoid maternal death.

The high frequency of PPH in the developing world is due to the lack of diagnosis and management methods as well as medications used in the active management of the third stage. Lack of experienced caregivers who can manage PPH and lack of blood transfusion services, anesthetic services, and operating capabilities also play a role.

A well-defined stepwise approach is recommended for treatment of uterine atony, including drugs and mechanical interventions, followed by surgery as a last intervention (3, 21, 22). The first diagnosis of PPH is performed by observing the amount of blood loss and the patient's clinical status. The amount of blood loss, the patient's level of consciousness and vital signs are continually assessed.

Photospectrometry is the gold standard blood loss measurement technique due to its accuracy. However, this technique is complicated, costly and impractical. It cannot be applied at all levels of healthcare and is more suitable for clinical research (23-25). Weighed soaked swabs or drapes after delivery are also used for early detection of PPH (26). However, this method substantially increases the workload of physicians and may not be suitable in a busy hospital setting. Bakri balloon (27), arterial embolization (28) and absorbable sutures (29) are other methods used to manage and reduce PPH. However, most of the techniques are either expensive and complex to apply in low resources settings or are associated with complications.

Currently, in low resource settings blood loss during delivery is estimated manually through visual inspection. Visual estimation of blood loss is subjective and generally inaccurate. Studies have shown that, irrespective of physicians' experience or skill level, visual estimation of PPH could result 25% - 89% measurement error (24).

In this project digitalized postpartum hemorrhage management device (DPHMD) is proposed to collect and measure blood loss, monitor vital signs and estimate the amount of IV fluid required to manage PPH at early stage. The proposed method can be used as a decision support system for physicians especially in low resource settings where both the expertise and medical devices are in scarce.

Methods

2. Proposed Design

The Proposed solution includes blood loss collection and measurement system, vital sign monitor (pulse rate and blood pressure), processor unit (Arduino microcontroller), low rate monitor and regulator, display and alarm system. Inputs from the blood loss measurement system, vital sign monitor as well as the number of gauze used from the key-pad are used to estimate the recommended IV fluid to be delivered. The alarm is used to notify the physicians in case of severe conditions. Under-buttock drape, which allows the blood loss to enter to the collection jar without loss, was constructed from locally available material. Ultrasonic sensor is used to measure the volume of blood collected in the jar. Figure 1 show the functional block diagram and general block diagram of our proposed design. The solenoid valve controls the amount of fluid to be delivered to the patient. Solenoid valve and flow sensor will stay on until enough

fluid is delivered. The flow rate will be used to calculate the amount of fluid delivered. If the measured value is larger than the clinical set value the solenoid value will be turned off automatically to prevent excess medication. Figure 2 show the slow chart of fluid medication controller.

Results

1. Final design

Different prototype iterations has been conducted to modify our design. Figure 3 shows parts of the Final design: (Left to Right: Top to Bottom) under-buttock drape for smooth flow of blood to the jar, collection jar and an ultrasonic sensor to collect and measure blood loss, heart rate and pressure sensor to measure the two parameters the two vital signs, a flow sensor and a solenoid valve to indicate flow rate and allow one directional flow of IV fluid, respectively and a display system.

The following components has been used in the final design: HC-SR04 Ultrasonic Sensor, Arduino Uno, Flow Sensor YF-S201, Liquid crystal display (LCD), Buzzer, 4x4 Keypad, Plastic solenoid valve, Pulse sensor, Blood pressure sensor, Plastic jar, Drape, Plastic tube, Resistors, Potentiometer, Jumper wires, and USB cable. Figure 4 shows the final design of DPHMD.

Several tests and iteration were used in order to verify whether the design criteria and specification were fulfilled. Accuracy, cost effectiveness and easy to use are the parameters tested. Table 1 shows the test results.

Criteria	Input	Method	Iterations	Result
Accuracy	Blood volume	By using known amount of water	Five times	91.28%
	Heart rate	By using manual counting method	Five times	
	Blood pressure	By using existing method	Five times	
Cost effectiveness	Market analysis	Total components cost	-	210 USD
Easy to use	Operating procedure	30 min training for Physicians	-	Simple

Table 1: Test methods and results

Discussion

The prevalence of PPH is disproportionately higher in low resource settings where there is limited access to skilled medical care and safe blood supplies. Despite the fact that it is largely preventable, by improving the quality of care, postpartum hemorrhage is the most common and most deadly form of obstetric bleeding (30). Initial treatment of PPH includes uterotonic medications such as oxytocin and misoprostol plus bimanual massage. However, proper collection and estimation of blood loss is required to manage PPH. This study presented a method for diagnosis and management of PPH digitally.

Visual estimation of blood loss including weighing of soaked pad, which is the current method for estimating amount of blood loss in low resource settings, is generally inaccurate and may result misdiagnosis. The *calibrated* blood collection *drape* was also proposed to assist in estimating postpartum blood loss in low-resource settings (31, 32). However, estimating blood loss alone may not give enough information about the status of the patient. Blood pressure and heart rate monitoring is key to hemodynamic assessment, with thresholds for systolic blood pressure (SBP) and pulse used in clinical trigger or early warning systems to prompt intervention (23, 33). Shock index, which is the ratio of heart rate and systolic pressure, are also used to predict blood loss in patients with PPH (34, 35). However, using vital signs in isolation may lead to inaccurate decision since vital sign change due to PPH can be masked by the hemodynamic changes of pregnancy (36). Our method provides both measurement of blood loss as well as vital signs monitoring to detect and manage PPH.

Every design is preferable to be easy to use, accurate and low cost. Our design is simple and user friendly. The traditional manual PPH managing method is digitalized by incorporating vital signs monitoring and blood loss measurement in one system. This helps physicians to easily adapt the digitalized system with a minimum training. The prototype costs only 210 USD making it affordable for low resource settings. The accuracy of the designed system is inspected by performing different tests with the assistance of obstetric physicians. The blood loss collection and measurement system, vital signs measurement and flow rate sensor were tested. A total of 91.28 % accuracy has been achieved with five iterations on different subjects. The blood loss estimation was 98% accurate which is much better than the accuracy of visual estimation, that was found to be 25%–89% accurate as reported in many studies (24-26, 37, 38). The proposed design provides high level of safety. It is free from electrical shock, contamination or infections and any type of hazardous radiation exposure.

Conclusion

In order to prevent complications, effective management of postpartum hemorrhage plays a huge role in treating and saving mothers suffering from PPH. Our Digitalized postpartum management device can be used as a decision support system for physicians by determining the amount of blood loss and the patient's level of consciousness through vital signs continuous monitoring. The prototype was built and undergo through different tests and iterations and it is 91.28 % accurate. The proposed method will have a great impact in low resource settings where both the expertise and means is in scarce.

List Of Abbreviations

DPHMD – Digital Postpartum Hemorrhage Management Device

LCD – Liquid crystal display

PPH – Postpartum Hemorrhage

SBP – Systolic Blood Pressure

Declarations

1. Ethics approval and consent to participate

Not applicable

2. Consent for publication

Not applicable

3. Availability of data and materials

Not applicable

4. Competing interests

The authors declare that they have no competing interests

5. Funding

Resources required for this study were provided by the school of Biomedical Engineering, Jimma institute of Technology, Jimma University, Ethiopia.

6. Authors' contributions

GL and HD are the overall coordinators of this study, which they conceptualized, designed, and implemented in collaboration with the main investigators DD, AG, BM, CA and KD.. All authors contributed to the preliminary study, the design, prototyping and testing. The study was initiated by DD. The article was drafted by GL, taking into account the comments and suggestions of the coauthors. All coauthors had the opportunity to comment on the manuscript and approved the final version for publication.

7. Acknowledgements

We would like to acknowledge Dr. Tigist Mekonen (Doctor of gynecology)) and obstetric staffs of Jimma University Referral Hospital for their valuable advises and guidance.

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Figures

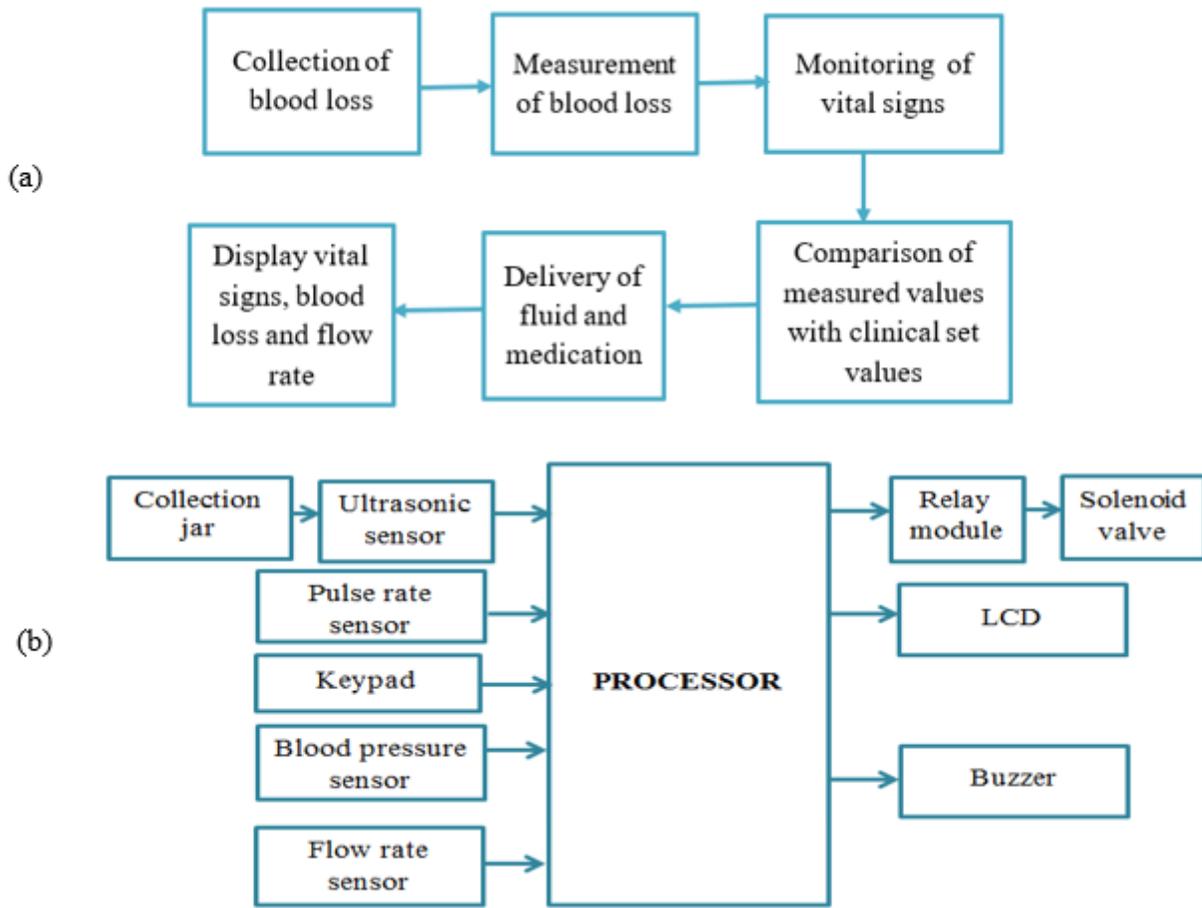


Figure 1

Functional and general block diagram of DPHMD

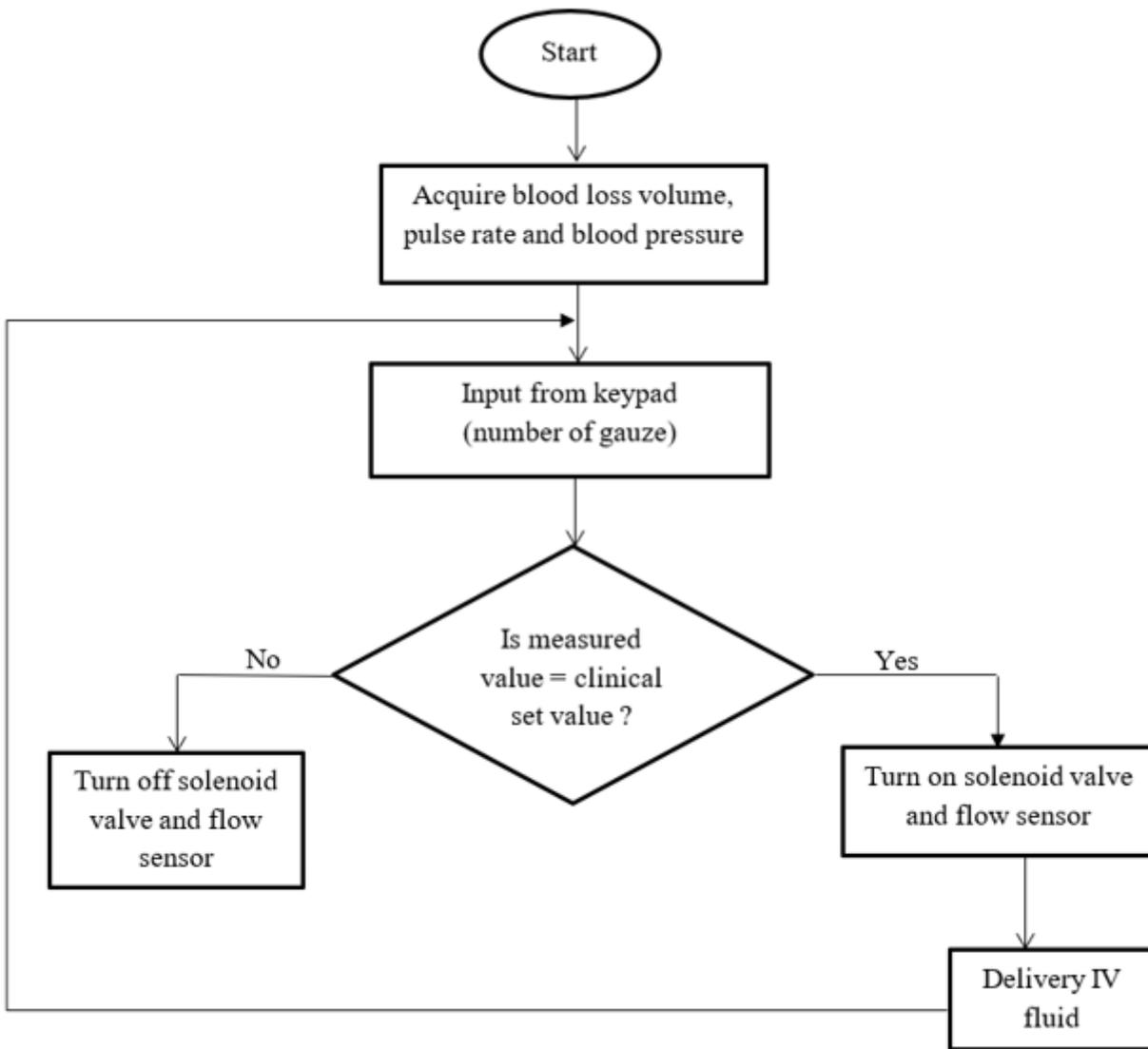


Figure 2

Flow chart of IV fluid delivery controller

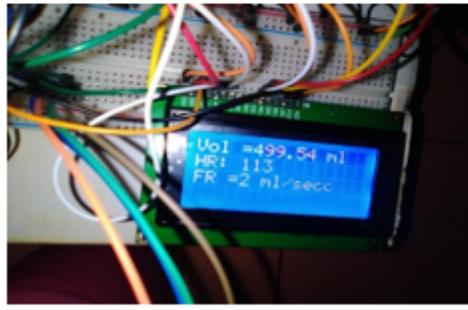
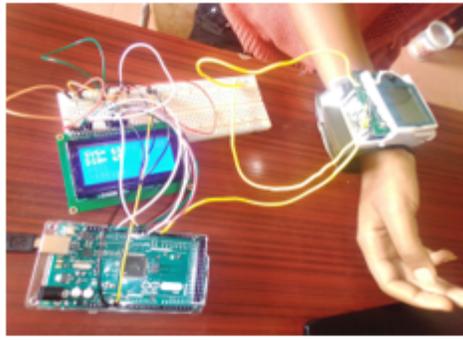
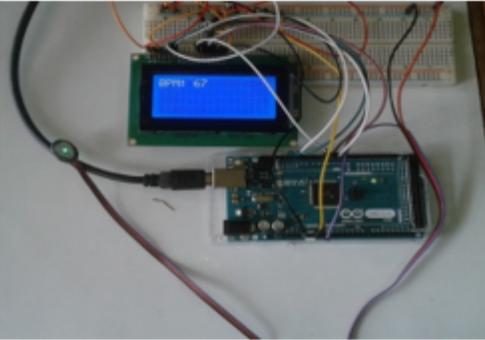


Figure 3

Components of DPHMD design

