The Validity of Sonographic Assessment of Intravascular Fluid Estimate (SAFE) Score in The Assessment of Volume State in Acute Kidney Injury Patients.

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ABSTRACT

Background: Ultrasonography has gained popularity in the last two decades, with many critical care units standardizing point-of-care ultrasonography (POCUS) for ICU patient diagnosis and treatment.

Aim: To develop a reliable fluid status scoring system for critically ill cases, evaluate SAFE score's effectiveness, and assess organ evaluation and hemodynamic measures' utility.

Patients and methods: Prospective observational research has been performed from March 2021 to December 2022 at Kasr Al Ainy Hospital, Cairo University, Egypt, on 150 adult cases with acute kidney injury admitted to the Critical Care Department. The ICU physician selected patients based on their need to evaluate hemodynamic and volume status.

Results: No statistically significant relationship between standard hemodynamic measures (SBP, DBP, MAP, HR, and CVP) and either the SAFE score or LVOT VTI in assessing volume status. Among hypovolemic patients, 52.4% (11 out of 21) were volume responsive, while 47.6% (10 out of 21) were non-responsive. In contrast, 73.9% (82 out of 111) of euvolemic patients were non-volume responsive, with the remaining 26.1% being volume responsive. For hypervolemic patients, 83.3% (15 out of 18) were non-volume responsive. Kendall's tau-c statistic (0.166) indicated a weak correlation between the SAFE score and volume responsiveness by LVOT VTI after the PLR test, suggesting that while the SAFE score provides valuable insights, it may not strongly predict fluid responsiveness in all cases.

Conclusion: Fluid status assessment is crucial for ICU patient management, aiding resuscitation and de-resuscitation, but over-administration can increase morbidity and mortality.

Introduction

Most critically ill patients are hemodynamically unstable; an important aspect of this hemodynamic instability is the volume status of such patients, so assessment of volume states in the ICU became a necessity. Patients in ICU are either euvolemic, hypervolemic, or hypovolemic. Prediction of fluid status of patients in ICU provides an important guide for the management of patients in such settings. Hypovolemic patients need intravenous fluid administration, which, if given, may have hazardous effects on the euvolemic and hypervolemic patients who do not require such administration. Fluids in such patients may impact their morbidity, length of hospitalization, and death. Many predictive tools for the assessment of volume status are available, and one of these tools is ultrasound (1,2).

Ultrasonography has become widely used, especially during the last two decades. Many critical care units have standardized point-of-care ultrasonography (POCUS) in medical practice for diagnosis and treatment of ICU patients. POCUS has even become an important tool in acute critical care settings, and one of the POCUS modalities is echocardiography, which has become the most important tool utilized for evaluating cardiac function and detecting the cause of hemodynamic instability in most compromised patients (1–3).

Standardized POCUS protocols have been developed after many years of research, such as focused assessment with sonography in trauma (FAST), extended FAST (E-FAST) (4,5), focused assessment of transthoracic echocardiography (FATE) (6), and rapid ultrasound for shock and hypotension (RUSH) (7),

however, none of them provided a score to portray the volume state of patients. After review of literature, only a few scoring systems including more than one organ were found. A scoring system evaluating more than one system may provide more data and information about the patient, which has a positive impact on clinical decision-making.

Sonographic assessment of Fluid Vascular Estimate (SAFE) score combines more than one individual organ to provide a numerical value that correlates with the volume status of ICU patients (8). Both dehydration and volume overload have detrimental effects, so proper assessment of fluid status is crucial in the evaluation and management of critically ill cases. The SAFE score assigns a numerical value to each category of volume state after cardiac, pulmonary, IJV, and IVC examinations all together (8).

The primary purposes of this research were to develop a reliable scoring system that integrates multiple parameters for assessing fluid status in critically ill cases and to assess the efficiency of the SAFE score in determining volume status in this population. The secondary objectives included assessing the role of individual organ evaluation (cardiac, pulmonary, IVC, and IJV) in detecting fluid status and examining the utility of standard hemodynamic measures (BP, HR, and CVP) in evaluating volume status in critically ill cases.

Patients and methods

A prospective observational research study has been performed from March 2021 to December 2022 at Kasr Al Ainy Hospital, Cairo University, Egypt, involving 150 adult cases with acute kidney injury admitted to the Critical Care Department. Patients were selected based on the ICU physician's need to assess hemodynamic and volume status.

Inclusion criteria: Cases older than eighteen years and cases with acute kidney injury according to KDIGO definition.
Exclusion criteria: Cases with end-stage renal disease, cases with IJV thrombosis, and cases with IVC thrombosis or severe TR

Evaluation of Patients

All patients underwent a thorough and systematic evaluation process designed to comprehensively assess their clinical condition. This began with detailed history taking, which included personal history, chronic health conditions (such as hypertension, diabetes mellitus, heart failure, ischemic heart disease, kidney illness, or chronic liver), comorbidities, habits of medical importance (e.g., smoking, alcoholism), history of endocrinal disorders (e.g., hyperthyroidism or hypothyroidism), drug history (with special emphasis on the use of diuretics), and previous surgical history. Following this, a full clinical examination was conducted, encompassing the assessment of vital signs (blood pressure, mean arterial pressure, heart rate, temperature, respiratory rate, oxygen saturation, and central venous pressure), evaluation of the conscious level and detailed neurological examination, and a thorough physical examination of the head, neck, cardiac, chest, abdominal, and lower extremities. Routine electrocardiography (ECG) was performed on admission to identify ischemic changes (such as ST-segment and T-wave abnormalities), signs of chamber enlargement, and any rhythm abnormalities that could be related to cardiac or pulmonary diseases. Laboratory investigations included a complete blood count (CBC: hemoglobin, hematocrit, white cell count, platelet count), coagulation profile (PT, PC, INR), kidney function tests (urea, creatinine), arterial blood gases (ABG), serum lactate level, liver function tests (ALT, AST, total and direct bilirubin, serum albumin), and serum electrolytes (sodium, potassium, calcium, magnesium). A chest X-ray was routinely performed on admission to evaluate the condition of the chest and identify any pulmonary abnormalities. To assess volume status, the Passive Leg Raising (PLR) test and echocardiographic measurement of the left ventricular outflow tract velocity time integral (LVOT VTI) were utilized. Patients were initially placed in a 45° semi-recumbent position for baseline cardiac output (CO) assessment. The PLR test was then performed for 2 minutes by adjusting the bed, followed by reassessment of CO. The LVOT VTI was measured using a clear apical 5-chamber view with proper alignment of the pulse wave Doppler sample volume parallel

to the aortic flow. A Δ LVOT VTI > 12% was considered indicative of volume responsiveness. Additionally, the SAFE score was employed to evaluate volume status by assessing four key components: heart, lungs, inferior vena cava (IVC), and internal jugular vein (IJV). Ejection fraction (EF) was measured via echocardiography and scored as: EF >70% (-1), EF 50-70% (0), EF <50% (+1). B-lines were counted across four lung sectors, and the average was scored as <1 B-line (-1), 1-2 B-lines (0), or ≥3 B-lines or B-line sheets (+1). The IVC diameter and collapsibility/distensibility indices were measured and scored as follows: <2.5 centimeters with >50% variation (-1), 1.5-2.5 centimeters with <50% variation (0), >2.5 centimeters with <50% variation (+1). IJV respiratory variation was measured and scored as follows: >40% (-1), 20-40% (0), <20% (+1). The final SAFE score (sum of scores from all four components) classified patients into hypovolemia (SAFE score of -2 to -4), euvolemia (SAFE score of -1 to +1), and hypervolemia (SAFE score of +2 to +4). All ultrasound examinations, including the SAFE score components, were performed by experienced operators using the Xario 200G ultrasound (Canon Medical Systems, USA). The ultrasound examiner was not involved in the clinical management of the patients to avoid bias, and all images were stored for review and documentation. This comprehensive evaluation protocol ensured a detailed and accurate assessment of each patient's hemodynamic and volume status.

Statistical analysis

Data have been entered and coded utilizing the statistical package SPSS (Statistical Package for the Social Sciences) version 25. Quantitative data have been summarized utilizing mean, standard deviation, median, maximum, and minimum, while categorical data have been summarized utilizing relative frequency (percentage) and frequency (count). Kendall's tau-c statistic was used to assess the correlation between the SAFE score and LVOT VTI. The evaluation of volume status by the SAFE score was performed by calculating specificity, sensitivity, positive predictive values (PPV), accuracy, and negative predictive values (NPV) utilizing LVOT VTI as the gold standard. A multinomial logistic model has been applied to predict volume status deepened on ultrasound scores, and the classification accuracy has been estimated. P-values less than 0.05 have been represented as statistically significant.

Results

Table (1): Demographic Data of the studied group.

Gender	**Number**	**Percentage**
Male	89	59.3%
Female	61	40.7%
	Standard deviation	**Mean**
Age	62.5	13
Co- Morbidities	**Number**	**Percentage**
Hypertension	90	60%
Diabetes Mellitus	75	50%
Ischemic Heart disease	37	24.6%
Heart Failure	9	6%
Old Cerebrovascular Stroke	25	16.7%
Chronic Liver Disease	14	9.3%
Hypothyroidism	10	6.6%
Hyperthyroidism	2	1.3%

Table 1 showed that the study included 150 patients, with a majority being males (89 patients). The mean age of the research group was 62.5 ± 13 years, varying between 25 and 91 years. Hypertension (HTN), ischemic heart disease (IHD), and diabetes mellitus (DM) were the most frequent comorbidities, representing 60%, 50%, and 24.6% of the study group, respectively. Additionally, 16.7% of the patients had a history of cerebrovascular stroke, 6% were heart failure patients, and other comorbidities such as chronic liver disease,

hypothyroidism, and hyperthyroidism were present in 9.3%, 6.6%, and 1.3% of the studied group, respectively.

Table (2): Descriptive Data and Distribution of SAFE Score Among the Study Group

SAFE score	Frequency	Percentage	Volume Status	Count	Percentage
-3	3	2.0%	Hypovolemia	21	14.0%
-2	18	12.0%	Euvolemia	111	74.0%
-1	29	19.3%			
0	51	34.0%			
+1	31	20.7%			
+2	13	8.7%	Hypervolemia	18	12.0%
+3	5	3.3%			
Total	150	100%	Total	150	100%

Table 2 shows the distribution of SAFE scores and volume status within the study group. The mean SAFE score was -0.01 (standard deviation: 1.31), with most patients (74.0%) classified as euvolemic (SAFE score -1 to +1). Smaller proportions were hypovolemic (14.0%, SAFE score -2 to -4) or hypervolemic (12.0%, SAFE score +2 to +4). Together, hypovolemic and euvolemic patients represented 88% of the population, while only 12% were hypervolemic. This highlights the SAFE score's effectiveness in evaluating volume status in critically ill cases, with the majority falling within normal or low volume ranges.

Table (3): Description of volume responsiveness in study group by LVOT VTI

Volume response by LVOT VTI	**Volume responsive**	43	28.7%
	Non- Volume responsive	107	71.3%

Table 3 showed that 28.7% of 43 patients were volume responsive, while 71.3% were non-volume responsive, indicating that a significant proportion of critically ill cases didn't show significant improvement in cardiac output with fluid challenge, emphasizing the importance of precise volume status assessment to avoid unnecessary fluid administration and potential complications.

Table (4): showing the relation between standard hemodynamic measures and Volume status by SAFE score.

Hemodynamics	**Volume Status by SAFE score**						**P-value**
	Hypovolemia		**Euvolemia**		**Hypervolemia**		**ANOVA**
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	
SBP	124.3	15.0	115.3	17.2	117.2	13.2	**0.076**
DBP	73.3	9.1	68.9	11.4	71.1	10.8	**0.214**
MAP	90.3	9.9	84.7	12.5	85.8	9.8	**0.142**
HR	82.8	14.7	89.1	14.6	88.7	12.2	**0.179**
CVP	10.5	3.6	10.9	4.1	12.8	5.6	**0.193**

Table 4 showed that statistically insignificant relation was discovered between various standard hemodynamic measures (SBP, DBP, MAP, HR, and CVP) and SAFE score regarding the assessment of volume status.

Table (5): Showing the relation between standard hemodynamic measure and Volume responsiveness by LVOT VTI.

Hemodynamics	**Volume status by LVOT VTI**				**P-value**
	Volume responsive		**Non-Volume responsive**		**t-test**
	Mean	**SD**	**Mean**	**SD**	
SBP	118.4	18.4	116.2	15.9	**0.465**

DBP	70.5	12.9	69.5	10.3	**0.643**
MAP	86.4	13.2	85.3	11.5	**0.604**
HR	88.0	15.7	88.3	14.0	**0.906**
CVP	11.6	4.4	10.9	4.2	**0.409**

Table 5 showed that statistically insignificant relation was discovered between various standard hemodynamic measures (SBP, DBP, MAP, HR, and CVP) and LVOT VTI regarding the assessment of volume status.

Table (6): showing the relation between Volume status by SAFE score and Volume responsiveness by LVOT VTI.

		Volume status by SAFE Score					
		Hypovolemia		**Euvolemia**		**Hypervolemia**	
		Count	**%**	**Count**	**%**	**Count**	**%**
Volume response by LVOT VTI	**Volume responsive**	11	52.4%	29	26.1%	3	16.7%
	Non- Volume responsive	10	47.6%	82	73.9%	15	83.3%
Kendall's tau-c statistic				**Value**			
				0.166			

Table 6 showed that 11 patients (52.4%) of 21 hypovolemic patients are volume responsive, and 10 out of 21 hypovolemic patients are non-volume responders, while 82 patients out of 111 euvolemic patients are non-volume responders (73.95%), and the remainder of euvolemic patients (26.1%) are volume responsive. 15 out of 18 hypervolemic patients (83.3%) are non-volume responsive. Kendall's tau-c statistic of value 0.166 showed weak correlation between SAFE score and volume responsiveness by LVOT VTI after the PLR test.

Discussion

In our study, it showed that the mean age of our study group was 62.5 + 13 years; the youngest was 25 years and the oldest was 91 years. Males and females were represented in a ratio of 59.3% and 40.7%, respectively. HTN, DM, and IHD were the most frequent comorbidities in the study group, representing 60%, 50%, and 24.6%, respectively. All patients in our study suffered from AKI, while most patients suffered from sepsis, chest infection, and disturbed conscious level, which represent 34.7%, 16.7%, and 16.7%, respectively.

In our study, we showed that, according to our study using the SAFE score, 21 (14% of total) patients were found to be hypovolemic, 111 (74% of total) patients were diagnosed with euvolemia, and 18 (12% of total) patients were hypervolemic, so both hypovolemic and euvolemic patients were 132 patients, which represent 88% of the population, while only 12% of patients were hypervolemic.

In our study, assessment of volume responsiveness by LVOT VTI showed that 43 (28.7% of total) patients were volume responsive, and 107 (71.3% of total) patients were non-volume responsive. It was also found in our research that statistically insignificant variance among was discovered hemodynamic measures (SBP, DBP, MAP, HR and CVP) and both SAFE score and LVOT VTI.

In our research, we showed that there is a statistically insignificant relationship among various standard hemodynamic measures (SBP, DBP, MAP, HR, and CVP) and LVOT VTI regarding the assessment of volume status.

In our study, we showed that the outcomes of our research have demonstrated that 11 cases (52.4%) of 21 hypovolemic patients are volume responsive, and 10 out of 21 hypovolemic patients are non-volume responders, while 82 patients out of 111 euvolemic patients are non-volume responders (73.95%), and the remainder of euvolemic patients (26.1%) are volume responsive. 15 out of 18 hypervolemic patients (83.3%) are non-volume responsive. Kendall's tau-c statistic of value 0.166 showed weak correlation between SAFE score

and volume responsiveness by LVOT VTI after the PLR test. However, SAFE may be particularly valuable in the assessment of hypervolemic patients.

Compared to the study done on SAFE score by Keith Killu et al., (8) who studied 61 patients admitted to surgical critical care. The mean age was 59 (±14.3) years, of which 61% are males. The mean SBP was 107+21.4, the mean DBP was 57.9+13.2, the mean MAP was 73+13.1, the mean HR was 105+17.7 and the mean CVP was 12.2+6.2. 25 patients (41%) were on vasopressor therapy, while 53 patients (87%) were intubated and mechanically ventilated.

In our study, the SAFE score was assessed in comparison to LVOT VTI change before and after PLR in AKI patients. This was in contrast to the SAFE study, 2020, which compared SAFE score results with standard measures of volume status, the measures whose role has become controversial recently. SAFE study also did not specify AKI patients (8).

Bouchra Lamia et al., (9) have compared both passive leg raising and echocardiographic response of stroke volume to left ventricular end-diastolic area and mitral (E/Ea). It was found that PLR predicted fluid responsiveness if stroke volume increased by more than 12.5% with specificity and sensitivity of 100% and 77%, respectively. According to their study, LVEDA, or E/Ea, has been found to be of limited value in the prediction of fluid responsiveness.

Wang et al., (10) have found in their study that LVOT VTI variation predicted volume responsiveness effectively in septic shock and mechanically ventilated cases. According to their study, the specificity and sensitivity were 95% and 87.5%, respectively, when the cut-off value was 15.9%.

Pablo Blanco et al., (11) have also assumed LVOT VTI to be a valuable tool in the assessment of stroke volume and Cardiac output in critical care setting.

SAFE score is based on 4 parameters: ejection fraction, B-line score, IVC collapsibility index, and IJV collapsibility index. Other studies assessed each of these parameters but in a separate fashion. Sonographic assessment of fluid The Vascular Estimate score of -4 to -2 characterizes hypovolemia, -1 to +1 characterizes euvolemia, and +2 to +4 characterize hypovolemia.

Pongdhep Theerawit et al., (12) have concluded in their study that B-line increase may suggest increased EVLW in septic shock patients.

Marc Saad et al., (13) used B-line score in their assessment of volume overload in patients on hemodialysis. This was in accordance with our study, which used B-line score in the evaluation of the volume state of critically ill patients.

Yan Zhuang et al., (14) studied 56 patients comparing lung B-line scores and BNP levels between heart failure and non-heart failure patients. Lung B-line score was found to be highly specific (95%) and moderately sensitive (77%) for detection of volume overload in HF patients.

Yusuke Iizuka et al., (15) studied the role of IJV distensibility in 27 patients on pressure support ventilation. PLR and arterial pulse contour analysis were performed to assess volume responsiveness. Right IJV collapsibility was found to be useful in the prediction of fluid response in cases on pressure support ventilation.

Kent et al., (16) studied 40 critically ill patients and found weak correlation between IJV collapsibility and IVC collapsibility, concluding that IJV collapsibility cannot be used as a surrogate for IVC collapsibility.

However, Murat Haliloğlu et al.,(17) found the opposite after performing paired sonographic measurements of hemodynamics using cardiac output monitor, IVC collapsibility index, and IJV collapsibility index at baseline and after PLR in 44 septic, non-mechanically ventilated patients. Results showed that IJV-CI of more than 36% before PLR maneuver had 78% sensitivity and 85% specificity to predict fluid response (17).

Fabio Guarracino et al., (18) involved 50 mechanically ventilated cases with sepsis in a study aimed at assessing the reliability of the IJV distensibility index to assess volume responsiveness. Before and after the fluid challenge, a radial arterial indwelling catheter connected to a continuous hemodynamic monitoring system was used to measure the heart's output. IJV measurements were done by sonography, and the IJV distensibility index was calculated. Results have shown IJV distensibility to be accurate in the prediction of fluid responsiveness, with 80% sensitivity and 85% specificity.

Fabiano Broilo et al., (19) also studied 39 mechanically ventilated, hemodynamically unstable patients in a critical care setting. They found a significant agreement between the distensibility of the right IJV and IVD. So IJV respiratory variation may be used as an alternative to IVC variation.

Many studies have included IVC collapsibility and distensibility in the assessment of volume status. Muller et al., (20) assessed the fluid responsiveness in 40 spontaneously breathing patients using aortic VTI and calculated IVC collapsibility index. It was found that IVC collapsibility index (>40%) is associated with fluid responsiveness, while values lower than 40% do not exclude fluid responsiveness.

Airapetian et al., (21) studied 59 spontaneously breathing cases and concluded that vena cava size and respiratory variability don't predict fluid responsiveness accurately.

Sebastien Preau et al., (22) studied 90 spontaneously breathing ICU patients with septic shock. The stroke volume index was measured and compared to the IVC collapsibility index during deep standard inspiration after a volume challenge with 500 ml of 4% gelatin. It was found that the IVC collapsibility index can predict volume responsiveness with a sensitivity of 84% and a specificity of 90%.

Christophe Barbier et al., (23) included 23 mechanically ventilated patients with sepsis. The researchers measured and calculated the IVC distensibility index. Cardiac index was determined by Doppler on the pulmonary artery after volume expansion with plasma. It was concluded that respiratory change in IVC predicted fluid responsiveness accurately.

Marc Feissel et al., (24) also studied 39 mechanically ventilated patients with septic shock in a medical ICU. Distensibility of IVC and cardiac output were both assessed by echocardiography before and after volume expansion. It was concluded that Delta (IVC) can detect fluid response in such cases.

Qian Ma et al., (25) have studied 56 abdominal surgical cases in critical care. Measurement of IVC distensibility and LVOT VTI was performed during intubation before and after five milliliters per kilogram of crystalloid within fifteen minutes. The same measurements have been repeated after extubation. Multivariable logistic regression analysis showed that IVC collapsibility predicted volume status independently in post-surgical disregarding mode of breathing.

Study Limitations

Our limitations in this research are the limited number of research populations and the various comorbidities affecting each item of the SAFE score. The presence of underlying cardiac dysfunction or pulmonary hypertension or severe tricuspid regurgitation may limit the use of the SAFE score in the evaluation of volume status.

Conclusion

Fluid status assessment is crucial in managing ICU patients, as it aids in resuscitation and de-resuscitation in hypovolemic and shocked patients. However, fluid over administration can increase morbidity and mortality. The SAFE score has a weak correlation with LVOT VTI variation before and after PLR but may be useful in hypervolemic patients. Additional investigations are required to assess its role in evaluating volume states in critically ill cases.

Recommendations

We recommend future studies with larger sample sizes for the evaluation of fluid status in critical care unit patients. We recommend further studies for the study of the role of sonographic assessment of fluid vascular estimate score in the evaluation of volume state of critically ill cases. We recommend further studies to develop combined scores using ultrasound for the evaluation of fluid status in ICU cases.

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