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DIAGNOSTIC ACCURACY OF SHOCK INDEX AS SCREENING TOOL FOR PRIMARY POSTPARTUM HAEMORRHAGE AFTER CAESAREAN SECTION AMONG WOMEN AT KAWEMPE NATIONAL REFERRAL HOSPITAL -A CROSS-SECTIONAL STUDY.

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ABSTRACT

Background:
Postpartum haemorrhage is the leading cause of maternal mortality globally and in sub-Saharan Africa. The shock index(ratio of the pulse to systolic pressure) is a quicker and more objective assessment tool for assessing the risk of deterioration as may occur in PPH, before apparent clinical deterioration. The diagnostic accuracy of the shock index in a Ugandan setting is not known.
The objective of the study was to determine the sensitivity and specificity, positive and negative predictive values of shock index in the diagnosis of primary postpartum haemorrhage after caesarean section among women delivering at Kawempe National Referral Hospital.

Methods:
A cross-sectional study design was used. The study was conducted in Kawempe National Referral Hospital among women who were delivered by a caesarean section between 1st January and 31st May 2021. A sample size of 594 was determined using formulae by Buderer. A consecutive sampling technique was used. The research assistants approached 650 participants; while 591 participants were fit for analysis. All participants were subjected to the determination of shock index at different intervals and the change in haematocrit as the gold standard for post-partum haemorrhage.

Results:
The sensitivity and specificity of the shock index at 2 hours were 40.0 and 82.8 percent respectively at a threshold of 0.8. The sensitivity and specificity were 70.0 and 54.6 percent after 24 hours when the shock index threshold of 0.7 was used. The PPV and NPV were 3.8 and 98.3 percent at 2 hours respectively while 2.6 and 99.1 percent at 24 hours.

Conclusion:
The shock index is a poor screening tool for diagnosing primary postpartum haemorrhage after caesarean section.

Recommendations :
Shock index may not be included in routine care of post-operative mothers for early recognition of those at risk of primary postpartum haemorrhage.

Key words: *Shock Index, Diagnostic Accuracy, Sensitivity, Specificity, Positive Predictive Value, Negative Predictive Value, Kawempe National Referral Hospital*
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Background

Primary postpartum haemorrhage (PPH) is among the leading causes of maternal deaths within the first 24 hours after delivery [1] contributing up to 25 % of all maternal deaths both globally and up to 30% of all maternal deaths in developing countries[2] [3]. The incidence of PPH in a high-resource country within Europe was found to be 6.4% [4] while that in low resource setting like Uganda was higher at 9% [5].

The risk for PPH is increased for mothers who deliver by caesarean section (C/S) compared to those who deliver vaginally due to acute blood loss that occurs before abdominal incision closure and contraction of the uterine musculature [6]. This is a result of general anaesthesia and the method of placental removal at delivery [7, 8]. There is an increasing rate of C/S between 2% and 19% per year both in the developed and developing countries [9]. Although the population-based C/S rate is still within the recommended range of 10 – 15% by WHO [10], standing at 4.7%, the caesarean section rate in referral hospitals was as high as 25% in 2016 [11], [12]. This means that there is an increasing number of women put at risk for PPH after C/S delivery.

Shock index (Shock Index) is one of the patient monitoring indices that can be used as a marker of clinical deterioration

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following acute illness, trauma, or surgery and is defined as a ratio of heart rate (HR) to systolic blood pressure (SBP) [13]. visual estimation frequently underestimates blood loss, and vital signs of SBP and HR are used to determine hemodynamic stability may be rather late in identifying patients at risk [14]. The African maternal early warning score has been recommended to identify women at risk of deterioration in Mulago National Referral and Kawempe National Referral hospitals. However, this tool is not often used since it has many parameters that may make patient monitoring difficult considering the high patient turnover and the low health worker-to-patient ratio[15]. Apart from the automated blood pressure and pulse rate, the AMEWS requires counting the respiratory rate for one minute[16] as well as time for accessing the level of consciousness, hence approximately 2 more minutes are needed. Additionally, many of the parameters are significant only after the patient has deteriorated, hence an altered level of consciousness and tachypnea may not be early warning signs [17]. The SI has only two parameters so it has simpler criteria than AMEWS thus it is easier to use as a screening tool for identifying mothers who would require comprehensive evaluation, rigorous monitoring, and further intervention. With an established threshold, lower cadres could easily use this index and offer appropriate intervention or referral.

This study aimed to find the sensitivity, specificity, and positive and negative predictive values for the shock index among women who were delivered by caesarean section in Kawempe National Referral Hospital. The results were hoped to determine whether the shock index could be included in the routine management of post-caesarean section to make an early diagnosis of postpartum haemorrhage before severe morbidity ensues.

Methods

Study Design:

The cross-sectional study design was employed for this study.

Study setting :

The study was carried out in Kawempe National Referral Hospital which specializes in maternal and child health and is a national referral hospital located in Kawempe division. Kawempe National Referral Hospital is also a teaching hospital for the Makerere University College of Health Sciences (MAKCHS). It has a capacity of 170 beds. The clinical staffing includes; 200 midwives, 55 specialists, 93 senior house officers, 15 medical officers, intern doctors, and intern nurses who are involved in the bedside management of patients. The hospital has five operating rooms with two dedicated to obstetric emergencies. The remaining three handle elective obstetric and gynecologic procedures, and gynaecological emergencies. From time to time, these can also be used to handle obstetric emergencies. Kawempe conducts antenatal, intrapartum, postnatal, and family planning services among others. In Kawempe National Referral Hospital, about 2,000 deliveries are conducted monthly, of which about 538 are by caesarean section. Approximately 18 caesarean deliveries are conducted per day. Caesarean sections are performed by intern doctors, medical officers, senior house officers, and specialists. Mothers who have undergone a caesarean section are monitored in the postnatal ward where intravenous fluids, antibiotics, and analgesia are administered. The postnatal ward has zero post-operative days and the high dependency unit sections, where mothers are admitted immediately after delivery. Patients are discharged on their 3rd postoperative day if there are no complications. The services offered are free of charge in the hospital. The study was conducted between 1st January and 31st May 2021.

Study participants:

Women aged 18 years and above who were delivered by caesarean section at Kawempe National Referral Hospital during the study period.

Inclusion Criteria:

Women aged 18 years and above who were delivered at Kawempe National Referral Hospital by caesarean section during the study period.

Exclusion criteria:

Mothers who received a blood transfusion within less than 24 hours prior to recruitment, since this could affect the study's gold standard.

Bias:

1. Transfusion with red cell products was a potential bias and this was avoided by excluding women who had received blood products within less than 24 hours

2. The fluid replacement was another potential bias, the study didn't attempt to control this and the results are as usual common practice. This was also noted as a limitation

Sample size estimation:

The sample size was estimated using the formulae by Buderer[18]. The sample size estimation was based on a study by Lee and colleagues which previously determined a PPH of 28.1% a Sensitivity (SN) of 93.75 and a Specificity (SP) of 51.22 for SI at a threshold of 0.9 with a PPH prevalence of 28.1% [19].

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The formula for Sensitivity;

$$N = \frac{Z^2{}_{\alpha/2} \times SN \times (1 - SN)}{W^2 \times P}$$

Where;

- Prevalence P= 28.1%
- Sensitivity SN = 93.75%
- Z value = 1.96 corresponding to 95% Confidence
- Precision (W) = 5%.

Therefore N = 321 participants.

The formula for Specificity;

$$N = \frac{Z^2{}_{\alpha/2} \times SP \times (1 - SP)}{W^2 \times (1 - P)}$$

Where;

- Prevalence P= 28.1%
- Specificity SP = 51.22%
- Z value = 1.96 corresponding to 95% Confidence
- Precision (W) = 5%.

Therefore N = 534.

The largest sample size calculated was considered therefore 534 participants were to be included in the study.

Considering 10% Non-response and dropouts, the adjusted sample size was $\frac{534}{(1-0.10)}$ = 594.

Therefore the final sample size was 594 participants.

Sampling procedure and data collection:

The participants were selected using a consecutive sampling method. Mothers who enlisted for caesarean delivery were told about the study and verbal consent was obtained. The mothers who gave verbal consent had 2 ml of a venous blood sample drawn into an EDTA-lined vacutainer and a complete blood count was determined. After the caesarean section, mothers or caretakers who earlier gave verbal consent were required to give informed consent to continue participating in the study; and were enrolled using consecutive sampling. Venous blood was drawn from the consented client in another EDTA coated vacutainer, for haemoglobin and hematocrit after 24 hours from delivery or before the first blood transfusion, for participants who needed to receive one. Face-to-face interviews were done after delivery. The blood pressure was taken using an automated electronic monitor and pulse rate by a pulse oximeter placed on the index finger, by the midwife or medical officer. The pulse rate at the end of the automated blood pressure reading was recorded. These measurements were taken every fifteen minutes within the first two hours of delivery with the mother in the left lateral position. The recordings were repeated every 2 hours for the next 4 hours, and 6 hours for the next 18 hours, measurements taken in left lateral or when seated upright position. The mothers were followed up until 24 hours when the second blood sample was drawn if no transfusion was received. Mothers who received blood a transfusion before a pretransfusion sample was taken were dropped from the study.

Bias:

1. Transfusion with red cell products was a potential bias and this was avoided by excluding women who had received blood products within less than 24 hours

2. Fluid replacement was another potential bias, the study didn't attempt to control this and the results are as usual common practice. This was also noted as a limitation

Data analysis

Statistical Analysis was done using STATA Version 14. Continuous baseline characteristics of the study participants were summarized using the mean and standard deviation or median and interquartile range for skewed data. Frequencies and proportions were used to summarize

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categorical variables. SI was dichotomized as positive and negative for participants who had a postpartum haemorrhage and those without respectively at different thresholds. The standard definition of PPH was a decline in haematocrit of 10% or more after 24 hours from delivery or before transfusion and was also dichotomized and coded as abnormal and normal for participants who had and those who didn't have postpartum haemorrhage respectively. The outcome measures of this study were presented using a 2X2 contingency table for objectives 1 and 2. The receiver operator curve was used to determine the threshold.

Ethical consideration:

Approval to do the study was sought from the School of Medicine Research and Ethics Committee (SOMREC) and administrative clearance from Kawempe National Referral Hospital. Short verbal consent was obtained on recruitment; eligible participants were told about the study and they verbally accepted or declined to participate in the study. Informed consent was obtained for continuation from the participants with an emphasis on voluntary withdrawal from the study. Confidentiality was observed by excluding the names of the participants on the questionnaires which had limited access.

Considering the era of the COVID-19 pandemic, all research assistants followed standard precautions of; sanitizing, handwashing with soap and water, and wearing a surgical mask during interviews. They used clean gloves during the examination and disposed of them safely.

Results :

A total of 650 mothers were eligible for participation and were approached, out of which 618 (95.07%) gave verbal consent for participation. Of those who gave verbal consent, 97.57% (n=603) gave informed consent while 98.51 (n=594) proceeded with the research procedures. During statistical analysis, 591 qualified, while 3 (0.7%) were excluded due to missing data.

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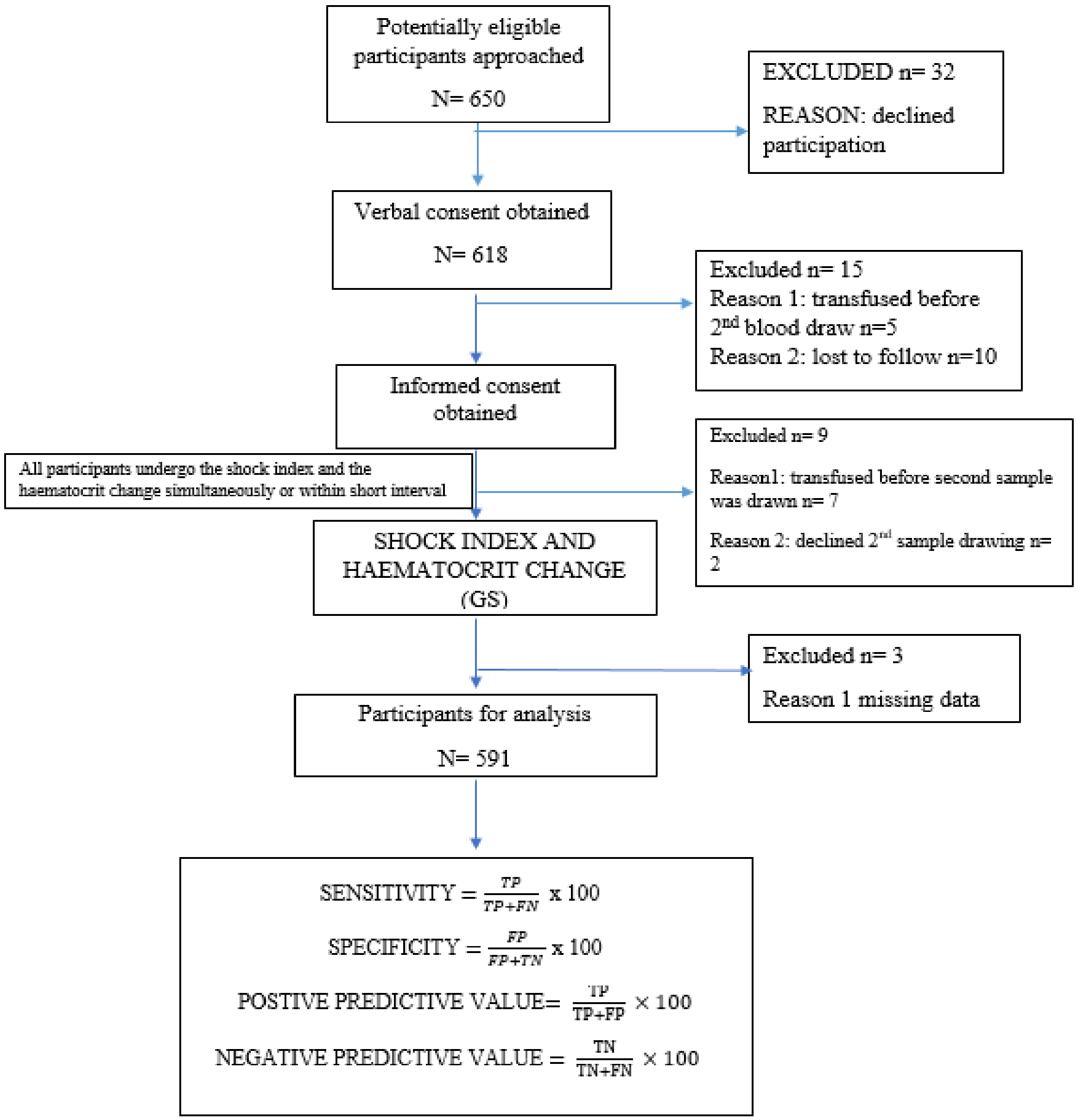
FLOW DIAGRAM



Sociodemographic characteristics:

The average age of participants was 26.4, minimum and maximum age was 18 and 47 years respectively. Forty-four 44% (258) of the participants were below 25 years, 27, 17, 10 percent were in ranges of 25 to 30, 35 to 40 years while 2% were above 40 years.

The majority of participants were catholic (31%) while moslems, Pentecostals, and Seventh-day Adventists constituted 25, 20, 21 and 3 per cent respectively.

The majority of the participants were married (88%) and the single mothers were only 12 %. Fifty-two percent of the participants had attended at least a secondary level of education, while primary and tertiary were 28 and 19 percent respectively.

The majority of participants were housewives/ unemployed (55%) while non-professional and professional job holders were 170 and 95 (29 & 16 percent) respectively.

Table 1.0 Demographic Characteristics of participants

	Frequency(n=591)	Percentage (%)
Age of the participants		
18-25 years	258	44
26-30 years	161	27
31-35 years	103	17
36-40 years	57	10
41-47 years	12	2
Religion		
Catholic	183	31
Moslem	149	25
Pentecostal	117	20
Protestant	125	21
Seventh-Day Adventists and others	17	3
Marital status		
Single	12	12
Married	88	88
Education level of participants		
Primary	168	28
Secondary	310	52
Tertiary	113	19
Occupation of the participants		
Housewife/Unemployed	326	55
Non-professional	170	29
Professional	95	16

Clinical characteristics of participants:

The average weight of participants was 70.6kg while the minimum and maximum weights were 40 and 127kg respectively. The average height was 158.3cm; the minimum and maximum heights were 131 and 176 cm respectively. Emergency caesarean section constituted 94% (n=556) of the participants while 6% were elective deliveries (n=35). The commonest indication of caesarean delivery was previous uterine scar for 33% (n=195) of the respondents, seconded by obstructed labour in 26% of the participants (n= 151). Fetal distress, hypertensive disorders of pregnancy, and cephalopelvic disproportion were the indications in 9, 9, and 10% of the respondents.

Spinal anaesthesia was used on 98% (n=579) of the participants on this delivery and 97% (n=571) delivered singletons. The Pfannenstiel incision of abdominal access was used on 95% (n=563) of the participants and the midline incision in only 5% (n=28). Ninety-nine percent of the participants reported that they didn't have a fever during labour or before delivery. A prior diagnosis of hypertension associated with pregnancy had been made in 9% (n=54) of respondents.

Non-pharmacological modes of pain control were used in 5% of the respondents, 6% received NSAIDS, 47% received weak opioids, and 53% received strong opioids. Blood transfusion was prescribed and given to 2 % of the participants who were kept in the analysis.

Postpartum haemorrhage was diagnosed in 2 percent of the study participants using the gold standard (haematocrit change of ≥10%).

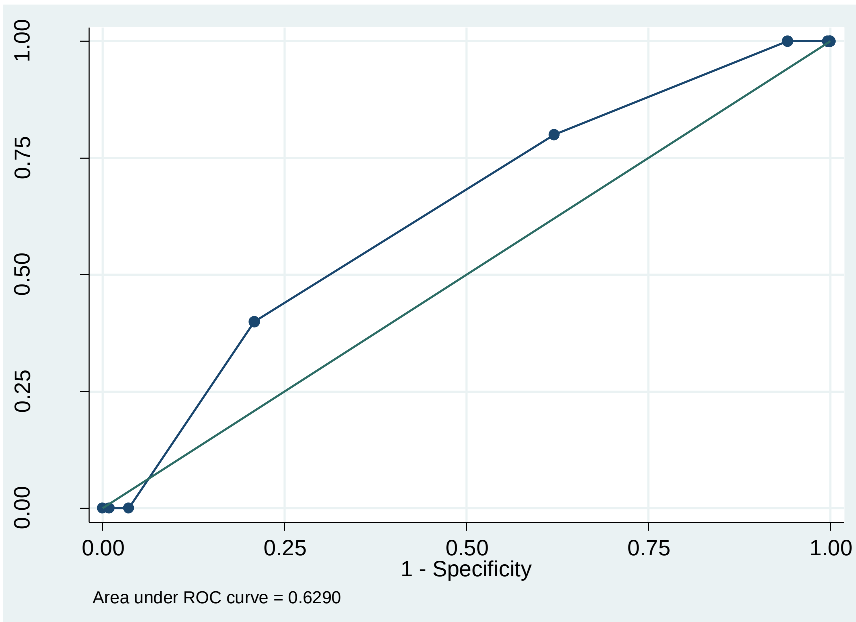
Table 2.0 gold standard and shock index

	Minimum	Maximum	Mean	Median	Standard deviation	1st Quartile	3rd Quartile
Hematocrit before delivery	21.6	82.2	41.0	40.3	7.1	36.8	45.3
Hemoglobin before delivery	6.7	24.2	12.3	12.3	2.0	11.3	13.3
Hematocrit before transfusion	25	34	31.2	32.9	4.2	28.9	33.5
HCT 24 hours after delivery	9.3	75.3	37.0	6.3	37.1	33.3	41.1
Average shock index up to 2 hours	0.40	1.19	0.73	0.72	0.09	0.67	0.79
Average shock Index up to 24 hours	0.43	1.06	0.72	0.71	0.08	0.67	0.77

Determining threshold

Using the receiver operator curve a threshold for shock index 0f of 0.8 gave the greatest AUC (0.61) for the shock index within 2 hours of delivery, while for 24 hours the threshold of 0.7 gave the greatest area under the curve (0.62) for averages over 24 hours.

Graph 1.0 ROC CURVE (Average shock index up to 2 hours)



From this ROC curve, the area under the curve was 0.6290 and corresponded to the threshold of 0.8.

Table 3.0 Sensitivity, specificity, AUROC, PPV and NPV at different cut-off points (with average shock index up to 2 hours)

Cut point	Sensitivity(95% CI)%	Specificity(95% CI)	ROC Area(95% C.1)	PPV(95% CI)%	NPV
≥ 0.4	0.0(0.0-30.8)	99.7(98.9-100.0	0.50(0.50-0.50)	0.0(0.0-84.2)	98.3(96.9-99.2)
≥ 0.5	0.0(0.0-30.8)	94.5(92.3-96.2)	0.46(0.46-0.48)	0.0(0.0-10.9)	98.2(96.7-99.1)
≥ 0.6	20.0(2.5-55.6)	68.0(64.0-71.8)	0.44(0.31-0.57)	1.1(0.1-3.8)	98.0(96.1-99.1)
≥ 0.7	40.0(12.2-73.8)	58.9(54.7-62.9)	0.49(0.33-0.66)	1.6(0.5-4.2)	98.3(96.3-99.4)
≥ 0.8	40.0(12.2-73.8)	82.8(79.5-85.8)	0.61(0.45-0.77)	3.8(1.1-9.6)	98.8(97.3-99.5)
≥ 0.9	0.0(0.0-30.8)	97.2(95.6-98.4)	0.49(0.48-0.49)	0.0(0.0-20.6)	98.3(96.8-99.2)
≥ 1.0	0.0(0.0-30.8)	99.1(98.0-99.7)	0.50(0.49-0.50)	0.0(0.0-52.2)	98.3(96.9-99.2)

Graph 2.0 ROC CURVE (Average shock index up to 24 hours)

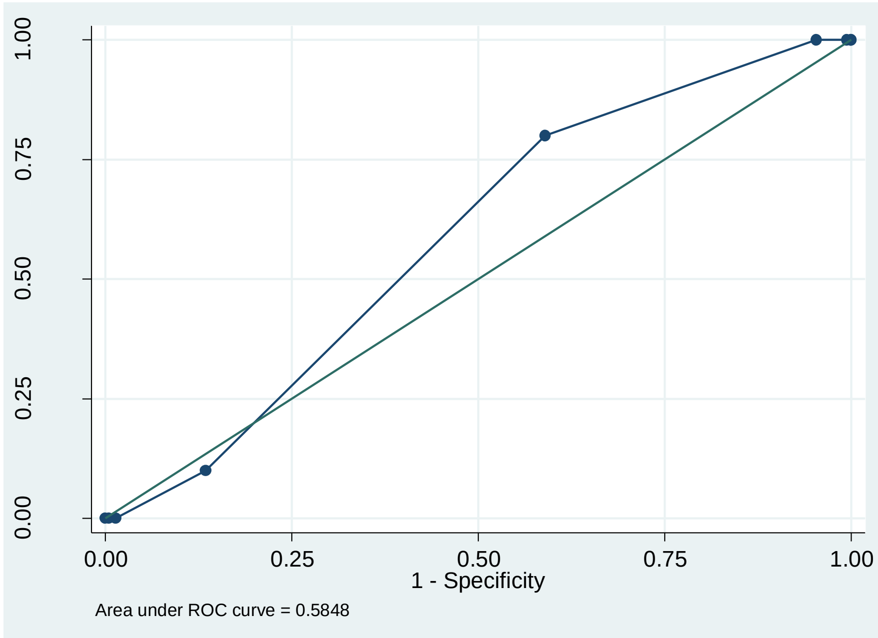


Table 4.0 Sensitivity, specificity, AUROC, PPV and NPV at different cutoff points (with average shock index up to 24 hours)

Cut point	Sensitivity(95% CI)%	Specificity(95% CI)	ROC Area(95% C.1)	PPV(95% CI)%	NPV
≥ 0.4	0.0(0.0-30.8)	99.5(98.5-99.9)	0.50(0.49-0.50)	0.0(0.0-70.8)	98.3(96.9-99.2)
≥ 0.5	0.0(0.0-30.8)	95.9(93.9-97.3)	0.48(0.47-0.49)	0.0(0.0-14.2)	98.2(96.8-99.2)
≥ 0.6	20.0(2.5-55.6)	63.7(59.6-67.6)	0.42(0.29-0.55)	0.9(0.1-3.4)	97.9(95.9-99.1)
≥ 0.7	70.0(34.8-93.3)	54.6(50.4-58.7)	0.62(0.47-0.77)	2.6(1.0-5.2)	99.1(97.3-99.8)
≥ 0.8	10.0(0.3-44.5)	88.0(85.0-90.5)	0.49(0.39-0.59)	1.4(0.0-7.6)	98.3(96.7-99.2)
≥ 0.9	0.0(0.0-30.8)	98.6(97.3-99.4)	0.49(0.49-0.50	0.0(0.0-36.9)	98.3(96.9-99.2)
≥ 1.0	0.0(0.0-30.8)	99.5(98.5-99.9)	0.50(0.49-0.50)	0.0(0.0-70.8)	98.3(96.9-99.2)

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Discussion:

This study sought to determine the diagnostic capability of shock index to screen for primary PPH after caesarean section. The participants had wide demographic and clinical characteristics and were, therefore,

representative of caesarean sections performed in Kawempe National Referral Hospital and other Ugandan health facilities. The study did not seek to determine the performance of the shock index when participants had specific demographic or clinic characteristics. Caesarean sections in Kawempe National Referral Hospital are performed by specialists (obstetrician and gynaecologist), senior house officers (residents of OBSGYN), and intern doctors, however, these were not part of the study variables.

Sensitivity and specificity.

After 2 hours of delivery, the threshold of 0.8 shock index gave the highest sensitivity and specificity, i.e. 40% and 82.6%, respectively. The threshold of 0.8 was used since it had the highest ability to distinguish between those who have the disease (PPH) and those without (AUC 0.61). The threshold determined in the study was in agreement with a study by Pinheiro and colleagues who determined the mean normal ranges of shock index within two hours of delivery to be between 0.68 to 0.74 [20]. The high sensitivity at this threshold means that a shock index of greater or equal to 0.8 can be used to rule out the presence of postpartum haemorrhage. The ability of the shock index to determine a patient without PPH was better than its ability to diagnose a person with the disease. After 24 hours, a threshold of 0.7 gave the highest sensitivity of 70% and specificity of 54 percent. A study by Taylor found a normal reference range between 0.46 and 1.07 [21], while Nathan and colleagues reported a median, lower, and upper quartiles of 0.66, 0.6, and 0.74[22]. A shock index threshold of 0.9 was reported by Alison and colleagues for postpartum [23] with 100% sensitivity and values higher associated with a need for invasive intervention, ICU admission, and blood transfusion. Postpartum haemorrhage is fatal contributing to between 30 to 50% of the maternal deaths in sub-Saharan Africa [24]. Since the incidence is quite high in Africa, a lower threshold should be considered for an evaluation, closer monitoring, and frequent reviews. This implies that the low resources and staffing should be focused on those who are above the threshold. It's worth noting that the chances of having false positives are high. In high-resource countries, a high threshold may be used because of its high sensitivity. The likelihood of the woman having no PPH or related morbidity would be low at the same threshold [23].

Positive and negative predictive values.

The positive predictive value is the probability that the individuals who are identified as positive by the shock index have postpartum haemorrhage, while the negative predictive value is the probability that those who test negative don't have the disease. These two predictive values are affected by the prevalence of disease as determined by the gold standard[25]. The positive predictive values determined in this study were 2.6 % and 3.8% for thresholds of 0.7 and 0.8 respectively. This was far below the results by Dziadodsz and colleagues who reported a PPV of 26% at a threshold of 0.9[26] but close to Alison and colleagues' findings of 6.6% and 6.5% for severe maternal outcomes at thresholds of 0.7 and 0.9

respectively[23]. The shock index had a PPV of 4.6% for PPH leading to maternal death at a threshold of 0.9 according to a study by Nathan and friends[27]. The negative predictive values determined in the study of 99.1% and 98.8% at 0.7 and 0.9 thresholds were similar to those determined in a study by Dziadodsz of 89% at 0.9 threshold and those by Nathan and colleagues of 100% and 93.8% for thresholds of 0.7 and 0.9 respectively[23, 26].

The study did not involve interventions that altered routine care at the study site. Also, the participants had wide variations in demographic and clinical characteristics. The finding can generalized among women delivered by caesarean section in Ugandan facilities.

Conclusion:

The prevalence of primary postpartum haemorrhage in Kawempe National Referral Hospital was lower than intervention-based prevalence. The shock index was a poor diagnostic tool and therefore was not a good predictor of postpartum haemorrhage. A lower threshold may be used since postpartum haemorrhage is fatal and quite common in resource-limited settings, while a higher threshold may be used in high-resource settings. Moreover, a lower threshold can be used to rule in while a higher threshold can be used to rule out.

Recommendations:

Shock index should be included in routine care of post-operative mothers for early recognition of those at risk of primary postpartum haemorrhage.

A further study using a similar gold standard should be done with a bigger sample size should be carried out to finetune the thresholds for the shock index and primary postpartum haemorrhage. A similar study that has a stringent follow-up on patients who receive blood transfusion after delivery should be carried out.

Limitations:

The gold standard for the diagnosis of postpartum haemorrhage could be affected by fluid therapy.

Many of the participants were eliminated because they received blood transfusions outside the study procedures, yet these could have influenced the study findings.

The positive predictive values were low in this study because of the low prevalence of postpartum haemorrhage as determined by the 10% decline in hematocrit after 24 hours of delivery.

Abbreviations:

AMEWS: African Maternal Early Warning Signs

AUROC: Area Under Receiver Operator Curve

C/S: Caeserean section

FN: False Negative

FP: False Positive

GS: Gold Standard

HCT: Haematocrit

HR: Heart rate

NPV:Negative Predictive Value

OBSGYN: Obstetrics and Gynaecology

PPH: Postpartum haemorrhage

PPV: Positive Predictive Value

ROC: Receiver Operator Curve

SBP: Systolic blood pressure

SI :shock index

SN: sensitivity

SP : specificity

TN: True Negative

TP:True Positive

WHO: World Health Organisation

Authors contribution:

LJNC developed the proposal, was the principal investigator, collected data and drafted the first manuscript. MS and TM conceived and supervised proposal development, data analysis and drafting of the manuscript read and approved the final manuscript. NJ and LJNC revised and proofread the final manuscript.

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Competing interests:

The others declare no conflict of interest.

Source of funding:

The study was funded by the principal investigator.

Author Biography:

Dr Lwasa Joel Njagala Calls was the principal investigator of the study and the main author of the manuscript. He graduated with a master's of Medicine in Obstetrics and Gynaecology at Makerere University Kampala in May 2022 and is currently practicing at Kawempe National Referral Hospital. He completed his Bachelor's degree in Medicine and Surgery at Makerere University in 2015. He is a lifelong learner and currently exploring a research career.

Dr Joannah Nalwoga is the study co-investigator. She is a graduate of Makerere University where she mastered

Obstetrics and Gynecology in 2022. She graduated from the same university in 2015 with a bachelor's degree in Medicine and surgery. Currently, she practises at Kayunga Regional Referral Hospital where she also doubles as the chairperson of the Training and Research Committee.

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