

## **Sensitivity and Specificity of Shock Index in Predicting Adverse Maternal Outcomes among Pregnant Women- A Prospective Study.**

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**Conflicts of Interest:** Nil

### **Abstract**

**Background:** Clinical parameters and vital signs are unreliable markers for assessing the haemodynamic status of pregnant women secondary to the physiologic and pathologic changes of pregnancy.

**Aim:** To determine the validity of the Obstetric Shock Index (SI) in identifying the adverse maternal outcome among pregnant around the time of childbirth.

**Material and Methods:** This was a single centre, hospital-based, open, prospective, observational study. We enrolled a total of 218 pregnant women coming to our institute for deliveries for 6 months. We collected data on obstetric history, haemoglobin, clinical parameters, and maternal outcomes of pregnancy. We followed women from admission to the hospital until 7 days postpartum.

**Results:** Of the total 218 women included in the study: about 80 % did not have any complications, 8.7% had a postpartum haemorrhage, 8.3 required admissions to a critical care unit and 3.2% women died. The sensitivity of  $SI \geq 1.0$  for detecting PPH, admission to critical care unit, and death was 89.8%, 92.8%, and 96.8%, respectively. The specificity of  $SI \geq 1.0$  for detecting PPH, admission to critical care unit, and death was 26.3%, 19.7%, and 14.2%, respectively. The sensitivity and specificity of  $SI \geq 1.0$  for detecting all three types of adverse maternal outcomes were 94.1% and 18.4%, respectively.

**Conclusion:** SI could sensitively aid in the earlier recognition of haemodynamic compromise before changes in heart rate or blood pressure alone. We

propose a threshold of  $SI \geq 1.0$  for identifying women requiring urgent high-level care.

**Keyword:** SI, MEOWS, PPH, WHO.

### **Introduction**

Childbirth is a natural physiological process, all women giving birth lose some amount of blood during the immediate postpartum period[1]. Furthermore, in most women, postpartum blood loss is well tolerated[2]. However, some women suffer from a myriad of complications during the process of childbirth. Consequently, a woman or her new-born child or unfortunately both can die during the process of childbirth[3]. Maternal mortality is still the most common cause of premature death among women of the reproductive age group, especially among those living in developing countries[3]. Haemorrhage, especially postpartum haemorrhage (PPH) is the most common cause of maternal mortality in the world in both the developing and developed countries[3], [4]. The empirical data suggests that approximately 8% of all deliveries are complicated by obstetric haemorrhage[3], [5]. Depending on the rate of blood loss and other factors such as hemoglobin level, untreated PPH can lead to hypovolemic shock, multi-organ dysfunction and maternal death within 2 to 6 hours[3], [4], [6]. World Health Organization (WHO) recommends active management of the third stage of labour to reduce the incidence of postpartum haemorrhage[7], [8]. Nevertheless, despite the best efforts, it is impossible to prevent haemorrhages, especially antepartum in every pregnant woman.

In 1990, the World Health Organization adopted the definition of PPH after vaginal delivery as the 'loss of 500 ml or more of blood from the genital tract after delivery of a baby'[9]. Direct measurement is the ideal

method for quantifying blood loss after birth. As the majority of PPH-related maternal deaths take place in resource-constrained settings, thus the use of direct methods (e.g., gravimetric, or photometric) for quantifying blood loss is not realistic[10]. Further, the Royal Society of Obstetricians, UK recommends the use of modified early obstetric warning score (MEOWS) charts in all pregnant and postpartum women to help more timely recognition of life-threatening conditions [11]. However, MEOWS is calculated by scoring the values of Temperature, Systolic blood pressure, Diastolic blood pressure, Heart rate, Respiratory rate, and Level of consciousness [11]. Similar to the methods for direct measurement of blood loss, such an elaborate set of observations is not feasible in a low resource setting. Therefore, traditionally, Visual estimation of blood loss (VEBL) is the most frequently used method around the world in the diagnosis of PPH [10]. However, several studies have confirmed that the use of VEBL has been associated with the underestimation of the amount of blood loss [12], [13]. Considering these limitations, other methods for estimating blood loss have been developed (e.g., hematocrit / hemoglobin assessment) together with alternative PPH definitions (e.g., 10% drop in hematocrit /hemoglobin) [12], [13]. However, the added benefit of these alternative methods in comparison with VEBL seems to be minimal and their applicability in resource-constrained settings is limited[12], [13].

Impending shock may be masked by the hemodynamic changes of pregnancy, making conventional vital signs less useful, and signs taken in isolation may miss impending deterioration[14]. The shock index (SI), the ratio of pulse rate to SBP, is proposed as an earlier marker of hemodynamic compromise than conventional vital parameters /signs [15]. Trauma literature suggests

the normal adult SI range is between 0.5–0.7 and during pregnancy, the provisional normal value of SI is 0.7 to 0.9 [16]–[18]. However, empirical research is necessary to establish the clinical utility of SI as an early marker of shock, due to antepartum and peripartum circulatory changes. Therefore, the present study was designed to determine the validity of the predetermined Obstetric Shock Index in predicting Maternal adverse outcomes among pregnant women.

### Methods and material

**Study Design:** A single centre, open, prospective, cohort, observational study.

**Study Setting:** Department of Obstetrics & Gynaecology, LN Mmedical College, and affiliated JK Hospital, Bhopal, Madhya Pradesh. It is a tertiary care institute. The study was approved by the Institute's ethical committee on Human Research.

**Study Duration:** Total 6 months; from March 2021 to August 2021.

### Study Outcomes

**Adverse Maternal Outcome: anyone of the following event**

- a. Post-partum haemorrhage: as a blood loss of 500 ml or more within 24 hours after birth, and severe primary PPH as blood loss of more than 1000ml or more within 24 hours after birth [19].
- b. Admission to the Maternal Critical Care Unit (CCU)
- c. Maternal Mortality within 7 days of admission.

**End Point of Study:** (i) A participant decided to withdraw from the study, (iii) After discharge from the hospital.

**Participants' recruitment:** The participants were recruited into the study after verifying that they fulfilled the following criteria

### Inclusion

- Pregnant women with the gestational age of more than 28-weeks at the time of hospital admission.
- Patients agree to provide written informed consent.

### Exclusion Criteria

- Pregnant women have any of the following pathologic conditions that could alter autonomic regulation; hypertension, hyper or hypothyroidism (untreated), any cardiac disease, infection with fever or sepsis and a history of coagulopathy.
- A patient who refused to take part in the study.

**Sample Size:** The smallest required sample size for the study was estimated following the recommendation of Charan et al (2012) for a cohort study[20]. Using the prescribed formula, the minimum sample size was calculated as 203.

**Informed Consent:** A bilingual (Hindi, & English) consent form was drafted following the prescribed guidelines for research on human participants. The consent form was given to all the participants to read. Thereafter, the contents of the consent form were explained to all the prospective participants. The participants were informed and explained that they have the right to withdraw from the study at any point in time. Thereafter, willing participants were asked to sign the consent form.

**Sampling Methodology:** we employed the non-random, purposive, convenience sampling methodology to recruit participants for the study. Pregnant women coming to the emergency/inpatient department were managed as per the recommended protocol. The prospective participants were approached for informed consent. The principal investigators approached all prospective participants and explained to the guardian/accompanying

person in detail the study procedure and participants' roles (and implications).

**Data Collection:** The data were collected in a paper-based proforma. The proforma had 5 parts as follows: (i) Demographic details (ii) Pregnancy and Obstetrics history (iii) Clinical Examination and Laboratory Investigations (iv) Intrapartum details (v) Postpartum detail (up to 7 days). We collected the following data from the participants: pulse rate, systolic- and diastolic blood pressure, pulse pressure, mean arterial pressure, urine output, blood loss, amount of IV fluids given, blood transfusion, and uterotonics administered. All the above-mentioned data variables were recorded at an interval of 30-minute intervals until the cause of bleeding was identified and treated. Predictor variables for the present study included Shock Index measured at the time of admission, the highest SI value, and the lowest SI value after the admission. The Shock Index (SI) was calculated as heart rate divided by systolic blood pressure. The heart rate was calculated by measuring the pulse in the radial artery at the wrist. BP was measured following the standard auscultatory technique with a mercury sphygmomanometer.

**Measurement of blood loss:** The blood loss was calculated by QBL, by the combination of gravimetric and direct methods [12].

**Statistical Analysis Plan:** The primary outcome was the validity i.e., sensitivity and specificity of pre-determined values ( $\geq 1.00$ ) of SI in predicting Maternal Outcomes among the study participants. The coded data were imported into Stata 17.1 version for analysis. For the continuous data, the author calculated the mean, median, mode, standard deviation, and inter-quartile range. For discrete data, we calculated and reported frequency, proportion, and percentage [21].

**Funding:** There was no funding for the present study. The participants were not paid any type of fees/incentives/freebees to participate in the study.

**Results**

To recruit participants for the present study we approached a total of 247 participants: 29 participants were excluded/refused/referred out and 218 participants were enrolled in the present study.

Table 1: Participant's Characteristics (n=218)

Variable	n	%
Gravida		
1	66	30.3
2	89	40.8
3 or more	63	28.9
Mode of Delivery		
Vaginal	154	70.6
Assisted	0	0.0
Caesarean	64	29.4
Haemoglobin decline >10%		
Yes	15	6.9
No	203	93.1
Blood Transfusion		
Yes	45	20.6
No	173	79.4
Age (Mean $\pm$ SD)	24.5 ( $\pm$ 6.5)	
Gestational Age (Mean, SD)	35.3 ( $\pm$ 6.3)	

Table 1 illustrates the participants' characteristics in detail. The mean and median age of the participants was 26.5 and 24 years, respectively. Most women were gravida=2. The mean gestational age was 35.3 weeks. The most common mode of childbirth/delivery among the participants was a normal vaginal delivery. Lastly, about 7% of women had a more than 10% decline in haemoglobin and about 20% of women required blood transfusion.

Table 2: Vital signs among participants at the time of admission (n=218)

Vital Sign	Mean	Median (IQR)	Range
Pulse	104.4	110 (102-126)	84-137
Systolic BP	116.1	114 (104-126)	88-148
Diastolic BP	71.4	74 (68-82)	59-88
MAP	81.8	86 (74-92)	68-98
Pulse Pressure	31.5	34 (28-42)	19-48
Haemoglobin	8.8	9.1 (8.5-9.8)	6.3-10.4

Table 2 gives the details about the vital parameters of the study participants at the time of admission to the hospital. About 7.2% of women in our study were severely anaemic (Haemoglobin < 7 mg/dl).

Table 3: Maternal and Foetal outcomes.

Outcome	n	%
Maternal Outcome (n=218)		
No Complications	174	79.8
PPH	19	8.7
Admission to CCU	18	8.3
Death	7	3.2
Foetal Outcome (n=220*)		
No complications	169	77.5
APGAR Score of <7 at 5 minute.	16	7.3
Admission to NICU	21	9.6
Early Neonatal Mortality	5	2.3
Stillbirth	9	4.1
*- 2 Twin pregnancies		

Table 3 gives details of the maternal and foetal outcomes among the participants. Of the total 218 women included in the study: about 80 % did not have a complication, 8.7% had PPH, 8.3% required admission to CCU, and 3.2% women died. In addition, about 78% of new-borns did not have any complications and about 10% of new-borns required admission to the NICU.

Table 4: Mean Shock Index value among participants (n=218)

Outcome	OSI <sup>A</sup>	OSI <sup>B</sup>	OSI <sup>C</sup>
Maternal Outcome			
No Complications	0.83	0.94	0.76
PPH	0.96	1.26	0.94
Admission to CCU	1.09	1.52	1.12
Death	1.16	1.89	0.98
A-At the time of admission, B- Highest (worst), C- Lowest (best)			

Table 4 gives details about the value of the Obstetrics index measured at various time points during the study. As can be noted from Table 4, as the severity of the complication increased, the mean SI at the time of admission increased: no complications (OSI=0.83), PPH (OSI=0.96), admission to CCU (OSI1.09), and maternal death (OSI=1.16).

Table 5: Performance of Shock Index\*  $\geq 1.00$  in predicting adverse maternal Outcome.

Maternal Outcome	Sensitivity (95%CI)	Specificity (95%CI)	PPV (95%CI)	NPV (95%CI)
PPH	89.8 (83.4–96.5)	26.3 (19.3–34.1)	18.5 (12.3–24.9)	96.5 (89.6–99.6)
Admission to ICU	92.8 (87.8–94.6)	19.7 (13.7–23.2)	14.5 (9.0–18.3)	93.8 (82.8–98.7)
Maternal Death	96.8 (91.2–100.0)	14.2 (9.6–18.6)	9.2 (6.4–15.7)	81.3 (67.4–91.1)
All adverse Maternal Outcomes	94.1 (90.2–97.8)	18.4 (11.6–21.1)	10.3 (7.5–14.7)	91.4 (78.4–95.1)
*.-The highest value of the Shock Index				

Table 5 shows the sensitivity, specificity, and positive- and negative predictive values of the obstetric Shock Index  $\geq 1.00$  among study participants. The suggested

normal value of SI for non-pregnant women is 0.7. Further, the suggested normal value of SI for women during the postpartum period is 0.9. Therefore, we assessed the value of  $OSI \geq 1.00$  in predicting the adverse outcomes among pregnant women. The sensitivity of  $OS \geq 1.0$  in predicting any of three adverse events (i.e., postpartum haemorrhage, admission to CCU or maternal death) in a pregnant woman was 94.1%. This means that  $OS \geq 1.0$  was able to identify 94 out of 100 women who suffered from any of the three adverse events. However, the specificity of  $OSI \geq 1.0$  in predicting adverse events was low at 18%.

The sensitivity of  $OSI \geq 1.0$  for detecting postpartum haemorrhage (the most common cause of maternal death) was 89.8 (95%CI= 83.4–96.5). In other words,  $OSI \geq 1.0$  was able to correctly identify 90 out of 100 women who suffered from PPH. The sensitivity of  $OSI \geq 1.0$  for identifying mothers who would require admission to the critical care unit (for either medical or surgical interventions) was 92.8 (95%CI= 87.8–94.6). Overall, at a value of  $SI \geq 1.0$ , the sensitivity was highest for maternal death ( $OSI=1$ : sensitivity 96.8 (95%CI= 91.2–100.0)). This means that 96% of all women who did not survive the process of childbirth were correctly identified by  $SI \geq 1.0$ .

Table 6 illustrates the validity (sensitivity and specificity) of various cut-off values of the Shock Index for identifying maternal death. As can be inferred from the table as the value of SI increased: the sensitivity decreased, and the specificity increased. The Shock Index value equals 1.3 and 1.4 were able to correctly identify more than 80% of pregnant women who suffered terminal events in the present study.

Table 6: Performance of various cut-offs of Shock Index\* in predicting maternal Death.

OSI	Sensitivity (95%CI)	Specificity (95%CI)
1.1	93.2 (87.2–97.1)	34.4 (27.8–39.4)
1.2	90.6 (84.1–95.3)	43.8 (37.6–47.1)
1.3	85.4 (80.1–92.6)	54.7 (49.4–62.1)
1.4	82.4 (74.3–93.6)	65.1 (66.9–73.0)

### Discussion

Conventional vital signs viz. heart rate and blood pressure have proven to be late markers of haemodynamic compromise in obstetric populations. A healthy woman can lose up to 30% of her blood volume before any significant decline in SBP is noted, thus leading to a false assumption of haemodynamic stability and delay in providing medical care [22], [23]. Hypovolemic shock secondary to obstetric (mostly encountered during the postpartum period) haemorrhage remains the single most important cause of maternal deaths worldwide[3]. The UK Confidential Enquiries into Maternal Deaths highlighted the lack of recognition of abnormal vital signs in the majority of women who died secondary to PPH[24]. Thus, the need for an obstetric early warning system is not only relevant for low- and middle- income countries. Modified early obstetric warning system charts are now commonplace in several developed countries [11]. However, these charts are complicated to use and inappropriate for low-resource settings, where temperature and oxygen saturation is often not routinely measured[11]. Our objective was to determine whether Obstetrics Shock Index (SI) could aid decision-making for healthcare providers. This study represents an evaluation of SI as a predictor of adverse maternal outcomes in pregnant women around the time of delivery. We conducted our study at a tertiary centre to ensure the sample size and

corresponding outcome rates were high enough for meaningful analysis. The haemodynamic changes of pregnancy and postpartum may delay the recognition of hypovolemia. Hence any thresholds for detecting adverse maternal outcomes must be derived from obstetric populations and be validated for various adverse maternal outcomes. Monitoring postpartum women with SI may help tailor treatment decisions and reduce adverse events, through timely resuscitation and referral. Thus, we conducted a prospective observational study of 218 pregnant women evaluating the performance of various SI cut-off thresholds for multiple adverse maternal outcomes viz. postpartum haemorrhage, admission to critical care unit, and maternal death. We drew upon a sample of women with a variety of obstetric complications and gestational age.

Previous research has suggested a normal SI range of 0.7–0.9 for obstetric populations, with 0.9 representing the transition into abnormality [15]. El Ayadi et al. have recommended the threshold of  $\geq 0.9$  for the need for referral,  $\geq 1.4$  for urgent intervention,  $\geq 1.7$  as indicating a high chance of adverse outcome [23]. The utility of SI may have the greatest impact in low-resource settings; however, healthcare providers may not always have access to technology enabling SI calculation. Research with non-pregnant populations confirms that an SI threshold of 1.0 indicates the need for intensive management and a higher risk of mortality [25], [26]. For a healthcare worker in low resource settings, the easiest way to identify women in need of immediate care would be to observe if the pulse rate is greater than systolic blood pressure ( $SI \geq 1.0$ ). In other words, a woman in immediate need of medical attention can be easily spotted if her HR exceeds SBP (indicating a  $SI \geq 1$ ). Lastly, Le Bas et al [15], also recommended that

referral or intervention be triggered where the pulse rate is greater than or equal to systolic blood pressure, indicating an SI threshold of 1.0, which may be useful in settings where health care workers are unable to compute the ratio of pulse to SBP. Hence, we decided to study the validity (sensitivity and specificity) of the SI threshold of 1.0 or higher for women suffering adverse maternal outcomes.

In our study, the mean SI value was significantly higher for those subjects who had an adverse outcome as compared to those who had normal outcomes. Similar to our findings Chaudhry M et al. also reported that the mean SI value was significantly higher for those subjects who had an adverse outcome as compared to those who had normal outcomes[27]. In the present study, the sensitivity of  $OS \geq 1.0$  in predicting any of three adverse events (i.e., postpartum haemorrhage, admission to CCU or maternal death) in a pregnant woman was 94.1%. This means that  $OS \geq 1.0$  was able to identify 94 out of 100 women who suffered from any of the three adverse events. However, the specificity of  $OSI \geq 1.0$  in predicting adverse events was low (18%). Within our sample, a SI threshold of  $\geq 1.0$  had high sensitivity but low specificity; most women with adverse outcomes were identified using this threshold, suggesting that it represents a relevant threshold for medical intervention.

The sensitivity of  $OSI \geq 1.0$  for detecting postpartum haemorrhage (the most common cause of maternal death) was 89.8 (95%CI= 83.4–96.5). In other words,  $OSI \geq 1.0$  was able to correctly identify 90 out of 100 women who suffered from PPH. Kohn et al. reported that specificity of  $SI \geq 0.9$  for PPH was only 24% and sensitivity was 85%. For  $SI \geq 1.143$  the sensitivity was 41% and specificity was 93% for PPH[28].

In the present study, the sensitivity of  $OSI \geq 1.0$  for identifying mothers who would require admission to the critical care unit (for either medical or surgical interventions) was 92.8 (95%CI= 87.8–94.6). Chaudhary M et al. reported that for  $SI \geq 0.9$ , and admission to ICU as the outcome, the sensitivity was 95.62% and specificity was low at 17.5% [27]. Overall, at a value of  $SI \geq 1.0$ , the sensitivity was highest for maternal death [96.8 (95%CI= 91.2–100.0)]. This means that 96% of all women who did not survive the process of childbirth were correctly identified by  $SI \geq 1.0$ . Chaudhary M et al. reported that the performance for  $SI > 1.0$  for mortality; the sensitivity was 92% and specificity was 34%, respectively [27]. Nathan et al. (2019) found that  $SI < 0.9$  performed well as a rule-out test and  $SI < 0.69$  and  $SI \geq 0.7$  indicated increased risk [29]. They found that for “first”  $SI < 0.9$  the sensitivity was 100% for maternal death and specificity was 55.2%. They suggested that this threshold of  $SI < 0.9$  can be used as a rule-out test. Our study reinforces the role of SI as a consistent marker of compromise in obstetrics. El Ayadi et al. found that at  $SI \geq 0.7$  sensitivity was 100% but specificity was very low [30]. A threshold of 0.9 again had increased sensitivity and decreased specificity. In the present study, at a value of  $SI \geq 1.4$ , the sensitivity for maternal death was 82.4 (74.3–93.6). Chaudhary et al. reported that  $SI \geq 1.4$ , sensitivity was 26.82% (21.09–33.19); specificity was 100% (99.53–100), PPV was 100% and NPV was 82.96% (81.8–84.06) [27]. Kohn et al. in reported that  $SI \geq 1.412$  predicted PPH and the need for transfusion with 100% specificity [28].

In Indian settings, for primary and secondary healthcare facilities, we suggest a lower SI threshold of 0.9 indicating a need for immediate referral to the tertiary facility or rigorous monitoring within tertiary care.

Given the long delays that such women in low-resource areas face in transport and receipt of definitive treatment upon arrival at tertiary facilities, this lower threshold prioritizes earlier recognition and more rapid intensive treatment, which is more suitable for such a context. Additionally, based on our results, we suggest higher SI thresholds of 1.3 to indicate the urgent need for intensive treatment, and 1.4 as indicative of a high risk of an adverse event. Further research should evaluate these thresholds prospectively and focus on implementing SI as a tool at multiple clinical levels with different categories of care providers to maximize its utility within clinical obstetric early warning systems. Future studies on the prediction of adverse outcomes should include the timing and impact of therapies on resuscitation.

### Conclusion

SI is the most consistently useful outcome predictor and could aid in the earlier recognition of haemodynamic compromise before changes in HR or BP alone. We propose a threshold of  $SI \geq 1.0$  for identifying women requiring urgent high-level care. This is higher than the upper limit of normal in non-pregnant populations, reflecting the haemodynamic changes of pregnancy and the postpartum period.

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