Diagnostic performance of serial bedside Capillary Hemoglobin, Lactate and Shock index for severe postpartum hemorrhage. A Prospective Cohort Study.

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Abstract

Objective: To evaluate the diagnostic capacity of bedside capillary lactate (CLact), capillary Hemoglobin (CHb), and Shock index (SI) for severe postpartum haemorrhage (SPPH), at diagnosis 15 minutes and 30 minutes post-diagnosis **Design:** A prospective cohort study. **Setting:** A reference hospital in San Luis Potosi Mexico from February 2020 to March 2021 **Population:** Sixty women in vaginal labour or c-section who presented bleeding [?]500ml **Methods:** SI, CLact, and CHb concentration were analyzed at diagnosis, 15 minutes, and 30 minutes time intervals. T-test or Wilcox test was used to compare the group of severe vs non-severe. A Receiver Operating Curve was done to determine their cut points, Sensitivity, specificity, and performance **Main Outcome Measures:** SPPH defined as bleeding [?]2000ml measured by gravimetric method. **Results** SI at the diagnosis was significantly differentiate between severe from non-severe group (0.70 + 0.20 vs 0.90 + 0.38 P-value 0.0228) with al cut-point of 1.17 AUC of 0.76 sensitivity of 0.43 and specificity of 0.98. A capillary lactate measurement at 30 minutes was also significantly different between the groups (4.0 +1.90 vs 4.8 + 1.15 P-value < 0.001, with an optimal cut point of 4.3 mmol/dl at AUC 0.75, sensitivity 0.85, and specificity of 0.62. Capillary haemoglobin was not able to significantly differentiate the groups **Conclusions:** Shock index is an early sign of severe haemorrhage; Capillary lactate can significantly identify severe haemorrhage after 30 min. Capillary haemoglobin is not an early detector of severe haemorrhage.

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ABSTRACT.

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Conclusions: Shock index is an early sign of severe haemorrhage; Capillary lactate can significantly identify severe haemorrhage after 30 min. Capillary haemoglobin is not an early detector of severe haemorrhage.

Synopsis:

With a prospective cohort study, we determined that elevated shock index is an early sign of severe haemorrhage, Capillary lactate can significantly identify severe haemorrhage after 30 min. Capillary haemoglobin is not an early detector of severe haemorrhage.

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Introduction

Postpartum haemorrhage is the leading cause of maternal mortality and morbidity in the world accounting for approximately 10% of all births and the most common form of obstetric haemorrhage, which traditionally has been defined as a blood loss greater than 500 ml after vaginal delivery or 1,000 ml after cesarean section.(1) In 2017 the American College of Gynecology and Obstetrics (ACOG) published a recent definition as a cumulative blood loss greater than or equal to 1,000 ml or a blood loss accompanied by signs or symptoms of hypovolemia within 24 hours of the delivery regardless of the route of birth. (1) Some institution still considers the traditional definition as appropriate. (2) In Mexico, obstetric haemorrhage continues to be one of the main causes of extremely serious maternal mortality and morbidity especially in a low-resourced facility due to failure to identify the causes and lack of timely and adequate treatment. One of the main

problems during the medical management of these cases is the early identification of patients with severe cases o may develop severe haemorrhage and may need immediate resuscitation and need for blood products. (3). Currently, there are multiple criteria to initiate blood transfusion and fluid reanimation, basically, the decision includes clinical and biochemical evaluation, however, clinical changes in vital signs may appear late. According to major clinical guidelines, one of the transfusion criteria is blood loss of more than 1500 to 2000 ml but the blood loss quantification is still a problem. (4–7). Serum lactate and shock index have shown to be a good and early predictor of complications and necessity for transfusion, but in most of the low resourced facilities, it may be difficult to timely get it realized (8–10). Understanding the need for reliable bedside clinical tools to identify patients at risk of reaching a critical condition if they are not provided immediate resuscitation we investigated the use of bedside and minimally invasive protocol by measuring capillary lactate and haemoglobin with Acuttrend(r) Lactate and HemoCue(r) respectively. As a point of care that allows a quick dynamic evaluation accompanied by a clinical marker, we integrated the shock index (SI), which has also shown a better prediction towards adverse outcomes in patients with obstetric haemorrhage than conventional vital signs (11)

Methods

A prospective cohort study was carried out from February 2020 to March 2021 in which were included pregnant women with postpartum haemorrhage ([?]500ml in labour or [?]1000ml in c-section, Institutional definition of postpartum haemorrhage) in a reference hospital in San Luis Potosi Mexico (Hospital Central Dr. Ignacio Morones Prieto). The study obtained approval from the Institutional Ethical Committee (Registration number 93-19)

We included Pregnant patients in labour or cesarean section with postpartum haemorrhage, without conditions that might elevate lactate concentration such as eclampsia, leukaemia, lymphoma, and solid tumours, poorly controlled diabetes, liver failure, and ingestion of antiretroviral drugs and biguanides, confirmed sepsis or diagnosed with severe shock or documented anaemia at the beginning of the study, Patients who decided to withdraw their consent or to leave the study were eliminated. Bleeding volume was calculated by the gravimetric method as described here, blood-Stained Surgical Gauzes from delivery or c-section were weighed, and its dry weight was subtracted from the total blood-stained weight. Blood weight (g) was converted into blood volume (ml) using the accepted approximation of blood density of 1 g = 1mL. At the diagnosis of postpartum haemorrhage ([?]500ml in labour or [?]1000ml in c-section, Institutional definition of postpartum haemorrhage), Capillary lactate and haemoglobin were determined by bedside equipment Acutrend plus$^{(c)}$, and Shock index was calculated as the heart rate (HR) divided by systolic blood pressure (SBP). These parameters were also measured at 15 and 30 minutes after the diagnosis.

Statistical analysis

Statistical analysis was performed using Statistical program R 3.6 version and R Studio 1.2.1335, version. The sample size was calculated by r package ("MKmisc"), with command *power. diagnostic.test,* for diagnostic test with sensitivity of 0.95, specificity of 95 Significant level = 0.05, delta = 0.1, power = 0.8 as suggested by Cohen. The sample size required was 68 patients. We decided to remain with 60 patients as it does not alter the statistical power. The distribution of continuous data was assessed by Shapiro-Wilk's test, a comparison of capillary Hemoglobin, lactate, and shock index values between severe and non-severe haemorrhage groups was done by t-Test in case of normal distribution and Wilcox test for non-normal distribution data. A Receiver Operating Curve analysis was done to determine cut points, Sensitivity, specificity, and performance of each test at 0, 15, and 30 minutes from the diagnosis.

Results

We included 60 patients, 18 (30%) patients were classified as severe and 42(70%) as non-severe. (Fig1).

SI at the diagnosis was significantly differentiate between severe from non-severe group (0.70 + 0.20 vs 0.90 + 0.38 P-value 0.0228) ;(Table 1). It's cut point of 1.17 have shown good performance with AUC of 0.76, sensitivity of 0.43 and specificity of 0.98 (Fig. 2). The same as SI at 30 minutes (0.70 + 0.27 vs 0.90 + 0.55

P 0.0228). (Table 1,2 & Fig 2)

Capillary lactate of 4.3 mmol/dl at 30 min had good performance (AUC 0.75), with sensitivity 0.85, specificity 0.62. Whereas at the diagnosis offers unsatisfactory performance (AUC 0.46) 5.5 mmol/dl, Specificity 0.62, Sensitivity 0.8 and at 15 min also had the same performance (0.46) 5.5 mmol/dl, AUC 0.46, Sensitivity 0.73 specificity 0.43. (Table 1,2 & Fig 3)

Capillary haemoglobin generally had unsatisfactory performance, but 9.6 mg/dl at 30 min had satisfactory (AUC 0.62) with a specificity of 0.71 and sensitivity of 0.58, although 8.4 mg/dl at 15 min was more sensitive (Sensitivity 0.90, specificity 0.42) had unsatisfactory performance (AUC 0.56), the same performance was obtained with 9.4 at the diagnosis (AUC 0.58), sensitivity 0.69 specificity 0.57 (Table 1,2 & Fig 4)

Discussion

Main findings and Interpretation

Results of this study have shown the capacity of shock index, serum lactate in identifying severe postpartum haemorrhage defined as blood loss of more than 2000 ml. Additionally, reports an optimal moment for analysis of these parameters. Most of the studies which investigated the clinical application of these biochemical changes have not determined an optimal moment for its determination. (5,11,12).

Shock index:

Shock index is defined as the heart rate divided by systolic blood pressure. It has been studied in patients either at risk of or experiencing shock from a variety of causes such as trauma, myocardial infarction, hemorrhage, pulmonary embolism, sepsis, and obstetric haemorrhage. Schroll R. Et al reported Shock Index [?]1 had a sensitivity of 67.7% (95% CI 49.5%-82.6%) and specificity of 81.3% (95% CI 78.0%-84.3%) for predicting massive transfusion in trauma patients. In obstetrics, Nathan et al reported that SI [?] 1.7 had 25.0% sensitivity (95% CI 5.5-57.2) and 97.7% specificity (CI 94.8-99.3), for predicting ICU admission in postpartum haemorrhage.(13). Welsh et al reported SI de 0.9 as a good predictor of necessity for transfusion in postpartum haemorrhage (14). This study determined that the value of the shock index, dynamically evaluated, at the time of diagnosis, and 30 minutes after diagnosis, allows early identification of those patients who present massive bleeding with the sensitivity of 0.43 and specificity of 0.98 and 0.64 sensitivity and specificity 0.7 respectively. Our study's cut point did not differ much from other studies. As a general rule SI > 1 is the predictor of adverse effects in most of the clinical scenarios independent of the moment of its determination. At initial phases of shock, the compensatory mechanism of the cardiovascular system responds by increasing the heart rate, increasing myocardial contractility and constricting peripheral blood vessels as a result of the direct stimulation via the sympathetic system although this compensatory mechanism makes the shock index an early indicator of severe haemorrhage.

Serum lactate

Serum lactate has been studied as a strong biochemical marker of tissue hypoperfusion and hypovolemia in patients with obstetric haemorrhage; increased lactate concentration may indicate hypovolemic shock before traditional markers such as haemoglobin concentrations, and vital signs. There are portable lactate analysers that require 15-50 µL of blood and take approximately 60 seconds to process which makes it easier for the bedside monitoring by capillary lactate. Our research revealed that the bedside serum capillary lactate as a point-of-care test can differentiate the severe group from non-severe for this reason allows quick during lactate-guided recusation and probably reduce risk of thrombophlebitis that may result from venous sampling. Previously it was reported that venous lactate of 2.6 mmol/dl at the diagnosis of postpartum haemorrhage may be a good predictor for severe haemorrhage (sensitivity of 0.85 and specificity was 0.76) (10). For the case of capillary lactate, these outpoint seem to be higher, this may be a multifactorial effect including lactate detection method and compensatory mechanisms of peripheric blood constriction to guarantee blood flow to vital organs. We obtained the cut point of 4.3 mmol/dl at 30 min had good performance (AUC 0.75), with sensitivity 0.85, specificity 0.62 AUC 0.75. At the diagnosis and 15 min we obtained higher cut points but with low performance.

Capillary haemoglobin

Although the use of capillary haemoglobin was not statistically significant in differentiating between patients with massive bleeding, we found that a capillary haemoglobin value of 8.4 at 15 minutes has a sensitivity of 90% to identify patients at risk of reaching a critical condition if immediate resuscitation is not provided, and thus assist in the rapid and objective recognition of patients with severe postpartum haemorrhage (those who require massive transfusion during the immediate phase of resuscitation, including fluids and blood products) since patients with haemorrhage obstetrics requiring blood transfusion are a significant cause of maternal morbidity in our setting.

Strengths and limitations

The limitation of this study is that it was carried out in a tertiary level hospital where there is the availability of human resources and materials to combat severe haemorrhage for this reason very few patients may present complications such as coagulopathy and needs for intensive care unit admission, for this reason, we cannot tell the exact risk those complications using our capillary scheme. On another side, one of its advantages is that the materials needed to obtain these results are portable devices that can be easily obtained in the market, and thus low resourced facilities can obtain them for their patient monitoring.

Conclusions

Shock index and capillary Lactate may be reliable bedside clinical tools to identify patients with severe haemorrhage. Shock index is an early clinical detector of severe postpartum haemorrhage as early as at diagnosis, whereas lactate gains its value at 30 minutes post-diagnosis. Capillary haemoglobin was not able to differentiate the severe from non-severe as early as the first 30 min.

Author contributions.

- **Study design** VBK, MPL, RAC
- **Patients' recruitment and data collection:** NPA, RAC
- **Statistical analysis:** VBK, MPL
- **Final Manuscript redaction:** VBK, NPA
- **Manuscript submission** : VBK
- **All the authors** approved the final manuscript.

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Conflicts of interest : None

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TABLE 1

VARIABLE	TOTAL	SEVERE PPH	NON SEVERE PPH	P VALOR
IC at Dx	0.70 + 0.30	0.70 + 0.20	0.90 + 0.38	0.0228* w
IC at 15 min	0.70 + 0.22	0.70 + 0.20	0.80 + 0.23	0.1717 w
IC at 30 min	0.70 + 0.20	0.70 + 0.27	0.90 + 0.55	0.0228* w
Lactate Dx	4.80 + 2.68	4.8 + 2.6	5.6 + 3.3	0.7645 w
Lactate 15 min	4.40 + 2.58	4.4+ 2.8	4.5 + 2.4	0.9174w
Lactate 30 min	4.10 + 2.58	4.0 +1.90	4.8 + 1.15	< 0.001* W
Hb at Dx	10.38 + 2.13	10.43 + 2.16	9.98 + 1.84	0.5738 t
Hb 15 min	10.37 + 1.74	10.43 + 2.3	9.91 + 4.35	0.5897 t
Hb 30	9.74 + 1.70	9.83 + 1.7	9.10 + 1.57	0.2915 t

Patients. 60 (100%) 18 (30 %) 42 (70%) -

Label

w- wilcox test for non-normal data IC: Shock index Lact: Capillary lactate

t – T test for normal data. Hb: Hemoglobin Dx: Diagnosis

* – statistically significant

TABLE 2

Variable	Moment	Sensitivity	Specificity	AUC	Cutpoints
Shock index	At diagnosis	0.43	0.98	0.76	1.17
	15 min	0.43	0.85	0.66	0.65
	30 min	0.64	0.71	0.74	0.73
Capillary lactate	At diagnosis	0.58	0.57	0.46	5.5

Variable	Moment	Sensitivity	Specificity	AUC	Cutpoints
	15 min	0.73	0.43	0.56	5.6
	30 min	0.85	0.62	0.75	4.3
Capilary Haemglobin	At diagnosis	0.69	0.57	0.58	9.4
	15 min	0.90	0.42	0.56	8.4
	30 min	0.58	0.71	0.62	9.6