"COMBINATION OF REVERSE SHOCK INDEX AND GLASGOW COMA SCALE

TO INITIATE MASSIVE TRANSFUSION PROTOCOL IN TRAUMA PATIENTS."

By

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P.G in EMERGENCY MEDICINE

DISSERTATION SUBMITTED TO

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MTP	Massive Transfusion Protocols
TASH	Trauma-Associated Severe Haemorrhage
ABC	Assessment Blood Consumption
FAST	Focused Assessment With Sonography For Trauma
SI	Shock Index
SBP	Systolic Blood Pressure
DBP	Diastolic Blood Pressure
HR	Heart Rate
GCS	Glasgow Coma Scale
rSI	Reverse Shock Index
rSIG	Reverse Shock Index * Glasgow Coma Scale
FASILA	Focused Assessment With Sonography In Trauma, Shock Index And Initial Serum Lactate
T-RTS	Triage Revised Trauma Score
PSP	Previous Simple Prediction
ISS	Injury Severity Score
SIA	Shock Index*Age
MT	Massive Transfusion
qSOFA	Quick Sequential Organ Failure Assessment
ROC	Reciever Operating Characteristics



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ABSTRACT

Background and goal: The reverse shock index multiplied by the Glasgow Coma Scale score (rSIG) predicts trauma patient mortality, according to previous studies. It is unclear if rSIG can predict massive transfusion (MT) in trauma patients. This study examines whether rSIG predicts MT in trauma patients. The study also tests whether rSIG can predict trauma patients' coagulopathy, in-hospital mortality, and 24-hour death, rSIG's prognostic value for MT in trauma patients is compared to TASH and ABC Scores.

Methods: This single-center prospective observational study at B.L.D.E.(DU), SHRI B.M. Patil medical college hospital and research centre's emergency medicine department In trauma patients, rSIG's prognostic value for MTP was compared to older scoring systems as TASH and ABC Scores.

Results: MT was given to 20 of 195 patients. MT, in-hospital mortality, 24-hour mortality, and coagulopathy are better predicted by rSIG than SI, SIA, and qSOFA. The in-hospital mortality AUROC for rSIG was 0.812, indicating its dependability. Prior study shows that rSIG can predict trauma patients' death and coagulopathy. All three tests are discriminatory, but evaluation assessment blood consumption is most accurate, followed by TASHScore and rSIG using ROC values.MT rSIG predicted better than SI, SIA, and qSOFA (AUROC = 0.842). rSIG predicted coagulopathy, in-hospital, and 24-hour mortality better than SI, SIA, and qSOFA. RSIG combines hemodynamic instability (reverse SI) and consciousness (GCS) for a more complete trauma patient evaluation. Detecting coagulopathy early with rSIG permits rewarming, acidosis correction, balanced transfusion, and massive transfusion regimens.

Conclusion: The study shows that rSIG can identify trauma patients at high risk for major transfusion, coagulopathy, and death. Assessment Blood consumption evaluation is most accurate, followed by TASH Score and rSIG, for managing severe trauma situations swiftly and effectively which could improve patient outcomes.

INTRODUCTION

Injuries rank as the leading cause of death for individuals under 40 years old and as the sixth most prevalent cause of death worldwide. The avoidable cause of death for patients with severe trauma is haemorrhage, which accounts for around half of deaths that occur within 24 hours of the trauma. [1,2] It has been demonstrated that massive transfusion protocols (MTPs) for severe bleeding enhance outcomes; still, it is critical to identify patients with enormous haemorrhage as soon as possible [3]. To predict massive transfusion (MT) in patients with severe trauma, numerous studies have been published [4,5].

Trauma-associated severe haemorrhage (TASH) Scoring methods and assessment blood consumption (ABC) are two of the very few helpful indications to anticipate the requirement for massive transfusion. These scoring systems are somewhat sophisticated, though, as they need the assessment of multiple criteria, including focused assessment with sonography for trauma (FAST), vital signs, pelvic fracture, and/or femur fracture. As a result, we must identify some practical MT indications that the emergency room may quickly and easily apply.

One tool for determining the degree of trauma in patients is the shock index (SI). It is the heart rate to systolic blood pressure ratio, first described by Allower and Burri in 1967 [6].

SI is easily collected at the patient's bedside and can assess the shock status more precisely than HR and SBP alone because it is calculated using HR and SBP readings [7-9]. SI is also useful in identifying occult shock patients. Numerous studies have shown that SI helps predict mortality and MT in trauma patients due to its simplicity and accuracy [10–13].

Hemodynamic instability, as defined by SI, often refers to a condition where the SBP is lower than the HR; it does not, however, mean that the HR is lower than the SBP. To improve this, Chung et al. created the idea of reverse shock index [14], which is derived by dividing SBP by HR, and a small rSIG value signifies that the patient's condition is critical. In contrast, the GCS, which evaluates consciousness, has been shown

to be a more reliable indicator of death in trauma patients. Reverse shock index and GCS are two straightforward but effective predictors combined to create rSIG.

They discovered that rSIG outperformed SI and SIA as a predictor of in-hospital mortality and 24-hour blood transfusion. Additionally, it has been shown in two other studies [16, 17] that rSIG is a reliable indicator of mortality in trauma patients. Although this study has limitations, Young Tark Lee et al.'s [18] recent study found that rSIG is a helpful biomarker for predicting Massive Transfusion in patients with severe trauma.

The current investigation attempts to ascertain whether rSIG can predict MT in trauma patients. It also seeks to ascertain whether rSIG can predict coagulopathy, in-hospital mortality, and 24-hour hospital mortality in trauma patients. rSIG's predictive value for MT in trauma patients is compared to earlier scoring systems, such as the trauma-associated severe haemorrhage (TASH) Scores and the assessment blood consumption (ABC) Scores.

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OBJECTIVES OF THE STUDY

Primary objective:

To assess the predictive ability of rSIG to initiate Massive Transfusion protocol in trauma patients.

Secondary objective:

The secondary goal of the present study is-

1. To assess the predictive ability of rSIG for coagulopathy, in-hospital mortality and 24-h mortality in trauma patients.

2. Comparing rSIG with previous scoring systems, such as assessment blood consumption (ABC) and traumaassociated severe hemorrhage (TASH) Scores for predicting MTP in trauma patients.

REVIEW OF LITERATURE

Uemura t et al. (2024) [35] Patients with severe trauma frequently need immediate treatments that take a significant amount of time and resources to provide, such as large transfusions, resuscitation techniques, and surgery. Nevertheless, there aren't many useful indices that are simple to apply to emergency situations. The ability to readily calculate the Reverse Shock Index multiplied by the Glasgow Coma Scale [GCS] score from vital signs has made it evident in recent years that rSIG is a potential predictor of mortality. Whether rSIG is helpful for urgent interventions is unknown, though. Analysis was done on data gathered by the Japan Trauma Data Bank for adult patients who were admitted straight from the trauma scene between April 2019 and December 2020. Massive transfusions, resuscitation techniques, surgery, and urgent interventions were the results. The combined effect of huge transfusion, resuscitation techniques, and surgical operations was referred to as an emergent intervention. Using receiver-operating characteristic curve analysis, the predictive capacity of rSIG for large transfusion was compared to that of the ABC and FASILA scores. They compared rSIG's predictive power to that of the GCS, Shock Index (SI), Triage Revised Trauma score (T-RTS), and Previous Simple Prediction (PSP) score for both resuscitation and surgery. We evaluated rSIG's predictive power to that of T-RTS, PSP, ABC, and FASILA for urgent interventions. Furthermore, studied as a supplement to rSIG was rSIM (Reverse Shock Index multiplied by best motor reaction score). 32,201 individuals were enrolled in the study, and 6,371 of them needed emergency care. For major transfusion, rSIG had the highest area under the receiver-operating characteristic curve (AUROC) (0.846 [95% confidence interval 0.832-0.859]), and it was considerably greater than rSIM, ABC, and FASILA (all p < 0.0001). rSIG had the greatest AUROCs (0.777 [0.769-0.785] and 0.731 [0.720-0.741]) for all resuscitative and surgical operations, and these were significantly higher than those for SI, rSIM, GCS, T-RTS, and PSP (all p < 0.0001). With respect to emergent interventions, rSIG had the highest AUROC (0.760 [0.753-0.768]) and was statistically superior to rSIM,

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T-RTS, PSP, ABC, and FASILA (all p < 0.0001). When managing trauma initially, rSIG is a straightforward and reliable point-of-care predictor of emergent treatments.

Kuo SC et al. (2016) [19] employed the reverse shock index (RSI), which measures the ratio of systolic blood pressure (SBP) to heart rate (HR), to assess the trauma patients' hemodynamic condition. The aim of this study was to investigate if, even in the absence of meeting the criteria for multidisciplinary trauma team activation (TTA), RSI<1 can be used to identify high-risk individuals who may undergo shock and have a poor outcome. This is because an SBP lower than the HR (RSI<1) may indicate hemodynamic instability. This is a cross-sectional study. They examined in retrospect the information on 20,106 patients who were admitted for trauma between January 2009 and December 2014, which was collected from the trauma registry system of a level I trauma centre. Patients with RSI<1 who were not assigned to a trauma team (regular patients) were compared to regular patients with RSI≥1. 95% of CIs were used in the calculation of the ORs for related illnesses and injuries. Regular patients with RSI<1 had a death rate of 2.1% vs. 0.5%; OR 3.9, 95% CI 2.10 to 7.08, p<0.001), and a substantially greater proportion of patients had an Injury Severity Score (ISS) \geq 25 (OR 2.4, 95% CI 1.58 to 3.62; p<0.001). Regular patients with RSI<1 had a longer length of stay in the intensive care unit than regular patients with RSI≥1. They came to the conclusion that, for patients who did not meet the TTA criteria, an RSI<1 suggests a possibly worse prognosis and calls for more intensive care in the ER.

Akio kimura et al. (2018) [20] The data utilised in this retrospective, multicenter analysis came from 168,517 patients who were recorded between 2006 and 2015 in the Japan Trauma Data Bank. By comparing the areas under receiver operating characteristic curves (AUROCs) of SIA, rSIG, SI (or rSI), and rSIG/A for in-hospital mortality and 24-hour blood transfusion, we were able to determine the discriminant ability. When it came to in-hospital mortality in younger patients (those under 55 years old),

rSIG had the greatest ROC AUC (AUROC), 0.901(0.894–0.908). The AUROC of rSIG/A, 0.845(0.840–0.850), was highest for in-hospital mortality in older patients (\geq 55 years). The distinction between rSIG and rSIG/A, however, was negligible and did not appear to have any clinical significance. Moreover, during a 24-hour blood transfusion, rSIG had the greatest AUROC of 0.745 (0.741–749). It is simple to compute rSIG ((SBP/HR) × GCS score) without the need for further data, equipment, or charts, and it can be a more accurate triage tool for determining risk levels in trauma patients.

Wan-Ting C et al. (2020) [21] For trauma patients, the prognosis is determined using the reverse shock index (rSI), which is a ratio of systolic blood pressure (SBP) to heart rate (HR). For trauma patients, rSI multiplied by the Glasgow Coma Scale (rSIG) may be a more accurate indicator of in-hospital mortality. Nevertheless, in adult severe trauma patients (Injury Severity Score [ISS] > 16) with head injuries (head Abbreviated Injury Scale [AIS] ≥ 2) in the emergency department (ED), rSIG has never been utilised to assess the mortality risk. Adult severe trauma patients (ISS \geq 16) with head injuries (head AIS > 2) who arrived at the emergency department of two major trauma centers between January 1, 2014, and May 31, 2017, were included in this retrospective case-control study. For the analysis, information on injury mechanisms, laboratory results, management, demographics, vital signs, ISS scores, and outcomes were included. Receiver operating characteristic analysis and logistic regression were employed to assess how well the rSIG score predicted in-hospital mortality. This study comprised a total of 438 patients (mean age: 56.48 years; 68.5% were male). Patients died within the hospital in 24.7% of cases. The interguartile range (median) for the ISS score was 20 (17-26). Individuals who had a rSIG of less than 14 were seven times more likely to die than those who did not (odds ratio: 7.64; 95% confidence interval: 4.69-12.42). The area under the curve values for the rSIG score and the Hosmer-Lemeshow goodness-of-fit test were 0.76 and 0.29, respectively. Sensitivity, specificity, positive predictive value, and negative predictive value for rSIG \leq 14 were, respectively,0.71,0.75,0.49, and 0.89. The rSIG score is a rapid and simple technique to utilise for predicting in-hospital mortality in adult severe trauma patients with head injuries.

Wu Sc et al. (2018) [18] With reference to mortality predictions made by the Revised Trauma Score (RTS), shock index (SI), and Trauma and Injury Severity Score (TRISS), this study aimed to externally assess the predictive accuracy of the rSIG in our cohort of trauma patients. This study comprised adult trauma patients who were ≥ 20 years old and admitted to the hospital between January 1, 2009, and December 31, 2017. Based on the patient's initial vital signs and GCS scores when they arrived at the emergency department (ED), the rSIG, RTS, and SI were computed. In-hospital mortality is the primary outcome's endpoint. The area under the curve (AUC) was used to plot the receiver operating characteristic (ROC) curve for 18,750 adult trauma patients. Of these, 24,38 patients had isolated head injuries (only head Abbreviated Injury Scale (AIS) \geq 2), and 16,312 patients did not have head injuries (head AIS \leq 1). The objective was to determine the discriminative power of each score to predict mortality. In patients with isolated head injuries (AUC 0.82 vs. AUC 0.85, p = 0.02) as well as in all trauma patients (AUC 0.83 vs. AUC 0.85, p = 0.02), the predictive accuracy of rSIG was considerably lower than that of RTS. There was no discernible difference in the prediction accuracy between rSIG and RTS for patients without head injuries (AUC 0.83 vs. AUC 0.83, p = 0.97). With a sensitivity of 61.5% and specificity of 94.5%, the rSIG can forecast the likelihood of death in trauma patients without a head injury based on a cutoff value of 14.0. Compared to TRISS, both rSIG and RTS had much lower predictive accuracy in all trauma patients (AUC 0.93), as well as in patients with (AUC 0.89) and without head injuries (AUC 0.92). Furthermore, SI significantly underperformed the other three models in terms of prediction accuracy in all trauma patients (AUC 0.57), as well as in patients who had either a head injury (AUC 0.53) or not (AUC 0.63). According to this study, in all adult trauma patients and adult patients with isolated head injuries, rSIG had a considerably higher predictive accuracy of mortality than SI, but in all other analysed populations, it had a lower predictive accuracy of mortality than RTS. Furthermore, when it came to the patients' prediction risk of death, rSIG performed about the same as RTS in the adult patients who had not suffered a head injury.

Massive transfusion:

A major transfusion occurs when 10 units or more of packed red blood cells (PRBCs) or whole blood are given in a 24-hour period. Any transfusion involving more than 20 units of PRBCs within a 24- to 48-hour period is considered an ultra-massive transfusion. The main goal of a huge transfusion is to achieve hemostasis while averting fatal outcomes from serious hypoperfusion-related complications. [22] This issue also examines the importance of major transfusion protocols (MTPs), as well as the uses, limitations, and possible side effects of this life-saving procedure. [23-25]

Massive transfusions may be necessary for patients from several medical specialisations. While heart and vascular surgery is the most prevalent reason for the need for large transfusions, liver transplants, trauma, and gastrointestinal and obstetric haemorrhages are all important causes. Approximately 3% to 5% of trauma patients in the civilian setting and 10% of trauma patients in the military usually require a large transfusion. Despite being relatively uncommon, individuals who require huge transfusions frequently have high mortality rates.

Massive transfusions are erratic and necessitate a large volume of blood products over a long period of time. Therefore, advance coordination between the emergency room, trauma service, surgical team, blood bank, and delivery staff is crucial. One way to forecast when large-scale transfusions may be required is to use the Assessment of Blood Consumption (ABC) score. Throughout a huge transfusion, it is critical to monitor the following: volume status, tissue oxygenation, haemorrhage control, coagulation problems, and acid-base balance. [26] Both the usage of blood products and death rates can be effectively decreased by the development and deployment of MTPs.

Indications:

A huge transfusion may be necessary in any circumstance that causes hemodynamic instability and abrupt blood loss. A huge transfusion may result from a variety of scenarios, including but not limited to bleeding associated with trauma, obstetrical haemorrhage, surgery, and gastrointestinal bleeding. [27,28] There is no

usefulness in trying to reduce confusion about when and whether huge transfusions are necessary by using metrics like the Shock Index. [29]

Based on four variables, a pulse rate greater than 120 bpm, a systolic blood pressure below 90 mm Hg, a positive result on the Focused Assessment with Sonography for Trauma (FAST) exam, and a penetrating thoracic injury, the ABC score is a clinically effective and proven scoring system.

Every variable is given a point, and patients who receive two or more points signal that an MTP is required. A positive predictive value of 50% to 55% is shown by the ABC score, meaning that 45% to 50% of patients who initiate the MTP will not require a large transfusion. The ABC score has a negative predictive value of less than 5%, yet it can identify almost 95% of individuals who need a large transfusion. [30] In general, the following factors indicate when an MTP should be activated:

- Two or more points on the ABC score
- Hemodynamic instability that persists
- Excessive bleeding necessitating angioembolization or surgery
- Transfusion of blood in the trauma bay

Equipment:

A huge transfusion requires two things: blood products must be available, and appropriate intravenous (IV) or intraosseous access must be established. Catheters with a bigger diameter and a shorter length will produce the highest flow rates, according to the Hagen-Poiseuille equation. The length of the catheter and the viscosity of the fluid flowing through it are inversely correlated with the flow rate, which is directly



proportional to the fourth power of the catheter's radius. For the majority of patients receiving a large transfusion, quick blood replacement is essential. Therefore, it is imperative that large-bore catheters, which usually have a gauge of 14 to 18, be assembled and inserted into the patient via intraosseous access or peripheral or central IV, as directed by a physician. [30] The following extra tools or resources could be required:

- Good communication about the changing circumstances around the significant blood loss with blood banks.
- Enough workers to ensure prompt sample collection and the acquisition of blood and blood products.
- ➤ A warmer for blood.
- A universal donor product supply, preferably consisting of 8 units of O-negative PRBCs and 8 units of thawed group AB or low titer anti-B group A plasma, should be kept in a blood refrigerator inside the resuscitation area. \
- > Surface and in-line fluid warmers are included.
- > Constant sensors of core temperature.
- > Arterial blood pressure monitor that is intrusive.
- > Colloid and crystalloid infusion sets are in sufficient supply.
- ➢ IV calcium solutions.
- Point-of-care testing for haemoglobin, electrolytes, lactate, arterial blood gas (ABG), and thromboelastography (TEG), among other physiological parameters.
- > To speed up the pace of fluid infusion, use pressure bags or rapid infusion pumps.

Preparation:

Having an MTP in place and promptly notifying the blood bank are critical components of the most efficient preparation. The blood bank can proactively prepare and provide the appropriate products prior to their requirement by promp tly activating the MTP. Healthcare providers are responsible for making sure



patients have appropriate IV or intraosseous access for the administration of blood products, as well as for monitoring their heart and breathing. [30]

Technique or treatment:

The main goals of a large transfusion are to maintain cardiac output and maximise oxygen transport capability. Ordering blood products and getting them quickly from the blood bank is made easier by procedures unique to each institution. MTPs should prioritise the delivery of PRBCs along with platelets and fresh frozen plasma (FFP), even though these protocols may vary throughout institutions. [31-33]

Baseline oxygen delivery to tissues is about four times the oxygen consumption rate of tissues. To preserve blood pressure and tissue perfusion during a transfusion, volume expanders like crystalloids may be used. Even in cases where haemoglobin levels are below normal, the body can nevertheless sustain tissue oxygenation because of the excess oxygen delivery that occurs during a normal physiological state.

Research indicates that in order to ensure that patients receive enough oxygen during transfusions, certain haemoglobin levels are required. It is important to remember, too, that these transfusion standards do not apply in situations involving sudden blood loss.

Haemoglobin measures the amount of haemoglobin molecules in blood, and this amount might vary rather than remain constant. Thus, in situations involving sudden blood loss, the concentration of haemoglobin won't alter. Crystalloid solutions can be used to provide volume expansion to patients who are mildly or moderately unwell. Dilutional coagulopathy is a concern when large amounts of crystalloid solutions are given to critically injured patients in an attempt to revive them.



Due to medical and military research, it has been determined that trauma patients benefit from getting fresh whole blood, which has led to the 1:1:1 ratio of PRBCs, platelets, and FFP transfusions. There is still debate over the ideal proportion of these three elements, and there isn't any strong data to suggest that lower platelet and FFP ratios are inferior. Advocates of the 1:1:1 ratio emphasise its possible advantages, like avoiding overuse of crystalloid solutions. This can lessen the risk of tissue edema, delayed wound healing, prolonged hospital stays, dilutional coagulopathy, and delayed wound healing. While the application of cryoprecipitate, fibrinogen concentrate, and recombinant factor VIIIa yields varying results, warming the blood aids in preventing hypothermia.

Extensive research has demonstrated that severe trauma inhibits fibrinolysis. Strong evidence from military research indicates that tranexamic acid (TXA) can help patients with combat injuries survive longer by reducing coagulopathy. There is more proof that TXA can lower mortality when treating injuries in civilian populations. TXA works by preventing fibrinolysis, or the disintegration of clots, and works best when given three hours after the trauma. Results are worse when TXA is given more than three hours after the trauma. Consequently, a lot of MTPs now include TXA in their processes. [34]

Patients receive O-negative blood at first until cross-matched PRBCs are available. It is advisable to have universally thawed plasma (AB plasma, usually) on hand for the first phase. Low anti-B titers in type A plasma can also be a good option. After blood typing, patients should get group-specific plasma right away. It is essential to observe the patient continuously during the resuscitation procedure.

Procedures for diagnosing coagulopathy and managing the care of acid-base imbalances, hypothermia, and electrolyte imbalances should be part of the protocols. It is customary to evaluate the following parameters following the administration of around five units of PRBCs:



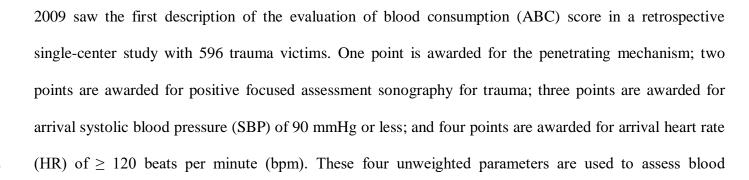
- Platelet count and complete blood count (CBC)
- Prothrombin Time (PT)
- Activated Partial thromboplastin time (aPTT)
- Fibrinogen concentration

Every 20 to 30 minutes, pH, blood gases, electrolytes, and metabolites, including lactate and glucose, should be measured as part of optimal monitoring. TEG evaluates fibrinolysis, clot strength, and platelet function. Thus, based on the particular TEG profile, the test results can help determine when to administer more platelets, plasma, cryoprecipitate, or antifibrinolytics when TEG is available.

The resuscitation objectives in the context of massive transfusion include:

- A mean arterial pressure (MAP) within the range of 60 to 65 mm Hg
- Hemoglobin level between 7 and 9 g/dL
- International normalized ratio (INR) below 1.5
- Fibrinogen levels within the range of 1.5 to 2 g/L
- Platelet counts above 50,000 µL
- pH between 7.35 and 7.45
- Core temperature above 35 °C

Assessment of blood consumption score:



consumption. An ABC score of two or above was 75% sensitive and 86% specific for predicting MT in the study. The score runs from 0 to 4. 2010 saw the publication of a revalidation of the ABC score based on a fresh retrospective multi-center research with 1,604 trauma victims. [3]

Trauma Associated Severe Haemorrhage (TASH):

The German Trauma Society (DGU) trauma registry contains clinical and laboratory characteristics. To estimate the likelihood of MT, univariate and multivariate logistic regression analysis were performed on the data [36]. The following seven independent variables were found and utilised to construct the TASH: SBP, Hb, IV, pelvic fractures, complex long bone and/or pelvic fractures, HR, base excess, gender, and seven other factors. The TASH score is between 0 and 28. There is a correlation between rising TASH-score points and rising MT probability. A risk of MT > 50% is indicated by a TASH score of \geq 16 points. Since its creation, the TASH score has been put to the test in numerous research and is often utilised in trauma centres in Germany.

The Shock Index:

HR divided by SBP is the definition of the shock index (SI). It has proven to be a helpful diagnostic tool for acute hypovolemia, even when SBP or HR are normal. A recent comprehensive analysis that examined SI's ability to predict MT following severe trauma found a link between increased SI and bleeding. ≥ 0.9 was the most commonly recommended ideal SI cut-off value [37]. A retrospective analysis of 8,111 trauma patients assessed the use of prehospital SI and found that patients with pre-hospital SI elevations above 0.9 had a higher risk of metastatic disease (MT) (risk ratio [RR] 1.61, 95% confidence interval [CI], 1.13 - 2.31 for MT when 0.9 < SI < 1.1; RR 8.13, 95% CI, 4.60 - 14.36 when SI > 1.3) [38] A patient is considered to be at risk for MT if their SI is 1 and their SBP is 100 mmHg in addition to their HR of 100 bpm.



GLASGOW COMA SCALE:

Graham Teasdale and Bryan Jennett, two professors of neurosurgery at the University of Glasgow, published the Glasgow Coma Scale for the first time in 1974.[39] The Glasgow Coma Scale (GCS) is used to objectively describe the level of decreased consciousness in all forms of acute medical and trauma patients. Eye-opening, motor, and vocal responses are the three responsiveness dimensions that the scale uses to evaluate patients. A concise, understandable picture of a patient's condition can be obtained by reporting each of these separately.

Each scale component's results can be added together to get a total Glasgow Coma Score, which offers a less thorough explanation but can be a helpful "shorthand" summary of the severity overall.[40]

When the first edition of Advanced Trauma and Life Support advocated using the Glasgow Coma Scale for all trauma patients, its use spread widely in the 1980s. In addition, it was incorporated into the 1988 subarachnoid haemorrhage patient grading system developed by the World Federation of Neurosurgical Societies (WFNS) [41]. Since then, many clinical recommendations and scoring systems for trauma or critical disease sufferers have included the Glasgow Coma Scale and its total score.[42] These include youngsters who are not yet verbal and patients of all ages. Used in more than 75 countries, the Glasgow Coma Scale is a mandatory part of the ICD 11 revision and the NIH Common Data Elements for investigations of head injury. [43-45]

FUNCTION:

Scoring and parameter

Three parameters make up the Glasgow Coma Scale: best motor response (M), best verbal response (V), and best ocular reaction (E). The Glasgow Coma Scale's component reaction levels are "scored" from 1 (no response) to 6 (motor response), 5 (verbal response), and 4 (eye-opening response).



With three being the lowest and fifteen being the highest, the total Coma Score consequently has values between three and fifteen.

The total of the constituent elements' scores makes up the score. For instance, GCS10 = E3V4M3 might be used to represent a score of 10.

Best eye response (4)

- 1. No eye opening
- 2. Eye-opening to pain
- 3. Eye-opening to sound
- 4. Eyes open spontaneously

Best verbal response (5)

- 1. No verbal response
- 2. Incomprehensible sounds
- 3. Inappropriate words
- 4. Confused
- 5. Orientated

Best motor response (6)

- 1. No motor response.
- 2. Abnormal extension to pain
- 3. Abnormal flexion to pain
- 4. Withdrawal from pain
- 5. Localizing pain
- 6. Obeys commands

Concerning Matter

The following elements could impede the Glasgow Coma Scale evaluation:

- 1. Pre-existing conditions
- Obstacles in language



Deficit in cognition or nervous system

Speech difficulty or hearing impairment

2. Consequences of the current course of treatment

Physical (e.g., intubation): A patient's score is marked with the suffix T to signify intubation if they are unable to talk and are only assessed on their motor and eye-opening responses.

Pharmacological (e.g., sedation) or paralysis: Prior to administering sedation, the physician ought to, if at all feasible, ascertain the patient's score.

3. Consequences of further wounds or lesions

cranial or orbital fracture

injury to the spinal cord

COLD-induced hypoxic-ischemic encephalopathy.

Sometimes, the Glasgow Coma Scale cannot be obtained even with the above-mentioned problems resolved. It is imperative that all components be tested and included before reporting the final score, as doing so will result in a low score and maybe misunderstanding.

Clinical significance:

The Glasgow Coma Scale is frequently used to assess responsiveness and inform the early management of patients who have suffered a head accident or other severe brain injury. Emergent care decisions for patients with more severe impairments involve securing the airway and triaging patients to decide which ones should be transferred. In individuals with less severe impairment, decisions are made regarding the necessity of neuroimaging, admission for observation, and discharge. Regular Glasgow Coma Scale evaluations are also essential for tracking a patient's clinical progress and directing therapy adjustments.



The three Scale components yield different information depending on where on the responsiveness spectrum one is [47]. In individuals with more severe impairments, changes in motor response are the main contributing component, with ocular and verbal responses being more helpful to a lesser extent.

It is therefore appropriate to record the clinical findings in each of the three components individually for individual individuals. A valuable summary of the overall index is communicated by the total score but with considerable information loss.

The Glasgow Coma Scale is a reliable indicator of clinically significant traumatic brain injury in paediatric patients, both verbal and preverbal (i.e., requiring neurosurgical intervention, requiring more than 24 hours of intubation, requiring more than two nights of hospitalisation, or resulting in death).[44]

Several recommendations and assessment scores have included the Glasgow Coma Scale. These include the Brain Trauma Foundation's severe traumatic brain injury standards (such as Advanced Trauma Life Support), advanced cardiac life support, intensive care scoring systems (such as APACHE II and SOFA), and trauma guidelines.

METHODOLOGY

SOURCE OF DATA: Trauma patients presenting to Emergency Medicine department of BLDE, Shri B.M Patil Medical College Hospital and Research Centre, Vijayapura, from August 2022 to April 2024 who fulfill the inclusion criteria.

STUDY DESIGN: HOSPITAL-BASED PROSPECTIVE OBSERVATIONAL STUDY.

METHOD OF COLLECTION OF DATA: The data is collected from patients with severe trauma who satisfy inclusion criteria and will undergo detailed history, clinical examination and laboratory investigations.

SAMPLE SIZE:

With the Anticipated Proportion of Trauma patients at 7.2% (ref: Young tark lee et al. study reverse shock index multiplied by Glasgow coma scale as a predictor of Massive Transfusion in trauma), the study would require a sample size of 195 to achieve a power of 80% for predicting Massive Transfusion protocol by rSIG at a two-sided p-value of 0.05 with effect size- 0.059 using G*power software 3.1.9.7 (Exact - Proportion: Difference from constant (binomial test, one sample case).

STATISTICAL ANALYSIS

- Continuous variables with normal distribution will be presented by Mean±SD and abnormal distribution by Median and Inter quartile range. Categorical variables will be presented by Frequency, percentage and Charts.
- For normally distributed continuous variables will be compared using an independent t-test. For not normally distributed variables, Mann Whitney U test will be used.
- Categorical variables will be compared using Chi-square test.
- AUROC curve [25] analysis will be carried out to compare rSIG with previous scoring systems, such as assessment blood consumption (ABC) and trauma-associated severe hemorrhage (TASH) Scores for predicting MTP in trauma patients.
- p<0.05 will be considered statistically significant. All statistical tests will perform two-tailed.
- The data obtained will be entered into a Microsoft Excel sheet, and statistical analysis will be performed using JMP Software.

Inclusion criteria:

Trauma patients aged more than 18 years.

Exclusion criteria:

- 1) Isolated head injury.
- 2) Cardiac arrest when presented to the ED.



RESULT

TABLE 1: GENDER DISTRIBUTION

Sex	Frequency	Percentage
Male	107	55%
Female	88	45%
Total	195	100%

The analysis of the sample distribution based on sex reveals insightful details about the composition of the sample group. Out of the total sample size of 195 individuals, a significant portion, comprising 107 individuals, are male. This group constitutes 55% of the overall sample. The prominence of males in the sample indicates a slight majority, reflecting their higher representation in this specific study.

Conversely, the female portion of the sample consists of 88 individuals, which translates to 45% of the total sample. While slightly smaller in number compared to their male counterparts, the female representation remains substantial and crucial for the study's findings. This balanced distribution between males and females, albeit with a slight male majority, ensures that the perspectives and characteristics of both sexes are adequately captured and analysed.

This proportional representation is essential for achieving a comprehensive and nuanced understanding of the study's focus. By maintaining a nearly equal distribution, the sample provides a robust foundation for analysing trends, behaviours, and outcomes across both sexes. The data derived from this well-rounded sample will contribute to more accurate and reliable conclusions, enhancing the overall validity of the study.



Variable	Massive transfusion group N=20 Mean sd	Non-Massive transfusion group N=175 Mean sd	P value
PT_INR	1.22 +_0.36	1.04 +_0.20	0.0007
aPTT time	34.50 +_8.6	27.40 +_6.0	< 0.0001
НЬ	12.70 +_1.05	12.80 +_ 1.6	0.7855
Lactic acid	5.07 +_1.6	2.50 +_ 1.4	<0.0001

TABLE 2: Comparative Analysis of Massive and Non-Massive Transfusion Groups

In a comparative study of patients undergoing massive transfusion (N=20) versus those not undergoing massive transfusion (N=175), several key parameters were analysed to identify significant differences between the two groups.

The Prothrombin Time International Normalized Ratio (PT_INR) was found to be higher in the massive transfusion group, with a mean of 1.22 ± 0.36 , compared to 1.04 ± 0.20 in the non-massive transfusion group, yielding a highly significant P value of 0.0007. Similarly, the activated Partial Thromboplastin Time (aPTT) was markedly elevated in the massive transfusion group, averaging 34.50 ± 8.6 , as opposed to 27.40 ± 6.0 in the non-massive transfusion group, with a P value of less than 0.0001.

Haemoglobin (Hb) levels were comparable between the two groups, with the massive transfusion group having a mean of 12.70 ± 1.05 and the non-massive transfusion group slightly higher at 12.80 ± 1.6 , showing no significant difference (P value = 0.7855). However, lactic acid levels were significantly elevated in the massive transfusion group, with a mean of 5.07 ± 1.6 , in contrast to 2.50 ± 1.4 in the non-massive transfusion group, also with a P value of less than 0.0001.



These findings highlight the marked differences in coagulation parameters and lactic acid levels between patients receiving massive transfusions and those who do not, underscoring the need for careful monitoring and management of these critical variables in transfusion practices.

Variable	Massive transfusion group N=20 Mean SD	Non-Massive transfusion group N=175 (MEAN SD	P value
Respiratory rate	25 +_2.7	22+_2.4	< 0.0001
Heart rate	132 +_7.8	85+_9.0	<0.0001
Systolic Blood pressure	75 +_8.0	120+_10.4	<0.0001
Diastolic blood pressure	60+_7.0	90+_87	<0.0001

TABLE 3: Physiological Parameters in Massive vs. Non-Massive Transfusion Groups

A detailed comparison of physiological parameters between patients undergoing massive transfusion (N=20) and those not undergoing massive transfusion (N=175) reveals significant differences. The respiratory rate in the massive transfusion group averaged 25 ± 2.7 , significantly higher than the 22 ± 2.4 observed in the non-massive transfusion group, with a P value of less than 0.0001. Similarly, heart rate was notably elevated in the massive transfusion group, with a mean of 132 ± 7.8 compared to 85 ± 9.0 in the non-massive transfusion group, also yielding a P value of less than 0.0001.

Blood pressure parameters further underscore the disparities between the two groups. The systolic blood pressure in the massive transfusion group was significantly lower, averaging 75 ± 8.0 , in contrast to 120 ± 10.4 in the non-massive transfusion group, with a P value of less than 0.0001. Likewise, the diastolic blood pressure was markedly reduced in the massive transfusion group, with a mean of 60 ± 7.0 , compared to 90 ± 8.7 in the non-massive transfusion group, again with a P value of less than 0.0001.



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These pronounced differences in respiratory rate, heart rate, and blood pressure between the two groups highlight the critical impact of massive transfusion on these vital physiological parameters, emphasizing the importance of vigilant monitoring and targeted management in patients undergoing such procedures.

Variable	Massive transfusion group N=20 Mean SD	Non-Massive transfusion group N=175 MEAN SD	P value
GCS	8[+_2.4	15+_1.3	<0.0001
shock index	1.34 [+_0.6	0.72[+_0.4	<0.0001
SIA: age shock index	61.02 +_4.5	34.34+_2.7	<0.0001
rSIG: reverse shock index multiplied by Glasgow Coma scale	6.37 [+_ 3	19.54+_2.9	<0.0001
qSOFA: quick Sequential Organ Failure Assessment.	2.00 +_1.0	1+_0.6	<0.0001
ISS: injury severity score.	31.00+_7.4	18.00+_6.1	<0.0001
assessment blood consumption (ABC)	2.00+_0.3	1+_0.2	<0.0001
TASH-Score	21.00+_5.6	10.00+_3.4	<0.0001

A comparative analysis of clinical severity and assessment scores between patients undergoing massive transfusion (N=20) and those not undergoing massive transfusion (N=175) reveals stark contrasts. The Glasgow Coma Scale (GCS) scores were significantly lower in the massive transfusion group, with a mean of 8 ± 2.4 , compared to 15 ± 1.3 in the non-massive transfusion group, indicating a higher degree of impaired consciousness (P value < 0.0001).

The shock index, which is a measure of hemodynamic instability, was markedly higher in the massive transfusion group, with a mean of 1.34 ± 0.6 , versus 0.72 ± 0.4 in the non-massive transfusion group (P value < 0.0001). The SIA (age-adjusted shock index) and rSIG (reverse shock index multiplied by Glasgow Coma Scale) further highlighted the severity in the massive transfusion group, with values of 61.02 ± 4.5 and 6.37 ± 3 , respectively, compared to 34.34 ± 2.7 and 19.54 ± 2.9 in the non-massive transfusion group (P value < 0.0001).

he quick Sequential Organ Failure Assessment (qSOFA) scores averaged 2.00 ± 1.0 in the massive transfusion group, significantly higher than the 1 ± 0.6 observed in the non-massive transfusion group, indicating a greater risk of organ failure (P value < 0.0001). The Injury Severity Score (ISS), which quantifies trauma severity, was also higher in the massive transfusion group, with a mean of 31.00 ± 7.4 , compared to 18.00 ± 6.1 in the non-massive transfusion group (P value < 0.0001).

Additionally, the assessment of blood consumption (ABC) score and the TASH (Trauma-Associated Severe Haemorrhage) score were both significantly elevated in the massive transfusion group, with means of 2.00 ± 0.3 and 21.00 ± 5.6 , respectively, compared to 1 ± 0.2 and 10.00 ± 3.4 in the non-massive transfusion group, underscoring the higher blood product usage and haemorrhage severity in these patients (P value < 0.0001).

These findings highlight the substantial differences in clinical severity and assessment scores between the two groups, emphasizing the critical condition of patients requiring massive transfusion and the need for intensive management and monitoring.



TABLE 5: Coagulopathy in the Massive Transfusion Group

Coagulopathy	Massive transfusion group N=20	P value
Yes	5 25%	< 0.0001
No	15 75%	

The relationship between coagulopathy and massive transfusion was investigated in a recent study. Coagulopathy, a condition in which the blood's ability to coagulate (form clots) is impaired, poses significant challenges during massive transfusions, often required in critical care settings.

The study focused on a sample of 20 patients who required massive transfusions. The objective was to determine the prevalence of coagulopathy within this group and to analyse the significance of this association. Out of the 20 patients, 5 (25%) were found to have coagulopathy. Conversely, 15 patients (75%) did not exhibit signs of coagulopathy. This distribution highlights the substantial proportion of patients who encounter coagulation issues when subjected to massive transfusions.

The statistical analysis conducted to evaluate the association between massive transfusion and coagulopathy yielded a P value of less than 0.0001. This extremely low P value indicates a highly significant relationship, underscoring the critical nature of this finding. In statistical terms, a P value below 0.05 is typically considered significant, and values below 0.0001 denote an even stronger significance. Therefore, the study conclusively demonstrates that patients undergoing massive transfusions are significantly more likely to develop coagulopathy.



This result has important clinical implications. The strong association between massive transfusion and coagulopathy suggests that healthcare providers must be particularly vigilant in monitoring coagulation parameters in these patients. Early detection and appropriate management of coagulopathy can potentially reduce the risk of adverse outcomes. Strategies to mitigate the risk of coagulopathy might include the use of targeted coagulation therapies, regular monitoring of coagulation status, and personalized transfusion protocols.

In conclusion, the study provides compelling evidence of the significant relationship between massive transfusion and the incidence of coagulopathy. These findings emphasize the necessity for enhanced clinical strategies to manage and prevent coagulopathy in patients requiring massive transfusions, ultimately aiming to improve patient outcomes in critical care settings.

TABLE 6: Mortality in the Massive Transfusion Group

Death	Massive transfusion group N=20	P value
Yes	2 10%	< 0.0001
No	18 90%	

A recent study investigated the mortality rate within a group of patients requiring massive transfusions, shedding light on the critical outcomes associated with this intensive medical intervention. The sample comprised 20 patients, with the goal of assessing the incidence of mortality and its statistical significance.

Out of the 20 patients in the massive transfusion group, 2 patients (10%) unfortunately succumbed, while 18 patients (90%) survived. This distribution highlights the relatively high survival rate but also points to the notable presence of mortality among these critically ill patients.



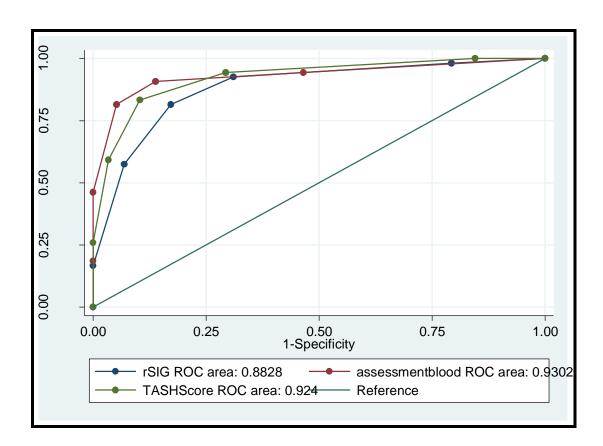
The statistical analysis revealed a P value of less than 0.0001, indicating a highly significant association between massive transfusion and mortality. In the realm of statistical analysis, a P value below 0.05 is typically considered significant, and a value below 0.0001 underscores a very strong statistical significance. This result strongly suggests that the need for massive transfusion is closely linked with increased mortality risk.

These findings have profound clinical implications. The significant association between massive transfusion and mortality underscores the urgency of comprehensive management strategies for patients requiring such interventions. This might include rigorous monitoring, timely and effective clinical responses, and possibly the development of protocols aimed at reducing mortality rates in this vulnerable patient group.

In summary, the study highlights a crucial aspect of patient outcomes related to massive transfusions, emphasizing the need for heightened clinical awareness and improved management practices to potentially enhance survival rates in patients undergoing massive transfusions.



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Graph 1: ROC-rSIG vs ABC vs TASH on X axis 1-specificity with y axis sensitivity.

The ROC curve analysis presented here evaluates the performance of three different diagnostic tests: rSIG assessment blood, and TASH Score. The ROC curve, which plots sensitivity (true positive rate) against 1-specificity (false positive rate), is a graphical representation of a diagnostic test's ability to discriminate between positive and negative cases. In this analysis, the area under the curve (AUC) serves as a crucial metric for assessing the accuracy of the tests. The results show that the AUC values are 0.8828 for rSIG, 0.930 for assessment blood, and 0.924 for TASH Score. These values indicate that all three tests have high discriminative power, with assessment blood showing the highest accuracy, followed closely by TASHScore and rSIG. The reference line, representing a test with no discriminative ability, is included for comparison. The ROC curves depicted in the graph highlight the superior performance of the assessment blood and TASHScore tests in terms of sensitivity and specificity compared to the rSIG test. This analysis underscores the effectiveness of these diagnostic tools in clinical practice, providing valuable insights into their relative strengths and potential applications in patient care.

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DISCUSSION

The current study was to assess the predictive capacity of rSIG in determining mortality time (MT) in patients with severe trauma. Additionally, the study aimed to compare the predictive abilities of rSIG with those of SI, SIA, and qSOFA. The results of the current study indicate that the predictive accuracy of rSIG for MT was significantly superior to SI, SIA, and qSOFA. In addition, the rSIG demonstrated superior AUROC in predicting coagulopathy, in-hospital mortality, and 24-hour mortality compared to other indices.

The rSIG may be quantified by use the reverse shock index and Glasgow Coma Scale (GCS). Systemic Inflammatory Response (SI) is very pragmatic and valuable in evaluating the hemodynamic condition of trauma patients. Nevertheless, the calculation of SI involves dividing HR (heart rate) by SBP (systolic blood pressure), which contradicts the fundamental principle of shock. Hemodynamic instability often refers to a condition where the systolic blood pressure (SBP) is lower than the heart rate (HR). However, it is important to note that hemodynamic instability does not always imply a situation where the HR is lower than the SBP, as shown by the stroke index (SI). In order to enhance this, Chung et al. established the notion of reverse shock index [48], which is computed by dividing SBP by HR, and a low rSI value indicates a serious situation in the patient. Furthermore, the Glasgow Coma Scale (GCS), which evaluates the degree of awareness, is recognised as a more reliable indicator of death risk in individuals with traumatic injuries [49]. rSIG is a fusion of two potent predictors: reverse shock index and GCS.

The rSIG was initially proposed by Kimura and Tanaka in 2018 [50]. An evaluation was conducted on trauma patients from 256 hospitals in Japan between 2006 and 2015 in order to identify a more accurate predictor than the Injury Severity Score (SI) for post-injury mortality and the need for early blood transfusion. The researchers conducted a comparison of several modified models using the SI method and determined that the rSIG model was a dependable tool for evaluating the risk in trauma patients. The reported AUROC of rSIG for in-hospital mortality was 0.901. Wu et al. conducted an external validation of the rSIG in patients who were hospitalised to a level 1 trauma centre in Taiwan [51]. The study's findings indicated that the predictive accuracy of death was

greater with rSIG compared to SI in trauma patients. The AUROC of rSIG for mortality prediction was 0.83. In a recent study, Chu et al. utilised rSIG to assess the in-hospital mortality rate among patients with severe trauma and brain damage [52]. They discovered that the use of rSIG was beneficial in predicting the mortality risk in severe trauma patients with brain damage. The current study found that the AUROC (Area Under the Receiver Operating Characteristic) of rSIG (a specific measure) for predicting in-hospital mortality was 0.812. Furthermore, the predictive value of rSIG for mortality was better than that of SI (another measure), SIA (another measure), and qSOFA (another measure). The findings align with the outcomes of previous investigations, indicating that rSIG serves as a valuable indicator of death in trauma patients. One noteworthy aspect of our investigation is that all instruments, including rSIG, have a low positive predictive value (PPV) and a high negative predictive value (NPV) for medical treatment (MT) and death. The low occurrence of MT (7.2%) and in-hospital death (8.4%) [53] is the likely cause of this phenomenon.

It is worth mentioning that the majority of prior research has examined the correlation between rSIG and mortality in trauma patients. As far as we know, there have been no studies that have revealed the ability to predict mortality in individuals with severe trauma. The AUROC of rSIG for MT in our study was 0.842, indicating that rSIG had a superior predictive value compared to SI, SIA, and qSOFA. The underlying cause for this outcome is ambiguous. One potential reason is that traumatic brain injury may be accompanied by scalp lacerations, facial bone fractures, and oronasal bleeding, which can cause bleeding [54]. Additionally, a trauma patient can experience significant mental decline even without brain injury if they fall into severe shock [55]. Therefore, the incorporation of both a bleeding measure (rSI) and consciousness assessment (GCS) provides a more comprehensive evaluation of the patient's trauma condition. _An advantage of our study is that we have determined that rSIG can serve as a prognostic indicator for coagulopathy. Approximately one-third of trauma patients treated through the Emergency Department (ED) experience coagulopathy, which can lead to multiple organ failure and a significant risk of death [56,57]. There are two forms of trauma-induced coagulopathy: acute traumatic coagulopathy (ATC) and resuscitation-associated coagulopathy. ATC in trauma patients refers to the coagulopathy that is caused directly by the trauma itself. On the other hand, resuscitation-associated

coagulopathy is coagulopathy that is worsened by factors such as hypothermia, metabolic acidosis, consumption of coagulating factors, and haemodilution [58]. Early identification of coagulopathy can result in the initiation of rewarming, correction of acidosis, balanced transfusion, and activation of massive transfusion protocol (MTP). Based on our current understanding, this study is the first to use rSIG to make predictions about coagulopathy. Furthermore, our investigation showed that rSIG has superior predictive accuracy compared to SI, SIA, and qSOFA.

 $P_{age}43$

CONCLUSION

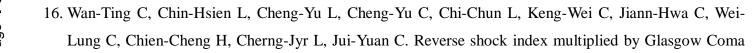
The present study aimed to evaluate the predictive capacity of the reverse Shock Index multiplied by the Glasgow Coma Scale (rSIG) for determining the need for massive transfusion (MT) in patients with severe trauma. Additionally, the study compared the predictive abilities of rSIG with those of the Shock Index (SI), ageadjusted SI (SIA), and quick Sequential Organ Failure Assessment (qSOFA). The results demonstrate that rSIG has superior predictive accuracy for MT, in-hospital mortality, 24-hour mortality, and coagulopathy compared to SI, SIA, and qSOFA. Specifically, the AUROC for rSIG in predicting in-hospital mortality was 0.812, highlighting its reliability as a prognostic tool. The study's findings align with previous research, confirming the effectiveness of rSIG as a valuable indicator of mortality and coagulopathy in trauma patients. The values in ROC suggest that all three tests exhibit significant discriminatory ability, with assessment blood consumption demonstrating the highest level of accuracy, closely followed by TASHScore and rSIG.Key findings from the study include the AUROC of rSIG for MT being 0.842, indicating a higher predictive value compared to SI, SIA, and qSOFA. rSIG outperformed SI, SIA, and qSOFA in predicting coagulopathy, in-hospital mortality, and 24-hour mortality. rSIG combines the assessment of hemodynamic instability (reverse SI) and consciousness (GCS), providing a more comprehensive evaluation of a trauma patient's condition. Early identification of coagulopathy using rSIG can facilitate timely interventions, including rewarming, correction of acidosis, balanced transfusion, and activation of massive transfusion protocols. Overall, the study supports the use of rSIG as a practical and effective tool for early identification of trauma patients at high risk for massive transfusion, coagulopathy, and mortality. Implementing rSIG in clinical settings could enhance patient outcomes by enabling of prompt and appropriate management severe trauma cases.

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ANNEXURE I

CERTIFICATE OF ETHICAL CLEARANCE



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BLDE (DEEMED TO BE UNIVERSITY) Declared as Deemed to be University u/s 3 of UGC Act, 1936 Accredited with 'A' Grade by NAAC (Cycle-2)

The Constituent College

SHRI B. M. PATIL MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, VIJAYAPURA BLDE (DU)/IEC/ 705/2022-23 30/8/2022

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Ethical Committee of this University met on Friday, 26th August, 2022 at 3.30 p.m. in the Department of Pharmacology scrutinizes the Synopsis of Post Graduate Student of BLDE (DU)'s Shri B.M.Patil Medical College Hospital & Research Centre from ethical clearance point of view. After scrutiny, the following original/ corrected and revised version synopsis of the thesis/ research projects has been accorded ethical clearance.

TITLE: "COMBINATION OF REVERSE SHOCK INDEX AND GLASGOW COMA SCALE TO INITIATE MASSIVE TRANSFUSION PROTOCOL IN TRAUMA PATIENTS"

NAME OF THE STUDENT/PRINCIPAL INVESTIGATOR: Rayala Saguna Datta

NAME OF THE GUIDE: Dr. B P kattimani, Dept. of Emergency Medicine.

Dr. Santoshkumar Jeevangi Chairperson IEC, BLDE (DU), VIJAYAPURA

Dr.Akram A. Maikwadi Member Secretary IEC, BLOE (DU), VUAYAPURA

Chairman, Institutional Ethical Committee, BLDE (Deemed to be University) Following documents were placed before Ethical Committee for Schutzandar, 5%:103. Karnataka

- Copy of Synopsis/Research Projects
 Copy of inform consent form
- · Any other relevant document

Smt. Bangaramma Sajjan Campus, B. M. Patil Road (Sholapur Road), Vijayapura - 586103, Kamataka, India. BLDF (DU): Phone: +918352-262770, Fax: +918352-263303, Website: www.bldedu.ac.in. E-mail:offlice@idedu.ac.in College: Phone: +918352-262770, Fax: +918352-263019, E-mail: bmpnac.principal@bldedu.ac.in

ANNEXURE II

RESEARCH INFORMED CONSENT FORM

BLDE (Deemed to be University) Shri. B.M. PATIL Medical College, Hospital & Research Centre, VIJAYAPURA-586103

TITLE OF THE PROJECT: COMBINATION OF REVERSE SHOCK INDEX AND GLASGOW COMA SCALE TO INITIATE MASSIVE TRANSFUSION PROTOCOL IN TRAUMA PATIENTS.

GUIDE: Dr. B.P. KATTIMANI, M.S. GENERAL SURGERY, ASSOCIATE PROFESSOR, DEPARTMENT OF EMERGENCY MEDICINE.

PG STUDENT: Dr. RAYALA SAGUNA DATTA DEPARTMENT OF EMERGENCY MEDICINE



PURPOSE OF RESEARCH:

I have been explained about the reason for doing this study and selecting me as a subject for this study. I have also been given free choice for either being included or not in this study.

PROCEDURE:

I am aware that in addition to routine care received, I will be asked a series of questions by the investigator. I have been asked to undergo the necessary investigations and treatment, which will help the investigator in this study.

RISK AND DISCOMFORTS:

I understand there is no risk involved and that the patient may experience some discomforts due to panic situation during the examination. This is mainly the observational study and no risk is involved in the study. All the data collected would be kept safe and private.

BENEFIT:

I do understand that my participation in this study will have no direct benefits to me, other than the potential benefit of the research and education.

CONFIDENTIALITY:

I understand that the medical information produced by this study will become a part of hospital records and will be subjected to confidentiality. Any information about sensitive, personal nature will not be a part of the medical record but will be stored in the investigations research file. If any of the data are used for publication in the medical literature or for teaching purpose, no name will be disclosed, and other identifiers such as photographs will be used only with special written permission taken priorly. I also understand that I may visualize the photograph before granting permission.

REQUEST FOR MORE INFORMATION:

I understand that I may ask questions about the study at any time; Dr. RAYALA SAGUNA DATTA at the department of Emergency Medicine is available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of the study, which might influence my continued participation. A copy of this consent form will be given to me to keep for careful reading.

REFUSAL FOR WITHDRAWAL OF PARTICIPATION:

I understand that my participation is voluntary and that I may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice. I also understand that Dr. RAYALA SAGUNA DATTA may terminate my participation in the study after he has explained the reasons for doing so.

INJURY STATEMENT:

I understand that in the unlikely event of injury to me, resulting directly for participation in this study; if such injury were reported promptly, the appropriate treatment would be available to the patient. But no further compensation would be provided by the hospital. I understand that by my agreements to participate in this study and not waiving any of my legal rights.



I have been explained about the purpose of the research, the procedures required and the possible risks to the best of my ability.

Dr. RAYALA SAGUNA DATTA (Investigator)

Date



STUDY SUBJECT CONSENT STATEMENT:

I confirm that Dr. RAYALA SAGUNA DATTA has explained to me the purpose of the research, the study procedures that I will undergo, and the possible risks and discomforts as well as benefits that I may experience in my own language. I have read the form and understand this consent.

Therefore, I agree to give consent to participate as a subject in this research project.

Participant / Guardian

Date:

Witness to signature

Date:



ANNEXURE III

PROFORMA FOR TAKING CASE

 $\mathsf{Page}57$

Name:	CASE NO:
Age:	IP NO:
Sex:	DOA:
Occupation:	DOD:
Residence:	Contact Number:
BLOOD GROUP and RH TYPE:	
DIAGNOSIS:	
Presenting complaints with duration:	
Past History:	
Vitals:	
HR:	
BP:	
RR:	
SPO2:	
Temp:	
GCS:	
eFAST (+/-):	
NATURE OF INJURY:	
Head-to-toe examination:	
ABC SCORE:	
TASH SCORE:	
Need for Mechanical ventilation(yes/	no):
Need for Massive Transfusion(yes/no):

No units of blood transfused within 24 hrs: packed red blood cells:

Platelets:

Fresh frozen plasma:

Mortality within 24-h(yes/no):

No of days of hospital stay:

In-hospital mortality(yes/no):

CAUSE OF DEATH (if died):

INVESTIGATIONS:

1) Hemoglobin gm. %

2) Platelet count

3) PT/INR

4) aPTT

5) LACTATE LEVEL

6) BASE EXCESS

7) PH

X-RAY FINDINGS:

Date: -

Signature: -



ANNEXURE IV

KEY TO MASTER CHART

SL.NO	Serial Number
IP NO	Inpatient Number
HB%	HEMOGLOBIN%
HR	Heart Rate
RR	Respiratory Rate
SBP	Systolic Blood Pressure
DBP	Diastolic Blood Pressure
SI	Shock Index
SIA	Shock Index*Age
GCS	Glasgow Coma Scale
ISS	Injury Severity Score
qSOFA	Quick Sequential Organ Failure Assessment
ABC	Assessment Blood Consumption
TASH	Trauma Associated Severe Hemorrhage
rSIG	Reverse Shock Index*Glasgow Coma Scale



ANNEXURE V: MASTER CHART

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88	2	89	87	86	84	90	125	76	91	88	79	80	92	78	90	88	98	85	92	82	85	132	89	92	88	84	91	91	86	81	8	90	130	92	84	90	98	80	136	75	79	80	92	90	88	98	78	82	56
124	126	128	116	110	116	114	69	120	118	122	110	128	120	118	122	122	128	116	110	126	124	81	118	122	130	131	110	128	122	110	128	116	75	129	122	110	127	117	72	128	114	122	110	128	128	114	118	122	110
91	84	97	84	90	83	86	60	95	94	68	86	95	94	89	90	83	84	90	83	84	97	54	95	94	68	86	84	90	83	95	94	68	63	94	68	98	84	97	65	84	97	84	90	83	87	87	85	84	1,6
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195 Kasturibai hittanalli	104 Rhimehi mujari	193 Siddappa kattimani	192 Shantabai Teli	191 Basamma Shinde	190 Kashinath Jadhav	189 Shivappa Kalappa	188 Rajaram Balasab	187 NAGAWWA ATHANUR	186 GURUMMA MATH	185 NEELAMMA YATGIRI	184 SHIVANGAUDA BIRAD	183 sanjay pawar	182 SHAKUNTALA DEVAK	181 kastturi chikkodi	180 RAJSHEKHAR TAMAV	179 AJAYSING NAIK	178 Shivappa Basappa Konnu	177 vaishnavi pujari	176 sidamma madar	175 Dulamma magari	174 Poornima malipatil	173 RANGAPPA PUJARI	172 Sharada Vikas Patil	171 Dulappa Magari	170 Babagouda Patil	169 Bisamila Mujavar	168 Vaishali Wagamode	167 sanjay rathod	166 Chandrashekhar Gulabal	165 Ashwini Mathapati	164 Sharanappa Madar	163 Gaurabhai Gudimani	162 Mahadev Devarnavadagi	161 Shankreppa Medegar	160 Chandaramma Managuli	159 Basamma Naikodi	158 Siddamma Girisagar	157 Devraj Nala	156 Channappa Shrigiri	155 Reshma Hamadagi	154 Devuba Manavar	153 Suresh Patil	152 shwetha biradar	151 Shantabai hireamath
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1	N 87	1.3	2	1.5	1.6	1.5	1.4	1.4	1.5	1.5	1.4	1.5	1.4	1.5	1.4	1.4	1.2	1.6	1.5	1.2	1.4	1.4	-	-	1.5	2	1.6	1.5	1.5	2.1	1.6	1.5	1.3	1.3	1.5	1.4	2.5	2.4	2.1	1.4	1.8	2	1.5	1.5
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112	110	128	127	81	124	128	116	110	128	126	117	118	122	112	75	126	127	115	118	122	110	128	118	115	122	128	116	110	118	122	79	122	128	116	110	128	129	127	72	125	130	128	116	110
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21	10	20	17	ω	20	21	19	20	17	19	18	21	17	20	9	17	19	18	19	18	21	19	20	17	18	18	17	19	18	20	S	17	23	21	17	20	19	23	4	18	17	20	21	17
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