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Research Article

Early Prediction of mortality risks Using Novel Biomarkers in Adult ICU Patients with Severe Respiratory Failure

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Abstract

Background: Mortality prediction in ICU patients remains a critical unmet need. This study aims to assess the early prediction of mortality risks using novel biomarkers in adult ICU patients with severe respiratory failure.

Methods: a prospective observational study included 188 patients who were followed throughout their ICU stay at Al-Azhar university hospitals and were categorized according to clinical outcome into survivors (n=70) and non-survivors (n=118). Demographic, clinical, and laboratory data were prospectively collected and analyzed to assess their association with ICU mortality.

Results: IL-6, IL-1B at (admission and 1st week) and IL-8 at 1st week were statistically significant lower in survivor patients than in dead patients. Furthermore, there was no statistically significant difference among the studied groups regarding IL-8 at admission. The ROC curve analysis showed that the cutoff point of biomarkers as a predictor of mortality in patients, IL-6 at (admission and 1st week) were 89.00, 59.00, with sensitivity of 95.7, 97.5%, specificity of 80.9, 86.1% at AUC 0.97, 1.00. Moreover, the cutoff points of IL-8 at (admission and 1st week) were 322.50, 229.50, with sensitivity of 95.7%, specifically of 89.8% at AUC 0.53, 0.67. As well as the cutoff points of IL-1B at (admission and 1st week) were 79.00, 55.50, with sensitivity of 96.8, 98.7%, specifically of 81.9, 90.7% at AUC 0.97, respectively.

Conclusions: In the current study, an enhanced level of IL-6, IL-1B at and IL-8 was significantly associated with mortality patients. As for, the ROC curve analysis showed that the cutoff point of biomarkers as a predictor of mortality in patients, IL-6 at 1st week scored the best diagnostic tool for prediction of adult ICU patients with severe respiratory failure, followed by IL-1B as compared to IL-8 which scored lower sensitivity and specifically.

Keywords: Adult ICU, Severe Respiratory Failure, Prediction tools, Mortality risks.

Introduction

Acute respiratory failure (ARF) is prevalent among critically ill patients and is a common cause of intensive care unit (ICU) mortality. Approximately 60% of patients with ARF require invasive mechanical ventilation (IMV), which is associated with adverse events, including ventilator-induced lung injury (VILI) and ventilator-associated pneumonia (VAP), [1]. Patients with ARF on IMV have high hospital mortality rates of up to 30%. Initial respiratory support, including conventional oxygen therapy (COT; e.g., nasal cannulas and facemasks), noninvasive positive-pressure ventilation (NPPV), and high-

flow nasal cannula (HFNC) use, are important treatments to prevent tracheal intubation and reduce mortality among patients with hypoxic respiratory failure [2].

Acute, diffuse inflammatory lung injury that quickly progresses to acute respiratory failure is the hallmark of acute respiratory distress syndrome (ARDS), a dangerous and complicated illness that presents substantial patient management concerns. The onset and severity of this syndrome can be influenced by several pulmonary and extrapulmonary pathogenic factors, such as severe infections, shock, trauma, and significant burns [3]. ARDS is a major concern in critical care medicine due to its significant impact and high rates of morbidity and mortality. According to results from LUNG SAFE, the biggest multinational cohort study on ARDS, 10.4% of patients hospitalized to intensive care units had an ARDS diagnosis. Sadly, up to 45% of these individuals may die [4]. The complicated pathophysiological mechanisms of ARDS, which include lung injuries as well as multisystem injuries, inflammatory responses, deregulation of coagulation pathways, and other interrelated biological processes, are closely related to this startling death rate. The goals of current pharmaceutical therapy for ARDS are to reduce pulmonary edema and inflammation, increase vasodilation, and improve extracellular matrix, endothelial, and epithelial tissue repair [5] These treatments are essential for lowering death rates and enhancing the general prognosis of those who are impacted. Therefore, early detection of possible mortality risks in ARDS patients, when combined with prompt and efficient therapies, has the potential to improve survival rates and reverse unfavorable clinical outcomes. In the field of clinical practice, there are currently no trustworthy scoring techniques for predicting death in patients with ARDS [6]. While scoring instruments like the Acute Physiology and Chronic Health Evaluation II (APACHE II) and the Sequential Organ Failure Assessment (SOFA) demonstrate some predictive value regarding mortality in critically ill patients, their actual efficacy in actual clinical settings is still up for debate among medical professionals. The practical use of these scoring systems in common medical situations is severely restricted by this controversy [7]. This study aims to assess the early prediction of mortality risks using novel biomarkers in adult ICU patients with severe respiratory failure.

Patient and Methods

Study Design

This study is a prospective observational study conducted over a six-month period in the Intensive Care Unit (ICU) at Al-Azhar university hospitals to evaluate the early prediction of mortality risk using novel biomarkers in adult patients with severe respiratory failure. The study initially included 200 adult ICU patients; however, 12 patients were excluded due to refusal to provide informed consent (n=3) or failure to meet the inclusion criteria (n=9). Consequently, a total of 188 patients were enrolled and included in the final statistical analysis. Patients were followed throughout their ICU stay and were categorized according to clinical outcome into survivors (n=70) and non-survivors (n=118). Demographic, clinical, and laboratory data were prospectively collected and analyzed to assess their association with ICU mortality.

Patients' Selection Criteria

We included in this study that adult patients aged 18 years or older who were admitted to ICU with a confirmed diagnosis of severe respiratory failure. Both male and female patients were enrolled during the study period provided that informed consent was obtained from the patient or their legal guardian. However, patients were excluded if they were younger than 18 years, declined participation, failed to meet the diagnostic criteria for severe respiratory failure, had incomplete clinical or laboratory data, or had terminal illnesses unrelated to respiratory failure that could affect short-term mortality outcomes.

Ethics Approval and Consent to Participate

The authors affirmed that the work described was completed in accordance with the World Medical Association's Declaration of Helsinki. The present study was run in concordance with international ethical standards and applicable local regulatory guidelines. An informed consent obtained from patients before enrolling in the study after explanation of the study objectives, methodology, risk, and benefit.

Sample Size Estimation

The sample size was estimated based on the expected difference in mortality-related biomarkers between survivors and non-survivors among adult ICU patients with severe respiratory failure. Considering a confidence level of 95%, a statistical power of 80%, and an anticipated moderate effect size, the minimum required sample size was calculated to be 180 patients. To compensate for potential dropouts and exclusions, 200 patients were initially recruited. After applying the eligibility criteria, 188 patients were included in the final statistical analysis, which was deemed sufficient to achieve reliable and statistically significant results.

All Patients were Subjected to the Following

All enrolled patients were subjected to a comprehensive evaluation upon admission to the Intensive Care Unit (ICU), including detailed demographic data collection (age, sex, and body mass index), thorough medical history taking, and full clinical examination with special emphasis on respiratory status and severity of illness. Continuous monitoring of vital signs and routine ICU assessments were performed for all patients. Laboratory investigations were carried out according to standard ICU protocols and included complete hematological and biochemical analyses in addition to the assessment of novel biomarkers for early prediction of mortality risk.

Radiological assessment was performed for all patients and included chest imaging, such as chest X-ray and/or computed tomography (CT) of the chest, to evaluate the extent and severity of pulmonary involvement. Patients were prospectively followed throughout their ICU stay to document clinical outcomes and were subsequently classified into survivors and non-survivors for comparative analysis.

Outcome Measures

The primary outcome of this study was ICU mortality among adult patients with severe respiratory failure. Patients were followed throughout their ICU stay and classified according to their clinical outcome into survivors and non-survivors. Secondary outcome measures included the association of demographic characteristics, clinical parameters, radiological findings, and novel biomarker levels with mortality risk, aiming to evaluate their predictive value for early identification of high-risk patients.

Statistical Analysis Methods

Statistical analysis was done by SPSS v26 (IBM Inc., Chicago, IL, USA). Quantitative variables were presented as mean and standard deviation (SD) and were analyzed by unpaired student t-test. Qualitative variables were presented as frequency and percentage (%) and were compared by chi-square test. Fisher's Exact or Monte Carlo correction to correct for chi-square when more than 20% of the cells have expected count less than 5. Mann-Whitney U test (U): is a test of significance used for comparison of quantitative variables between two groups of not normally distributed data. The ROC (receiver operating characteristic) curves: This procedure is used to evaluate the performance of classification schemes in which there is one variable of two categories by which subjects are classified. They were constructed by calculating the sensitivities and specificities of the variable Paired t test is a method used to test whether the mean difference between pairs of measurements. Pearson correlation coefficient was represented using Heatmap plot correlation. P value <0.05 was considered statistically significant.

Results

A flowchart of the study was conducted on 200 Adult ICU Patients with Severe Respiratory Failure who to Early Prediction of mortality risks Using Novel Biomarkers in Adult ICU Patients with Severe Respiratory Failure over a 6-month period. 12 patients were excluded from the study (3 patients declined consent, and 9 did not meet the inclusion criteria), So, 188 children participated in the study statically analyzed, 70 of them were survivors and 118 patients were dead (Figure 1). In our study, age and BMI were statistically significantly higher among dead patients than in alive patients, also, there was statistically significant difference among studied groups regarding sex (Table 1).

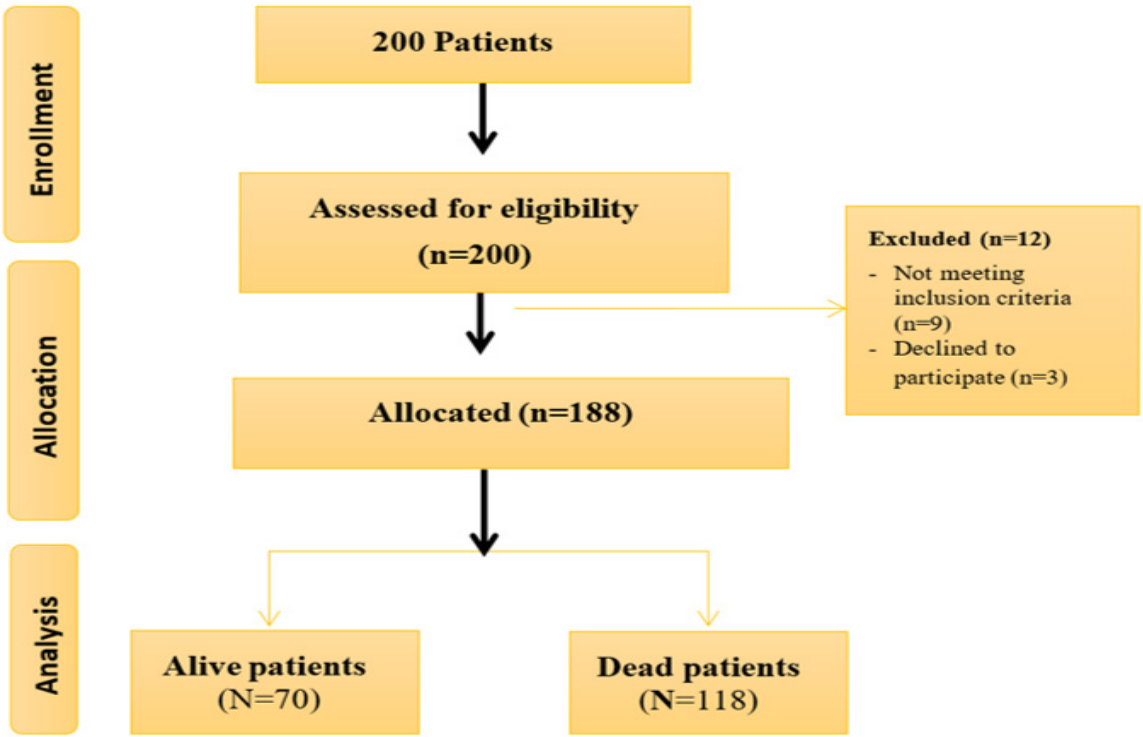

Figure 1. Flowchart of the studied patients.

	Survivor (n=70)	Dead (n=118)	U	P value
Age (years) Mean ± SD. Median (Range)	 53.29 ± 8.52 56 (35–65)	 61.41 ± 13.04 64.5 (42–78)	2593.5	<0.001*
BMI (kg/m2) Mean ± SD. Median (Range)	 28.17 ± 2.24 28 (25–34)	 33.31 ± 4.28 33 (26–40)	1434.0	<0.001*
Sex, N (%) Male Female	 46 (65.7%) 24 (34.3%)	 53 (44.9%) 65 (55.1%)	7.624	0.006*

Mann-Whitney U test (U), Chi-Squared ($\chi 2$), Standard deviation (SD) * Significant for P value <0.05.
Table 1. Demographic data of the studied patients.

Additionally, SOFA score was statistically significant lower in alive patients (8.62 ± 3.71) than in dead patients (10.84 ±4.98). While, there was no statistically significant difference among the studied groups regarding APACHE II (Table 2).

	Survivor (n=70)	Dead (n=118)	U	P value
APACHE II Mean ± SD. Median (Range)	 70.86 ± 8.91 70 (50–100)	 91.67 ± 33.13 104.5 (52–130)	3717.5	0.253
SOFA Mean ± SD. Median (Range)	 8.62 ± 3.71 8.5 (3–15)	 10.84 ± 4.98 10.85 (3–19)	3085.5	0.004*

Acute physiology and chronic health evaluation II (APACHE II), Sequential organ failure assessment (SOFA), Mann-Whitney U test (U), Standard deviation (SD) * Significant for P value <0.05.
Table 2. APACHE II and SOFA scores among the patients studied.

Moreover, there was no statistically significant difference among the studied groups regarding sepsis, trauma and pneumonia (Table 3).

	Survivor (n=70)	Dead (n=118)	X2	P value
Sepsis	32 (45.7%)	66 (55.9%)	1.838	0.175
Trauma	10 (14.3%)	30 (25.4%)	3.254	0.071
Pneumonia	36 (51.4%)	74 (62.7%)	2.304	0.129

Table 3. ARDS etiology among the studied patients.

Additionally, IL-6, IL-1B at (admission and 1st week) and IL-8 at 1st week were statistically significant lower in survivor patients than in dead patients. Furthermore, there was no statistically significant difference among the studied groups regarding IL-8 at admission (Table 4, Figure 2).

Mean ± SD. Median (Range)	Survivor (n=70)	Dead (n=118)	U	P value
IL-6 at admission	41.24 ± 26.88 40 (7–90)	113.07 ± 19.59 120 (50–130)	252.0	<0.001*
IL-6 at 1st week	19.89 ± 11.40 19 (5–49)	65.36 ± 9.70 66 (26–76)	42.0	<0.001*
IL-8 at admission	138.64 ± 52.43 108.5 (62–340)	199.68 ± 107.10 232.5 (85–412)	3903.0	0.529
IL-8 at 1st week	99.53 ± 65.54 48 (39–285)	126.70 ± 64.30 84 (76–365)	2727.0	<0.001*

IL-1B at admission	41.64 ± 17.24 41 (20–70)	84.47 ± 10.50 86 (39–96)	252.0	<0.001*
IL-1B at 1st week	35.47 ± 14.15 35 (17–58)	64.19 ± 14.83 68 (35–82)	888.5	<0.001*

Mann-Whitney U test (U), Standard deviation (SD) * Significant for P value <0.05.
Table 4. Prediction biomarkers levels among the patients studied.

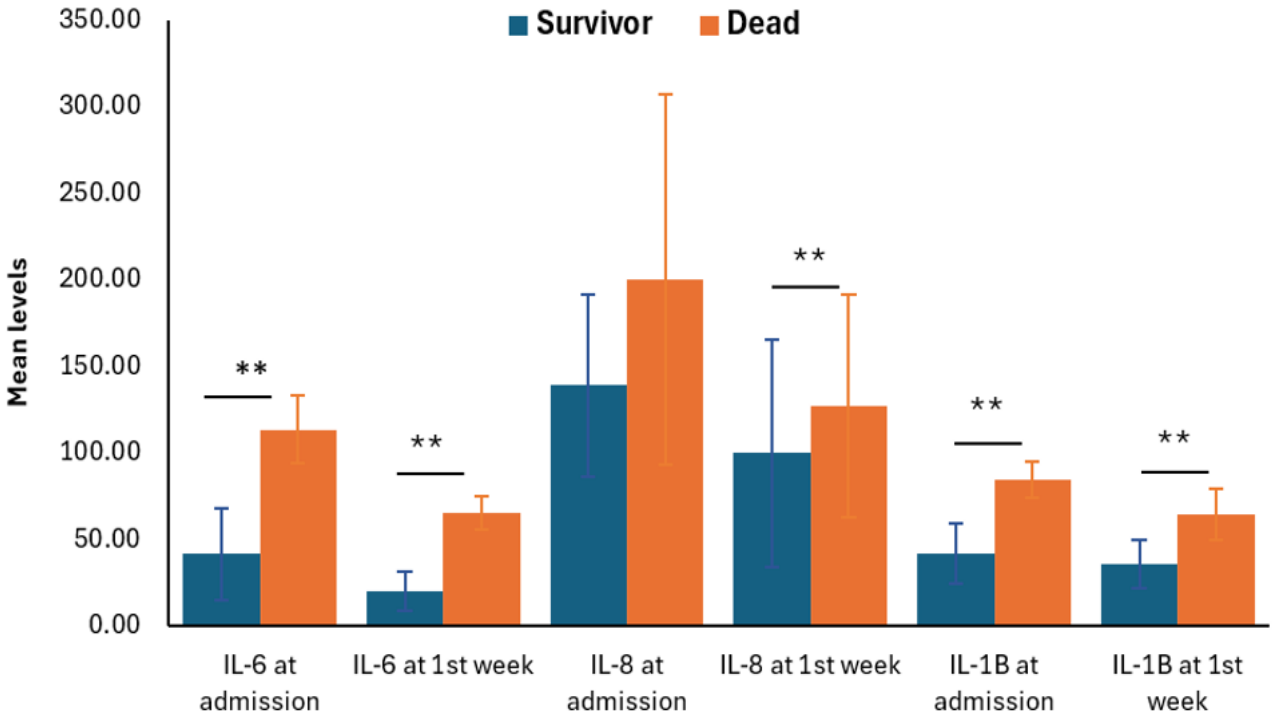

Figure 2. Biomarkers levels among the studied patients.

As for, the ROC curve analysis showed that the cutoff point of biomarkers as a predictor of mortality in patients, IL-6 at (admission and 1st week) were 89.00, 59.00, with sensitivity of 95.7, 99.5%, specificity of 80.9, 88.1% at AUC 0.97, 1.00. Moreover, the cutoff points of IL-8 at (admission and 1st week) were 322.50, 229.50, with sensitivity of 95.7%, specifically of 89.8% at AUC 0.53, 0.67. As well as the cutoff points of IL-1B at (admission and 1st week) were 79.00, 55.50, with sensitivity of 96.8, 98.7%, specifically of 81.9, 90.7% at AUC 0.97, respectively (Table 5, Figure 3a, b, c).

Test Result Variable(s)	AUC	P value	Sensitivity %	Specificity %	Cutoff value	95% C I	
						Lower	Upper
IL-6 at admission	0.97	<0.001*	95.7	80.9	89.00	0.95	0.99
IL-6 at 1st week	1.00	<0.001*	99.5	88.1	59.00	0.99	1.00
IL-8 at admission	0.53	0.529	95.7	89.8	322.50	0.44	0.62
IL-8 at 1st week	0.67	<0.001*	95.7	89.8	229.50	0.58	0.76
IL-1B at admission	0.97	<0.001*	96.8	81.9	79.00	0.95	0.99
IL-1B at 1st week	0.97	<0.001*	98.7	90.7	55.50	0.85	0.94

AUC: Area Under Curve * for significant P value
Table 5. ROC curve of biomarkers as a predictor of mortality in patients.

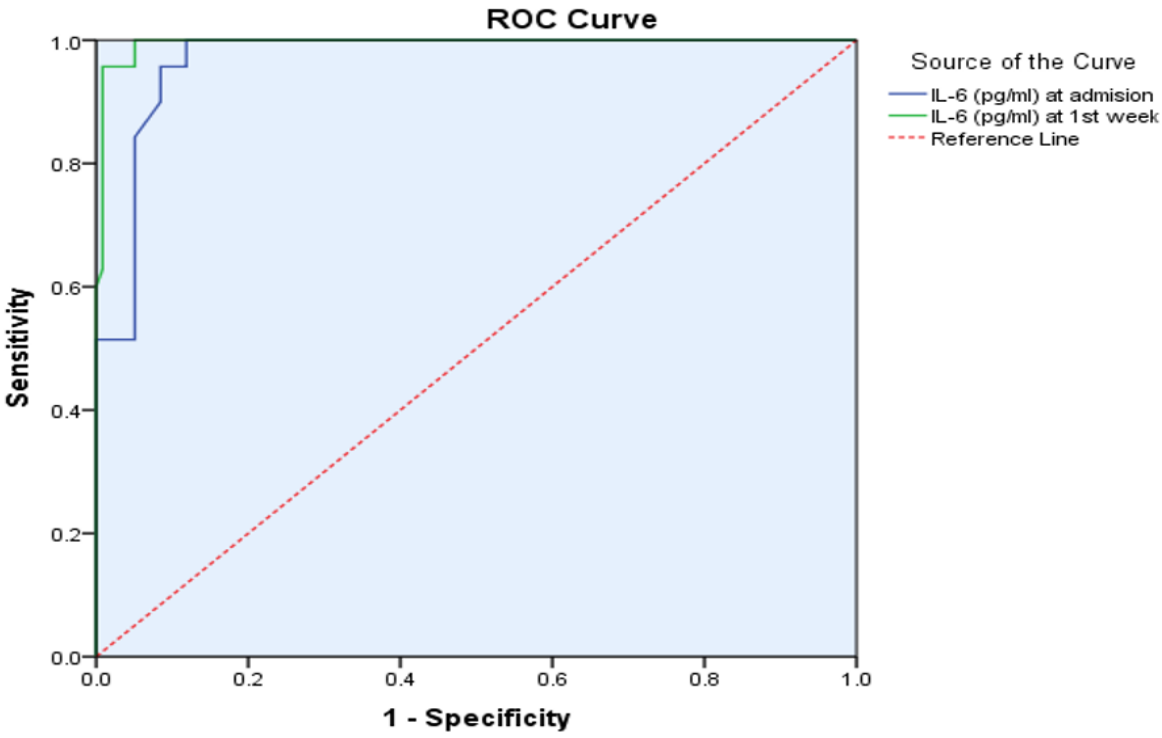

Figure 3a. ROC curve of IL-6 levels as a predictor of mortality in patients.

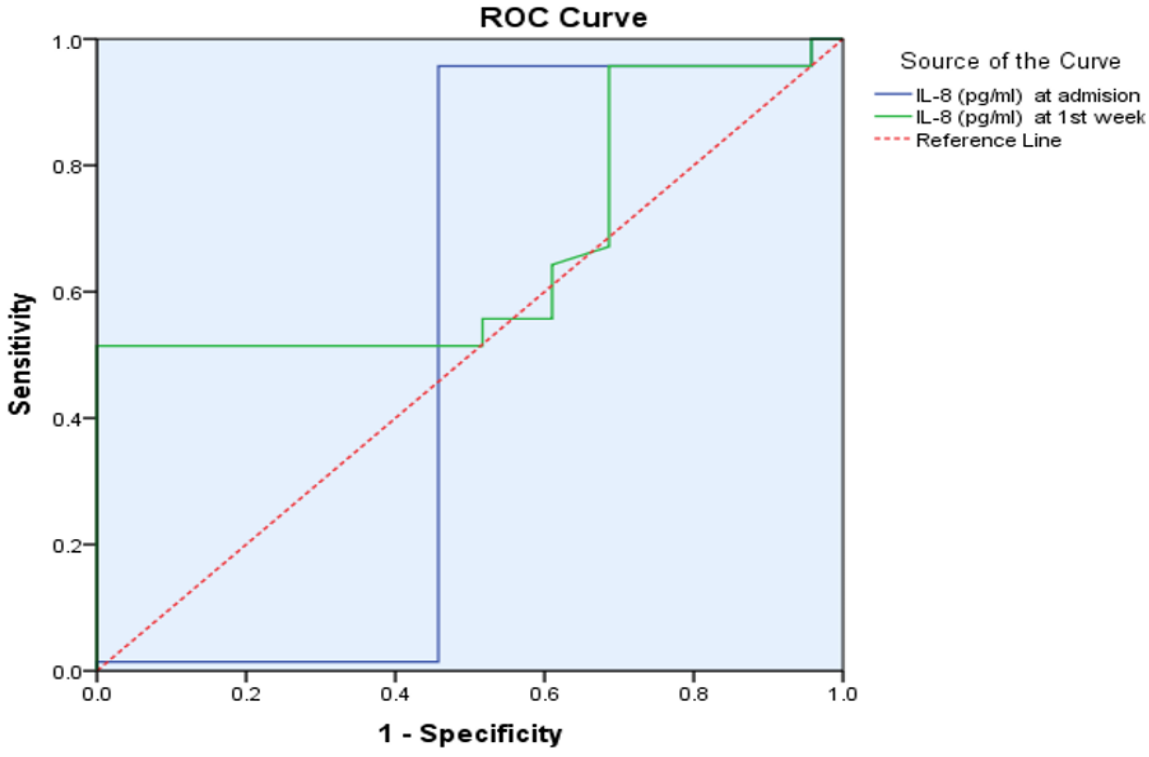

Figure 3b. ROC curve of IL-8 levels as a predictor of mortality in patients.

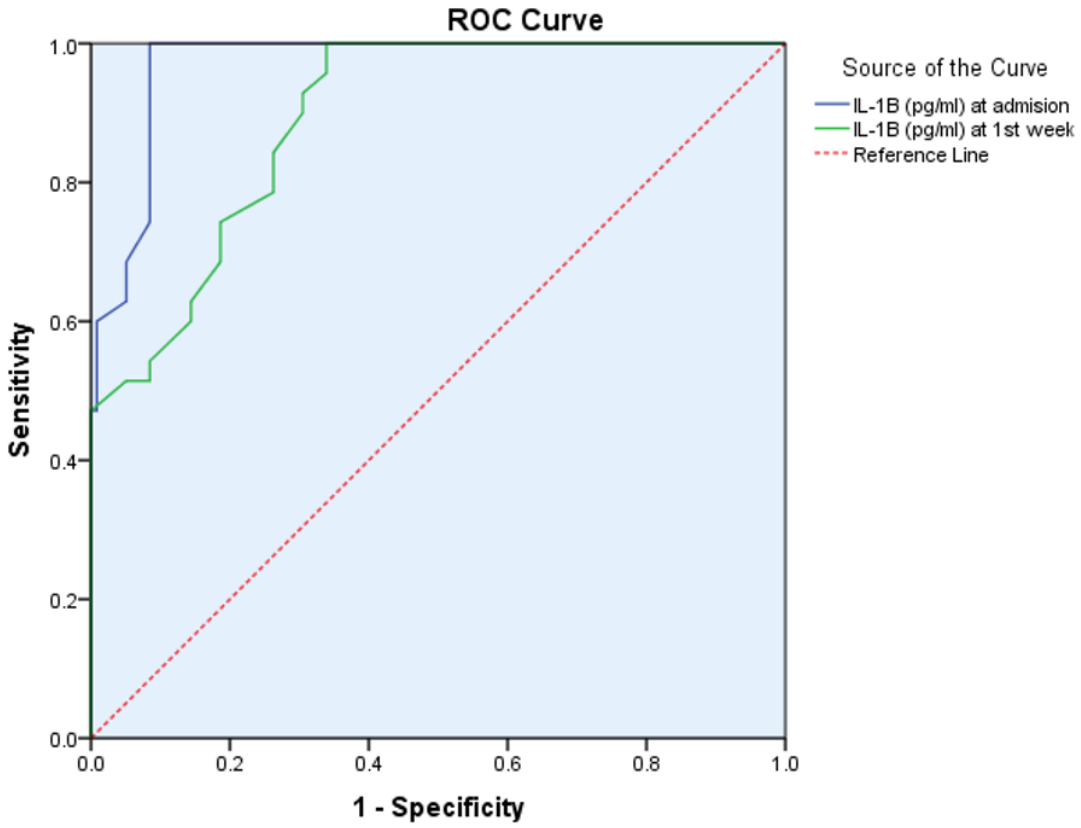

Figure 3c. ROC curve of IL-1B levels as a predictor of mortality in patients.

Regarding survivor patients, the IL-6, IL-8 and IL-1B showed highly significant decrease in the 1st week compared to admission (P<0.001). Also, regarding dead patients IL-6, IL-8 and IL-1B showed significant decrease in the 1st week compared to admission (P<0.001), (Table 6).

	Paired Differences			Paire t test	P value
	Mean difference ± SD	95% Confidence Interval of the Difference			
		Lower	Upper		
Survivor patients					
IL-6 at admission Vs at 1st week	21.36 ± 16.01	17.54	25.17	11.163	<0.001*
IL-8 at admission Vs at 1st week	39.11 ± 35.44	30.66	47.56	9.234	<0.001*
IL-IB at admission Vs at 1st week	6.17 ± 3.14	5.42	6.92	16.424	<0.001*
Dead patients					
IL-6 at admission Vs at 1st week	47.70 ± 17.38	44.53	50.87	29.815	<0.001*
IL-8 at admission Vs at 1st week	72.98 ± 67.82	60.62	85.35	11.689	<0.001*
IL-IB at admission Vs at 1st week	20.28 ± 13.49	17.82	22.74	16.332	<0.001*

Mean Platelet Volume (MPV), Platelet-to-Creatinine Ratio (PCR), Standard deviation (SD) * Significant for P value <0.05.
Table 6. Mean change of the studied biomarkers among survivors and dead patients.

In the current study, there was a significant strong positive correlation between the IL-6, IL-8 and IL-1B levels with age of the studied patients, body mass index, APACHE II score, SOFA score (p<0.001), all these parameters were significantly positive correlation between each pair, as shown in Figure 4.

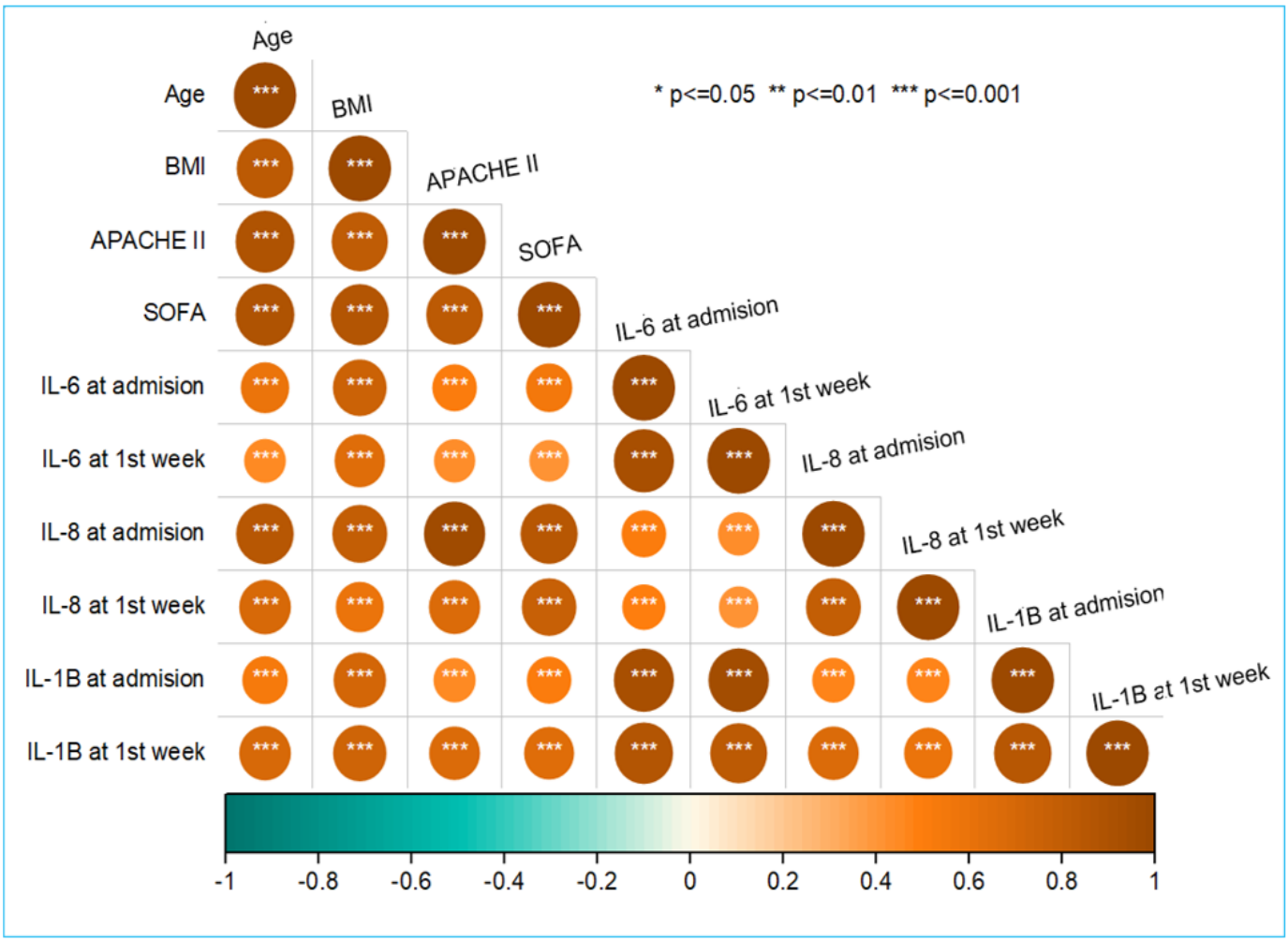

Figure 4. Correlation between the studied biomarkers and variables among the studied patients.

Discussion

Severe respiratory failure remains a leading cause of mortality among adult patients admitted to intensive care units (ICUs), despite advances in ventilatory support and critical care management [8]. Early and accurate prediction of mortality risk is essential for timely clinical decision-making, individualized treatment strategies, and optimal allocation of limited ICU resources [9-11]. Identifying high-risk patients at an earlier stage may facilitate prompt escalation of care, improve monitoring strategies, and support evidence-based discussions with patients' families. Furthermore, the findings may contribute to improved risk stratification models, guide future research on biomarker-driven interventions, and ultimately enhance patient outcomes in critical care settings [9]. In the current study, IL-6, IL-1B at (admission and 1st week) and IL-8 at 1st week were statistically significant lower in survivor patients than in dead patients. In the current study, there was a significant strong positive correlation between the IL-6, IL-8 and IL-1B levels with age of the studied patients, body mass index, APACHE II score, SOFA score. As for, the ROC curve analysis showed that the cutoff point of biomarkers as a predictor of mortality in patients, IL-6 at 1st week was 59.00, with sensitivity of 99.5%, specificity of 88.1% at AUC 1.00, followed by IL-1B at 1st week at the cutoff points of 55.50, with sensitivity of 98.7%, specifically of 90.7% at AUC 0.97, as compared to. IL-8 at 1st week at cutoff value 229.50, with sensitivity of 95.7%, specifically of 89.8% at AUC 0.67.

Another study by [10] concluded that Values of IL-6, IL-1RA, IL-8, Ang-2, and S1PR3 were significantly higher on day 0 compared to day 7. There was no significant difference between levels of MIF and IL-1B on days 0 and 7. From eight biologically relevant biomarker candidates, six demonstrated an enhanced capacity to predict mortality at day 0. Latent-class analysis identified two biomarker-based phenotypes. Phenotype A exhibited significantly higher plasma levels of angiopoietin-2, macrophage migration inhibitory

factor, interleukin-8, interleukin-1 receptor antagonist, interleukin-6, and extracellular nicotinamide phosphoribosyl transferase (eNAMPT) compared to phenotype B. Mortality at 28 days was significantly higher for phenotype A compared to phenotype B (32% vs 19%, p = 0.04).

Studies exploring the byproducts of acute dysregulation of various cellular pathways have generated more than 45 potential biomarkers. However, no single biomarker or clinical variable has demonstrated adequate prognostic or predictive ability to identify sub-phenotypes of ARDS [12]. The ability to stratify ARDS patients by pathobiology and likelihood of treatment response would greatly enrich future clinical trials and enhance the ability to detect a treatment effect .Sub-phenotyping/endotyping has been successfully accomplished in airways diseases such as asthma and COPD with important therapeutic implications and may exist within severe sepsis [13] However, there is a paucity of data elucidating ARDS sub-phenotypes/endotypes.

Recent studies utilizing two ARDS cohorts identified two ARDS sub-phenotypes that markedly differed in natural history, clinical and biological characteristics, biomarker profiles, response to positive end-expiratory pressure (PEEP), and ventilator- and organ failure free days and in mortality [14]. The hyperinflammatory ARDS sub-phenotype is characterized by a higher prevalence of sepsis and severe shock, high plasma levels of inflammatory biomarkers (IL-6, IL-8, etc.), greater vasopressor use, and metabolic acidosis [15]. In contrast, the low inflammatory ARDS sub-phenotype exhibited less severe inflammation and shock. Surprisingly, the level of ARDS severity (PaO2/FiO2 ratio), renal or hepatic injury severity, or leukocytosis level failed to distinguish these two phenotypes [16].

The hyperinflammatory phenotype was associated with higher mortality, fewer ventilator-free and organ failure-free days and altered responses to ventilator strategies when compared to the low inflammatory phenotype [17]. Importantly, no single clinical or biological variable was sufficient to identify the sub-phenotype including the severity of ARDS APACHE scores (PaO2/FiO2 ratio), severity of renal or hepatic failure, or leukocytosis, suggesting that phenotype membership was not merely a reflection of severity of illness as measured by traditional indices [18].

Conclusion

In the current study, an enhanced level of IL-6, IL-1B at and IL-8 was significantly associated with mortality patients. As for, the ROC curve analysis showed that the cutoff point of biomarkers as a predictor of mortality in patients, IL-6 at 1st week scored the best diagnostic tool for prediction of adult ICU patients with severe respiratory failure at level 59.00, with sensitivity of 99.5%, and specificity of 88.1% at AUC 1.00, followed by IL-1B at the cutoff points of 55.50, with sensitivity of 98.7%, specifically of 90.7% at AUC 0.97, as compared to IL-8 which scored lower sensitivity of 95.7%, and specifically of 89.8% at AUC 0.67.

Declaration

Consent for publication: All authors have read and revised the manuscript and agreed to its publication.

Availability of data and material: All data supporting the study are presented in the manuscript or available upon request.

Acknowledgments: Not applicable

Authors' information (optional): Not applicable

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