ORIGINAL ARTICLE

A Prospective Observational Study Comparing Oxygen Saturation/Fraction of Inspired Oxygen Ratio with Partial Pressure of Oxygen in Arterial Blood/Fraction of Inspired Oxygen Ratio among Critically Ill Patients Requiring Different Modes of Oxygen Supplementation in Intensive Care Unit

Rakesh Alur T[1], Shivakumar S Iyer[2], Jignesh N Shah[3], Sampada Kulkarni[4], Prashant Jedge[5], Vishwanath Patil[6]

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Abstract

Background: Intensive care unit (ICU) patients face a significant rise in mortality rates due to acute hypoxemic respiratory failure (AHRF). The diagnosis of AHRF is based on the PF ratio, but it has limitations in resource-constrained settings. Instead, the Kigali modification suggests using the oxygen saturation/fraction of inspired oxygen (SF) ratio. This study aims to correlate SF ratio and arterial oxygen pressure (PF) ratio in critically ill adults with hypoxemic respiratory failure, who required O_2 therapy through different modes of oxygen supplementation.

Materials and methods: In an ICU, a prospective observational study included 125 adult AHRF patients receiving oxygen therapy, with data collected on FiO_2, PaO_2, and SpO_2. The SF ratio and PF ratio were calculated, and their correlation was assessed using statistical analysis. The receiver operator characteristics (ROC) curve analysis was conducted to assess the diagnostic precision of the SF ratio in identifying AHRF.

Results: Data from a total of 250 samples were collected. The study showed a positive correlation ($r = 0.622$) between the SF ratio and the PF ratio. The SF threshold values of 252 and 321 were established for PF values of 200 and 300, respectively, featuring a sensitivity of 69% and specificity of 95%. Furthermore, it is worth noting that the PF ratio and SF ratio are interchangeable, regardless of the type of oxygen therapy, as the median values of both the PF ratio and SF ratio displayed statistical significance ($p < 0.01$) in both acidosis and alkalosis conditions.

Conclusion: For patients with AHRF, the noninvasive SF ratio can effectively serve as a substitute for the invasive PF ratio across all oxygen supplementation modes.

Keywords: Acute hypoxemic respiratory failure, Berlin criteria, Kigali modification, Oxygen saturation/fraction of inspired oxygen ratio.

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Highlights

This study highlights a positive correlation between the noninvasive SF ratio and the invasive PF ratio in critically ill adults with AHRF. This suggests that the SF ratio could serve as a reliable surrogate for the PF ratio, which is traditionally used for diagnosing ARDS and also correlates well in both acidosis and alkalosis.

Introduction

Respiratory failure, resulting from various diseases, is a more prevalent and severe condition that requires admission to the intensive care unit (ICU). It can be classified into two types: Hypoxemic respiratory failure [arterial oxygen levels (PaO_2) below 60 mm Hg] and hypercapnic respiratory failure ($PaCO_2 > 45$ mm Hg). Oxygen therapy is the mainstay treatment for acute hypoxemic respiratory failure (AHRF) due to its association with improved outcomes. Continuous monitoring of oxygen levels using pulse oximetry is commonly utilized in patients receiving oxygen therapy.[1]

A substantial drop in arterial oxygen levels is a characteristic of acute respiratory distress syndrome (ARDS), a severe kind of hypoxemic respiratory failure.[2] ARDS carries higher rates of both morbidity and mortality, with figures ranging between 30 and 45%.[2,3] Acute lung injury (ALI) and ARDS are diagnosed using parameters such as the PaO_2/FiO_2 ratio (PF ratio), which has thresholds of less than 300 for ALI and less than 200 for ARDS.[4] The Berlin criteria, established in 2012, provide a comprehensive diagnostic framework for ARDS, incorporating clinical presentation, positive end-expiratory pressure (PEEP) of at least 5 cm H_2O in conjunction with PF ratio, and chest X-ray findings. These criteria also help stratify the severity of ARDS based on specific PF ratio thresholds.[5]

[1–6]Department of Critical Care Medicine, Bharati Vidyapeeth (Deemed to be University) Medical College, Pune, Maharashtra, India

Corresponding Author: Shivakumar S Iyer, Department of Critical Care Medicine, Bharati Vidyapeeth (Deemed to be University) Medical College, Pune, Maharashtra, India, Phone: +91 9822051719, e-mail: shivkumar.iyer@bharatividyapeeth.edu

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The utility of the Berlin definition is constrained in resource-limited environments because of the absence of mechanical ventilators, arterial blood gas testing, and chest radiography.[6,7] This can lead to an underestimation of the ARDS burden and hinder proper treatment.[8] The significance of PEEP in delineating ARDS is a subject of ongoing debate.[4,8]

In low-income countries such as Rwanda, the Kigali modification of the Berlin criteria has been proposed, eliminating the need for PEEP and utilizing a hypoxia cut-off based on SpO_2/FiO_2 (SF ratio) $\leq$315.[9] However, there is limited studies comparing the SF ratio with the PF ratio in critically ill adults with AHRF receiving various oxygen therapy modalities, with variable cut-off for SF ratio from 181 to 285 mm Hg and 235–323 mm Hg for PF ratio of 200 and 300 respectively, most studies used on the pediatric population.[10–14]

The objective of this study is to establish the relationship between the SF and PF ratios in critically ill adults experiencing AHRF. Furthermore, the study seeks to advocate for the adoption of the SF ratio as a viable substitute for the PF ratio in diagnosing AHRF, regardless of the method of oxygen administration, and in the presence of both acidosis and alkalosis.

Materials and Methods

Study Design and Setting

In the ICU, this prospective observational study was carried out from September 2021 to January 2022. The study has been approved ethically by the Institutional Ethics Committee and is listed in the Clinical Trials Registry – India (CTRI/2021/09/036210). From all participants, informed, written consent was obtained.

Inclusion and Exclusion Criteria

Adult patients with AHRF who were admitted to the ICU and needed oxygen therapy using both invasive and noninvasive ventilation (NIV) using fixed and variable oxygen delivery devices comprised the study population. Patients with a history of chronic lung disease, refractory shock (>1 vasopressors), severe hypothermia, anemia (hemoglobin <7 gm/dL), carbon monoxide poisoning, methemoglobinemia, and pregnant patients were excluded.

Sample Size

Based on the findings of correlation coefficient of 0.66 between the PF and SF ratios from Sheetal Babu et al.[12] using G*power software, assuming an effect size of 0.5, α error of 5, and 80% power, the required sample size was 135.[15]

Data Collection

At admission and during deterioration or within 24 hours, measurements of FiO_2, PaO_2, and SpO_2 were obtained and documented in a designed pro forma; SpO_2 was recorded using a Nihon Kohden multipara monitor. An ABL 800 FLEX blood gas analyzer was used to analyze arterial blood gas. Because the oxyhemoglobin dissociation curve is flat, above 97%, values above 97% were excluded, and SpO_2 values between 85 and 97% were taken into consideration for analysis. Alkalosis was defined as pH above 7.40, while acidosis was defined as pH below 7.40. For variable flow oxygen delivery devices, FiO_2 was calculated using the formula $FiO_2 = 20\% + (4 \times \text{oxygen liter flow})$.

Statistical Analysis

Data analysis was conducted using the statistical package for social sciences (SPSS, version 22.0, IBM Inc., Chicago, USA). Numbers, percentages, means [standard deviations (SDs)], and medians (interquartile ranges) were used to depict descriptive data. The groups were compared using the independent *t*-test and the Chi-square test. To measure sensitivity and specificity, a receiver operator characteristics (ROC) curve was created, and the area under the curve (AUC) was computed. Correlation was found using linear regression. A significance level of $p < 0.05$ was deemed statistically significant.

Table 1: Baseline characteristics of the study population

Parameters	*Number of patients (N = 125)*
Age, years, mean (SD)	54.3 (16.7)
Age-groups, years	
<30	13 (10.4)
31–50	37 (29.6)
>50	75 (60.0)
Sex	
Men	86 (68.8)
Women	39 (31.2)
Comorbidities	*n* = 89
CKD	7 (5.6)
DM	83 (66.4)
HTN	89 (71.2)
CAD	20 (16.0)
CVA	6 (4.8)
Mode of oxygen therapy	
Invasive mechanical ventilation	63 (50.4)
Noninvasive oxygen therapy	62 (49.6)
Nasal prongs	6 (4.8)
Oxygen mask	13 (10.4)
Venturi mask	10 (8.0)
NRBM	2 (1.6)
HFNC	10 (8.0)
NIV	21 (16.8)

Data presented as *n* (%), unless otherwise specified. CAD, coronary artery disease; CKD, chronic kidney disease; CVA, cerebrovascular accident; CVD; cardiovascular disease; DM, diabetes mellitus; HFNC, high-flow nasal cannula; HTN, hypertension; NIV, noninvasive ventilation; NRBM, nonrebreather mask

Results

A total of 125 patients with a mean age of 54.3 years and a male predominance (68.8%) were included in the study. The majority of the patients had comorbidities such as hypertension (71.2%) and diabetes mellitus (66.4%). Most patients received invasive mechanical ventilation (50.4%) and noninvasive oxygen therapy (49.6%). Of the NIV, the majority had (NIV, $n = 21$) followed by oxygen mask ($n = 13$), venturi mask ($n = 10$), high-flow nasal cannula ($n = 10$), nasal prongs ($n = 6$), and nonrebreather mask ($n = 2$) (Table 1). Table 2 represents the median SF ratio and PF ratio at admission (188 and 183.3, respectively) and at 24 hours (235 and 241, respectively). The median values of FiO_2, PaO_2, SpO_2, PF ratio, and SF ratio at admission and at 24 hours were comparable in patients receiving invasive and those receiving noninvasive oxygen therapy ($p > 0.05$).

Table 2: Respiratory investigations at admission and 24 hours

Respiratory investigations	*At admission*	*At 24 hours**
FiO_2, mm Hg	0.5 (0.4–0.6)	0.4 (0.5–0.5)
SpO_2, %	95.0 (94.0–96.0)	96.0 (94–96)
PaO_2, mm Hg	82.0 (67.0–117.0)	77.0 (120)
SF ratio	188.0 (156.6–235.0)	235.0 (184–308)
PF ratio	183.3 (116.5–240.6)	241.0 (163.4–314.6)

*At 24 hours or at deterioration whichever is earlier. Data presented as median (interquartile range). FiO_2, fraction of inspired oxygen; PaO_2, partial pressure of oxygen in arterial blood; PF, PaO_2/FiO_2; SF, SpO_2/FiO_2; SpO_2, arterial oxygen saturation

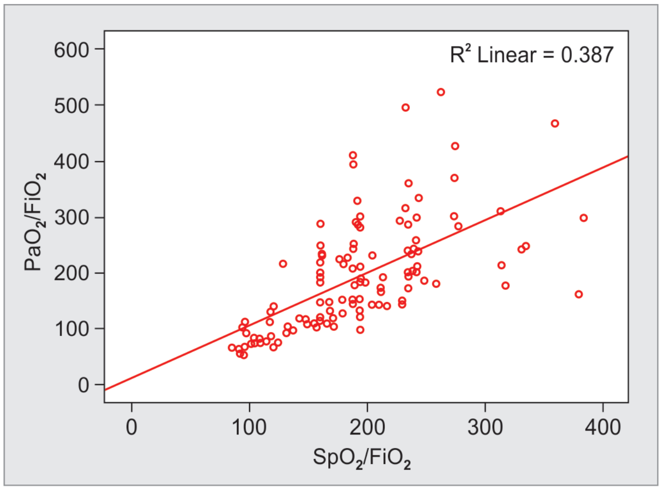

Fig. 1: Correlation between the SF and PF ratios

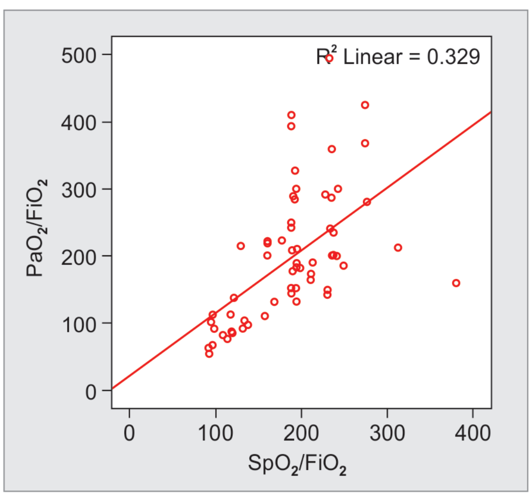

Fig. 2: Correlation between the SF and PF ratios in invasive ventilation

Patients admitted with acidosis and alkalosis did not differ significantly from one another in terms of median FiO_2, PaO_2, SpO_2, PF ratio, and SF ratio ($p > 0.05$) at 24 hours. The SF and PF ratios are significantly correlated ($r = 0.622$, $p < 0.01$), as shown in Figure 1. A significant correlation between the SF and PF ratios in patients receiving invasive mode of ventilation ($r = 0.574$) as illustrated in Figure 2 and in those with noninvasive mode of oxygen therapy ($r = 0.687$) as illustrated in Figure 3 ($p < 0.001$). On parallel lines,

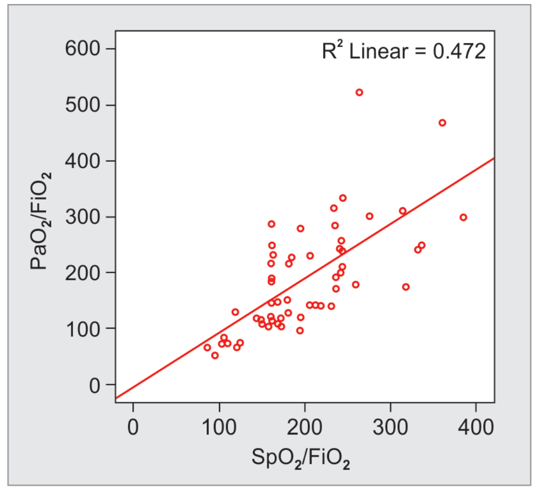

Fig. 3: Correlation between SF ratio and PF ratio in NIV

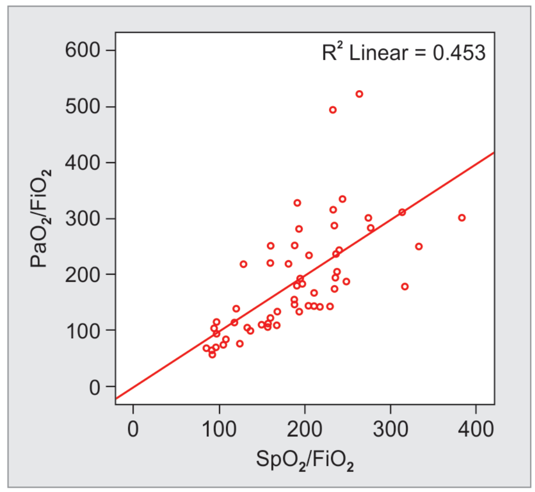

Fig. 4: Correlation between the SF and PF ratios in patients with acidosis

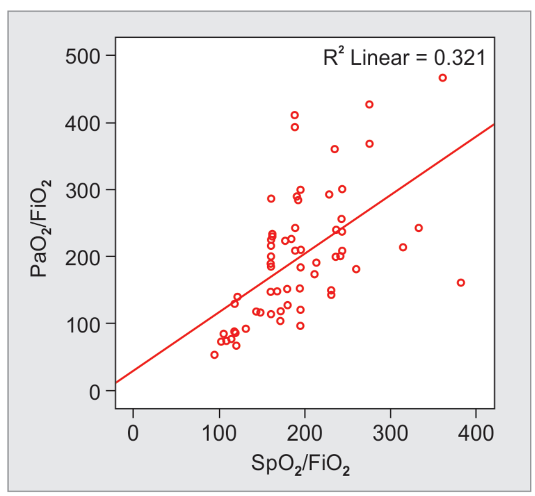

Fig. 5: Correlation between the SF and PF ratios in patients with alkalosis

Figures 4 and 5 demonstrate a significant correlation ($p < 0.001$) between the SF and PF ratios in patients with acidosis ($r = 0.673$) and alkalosis ($r = 0.567$), respectively.

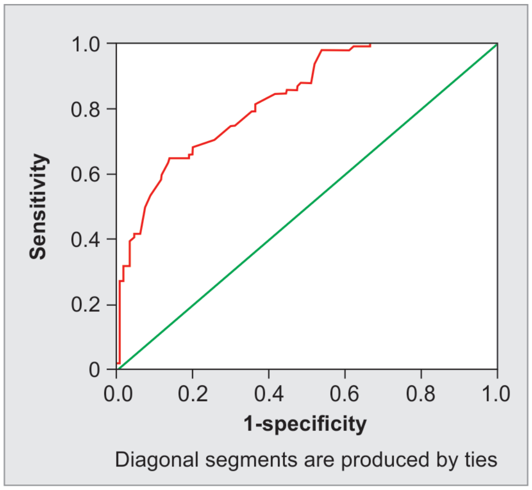

Fig. 6: The ROC curve of the SF ratio at PF above 200

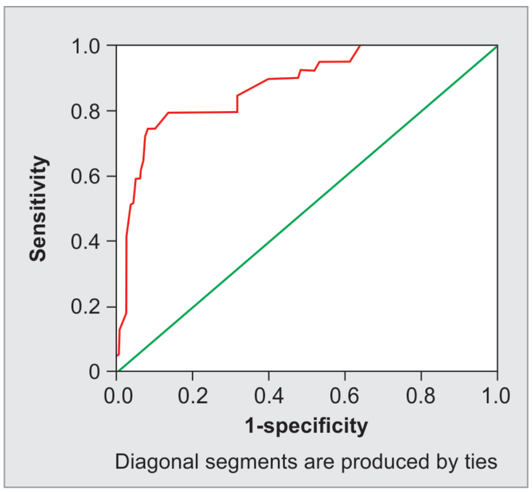

Fig. 7: The ROC curve of the SF ratio at PF above 300

As shown in Figure 6, ROC curve analysis showed that an SF ratio of 252 correlated with a PF ratio of 200, yielding a 68.9% sensitivity and a 95% specificity. As seen in Figure 7, an SF ratio of 321 also correlated with a PF ratio of 300, indicating a 97.5% specificity and 69.8% sensitivity. The AUC values for PF ratio above 200 and PF ratio above 300 were 0.831 and 0.877, respectively.

Discussion

Respiratory failure is a frequent cause of patients being admitted to the ICU. Additionally, disorders of acid-base balance can cause severe complications and become life threatening in various diseases. Detecting it as early as possible and providing suitable treatment is crucial to prevent complications and death. To assess the severity of early respiratory failure without invasive procedures, calculating the SF ratio was considered. Thus, our study aimed to explore the hypothesis that the noninvasive SF ratio could offer advantages compared to the PF ratio. The key findings of the present study were (A) a higher proportion of patients were in the age-group above 60 years; (B) male predominance; (C) comorbidities, hypertension, and diabetes mellitus were observed in the majority of patients; (D) median respiratory investigations such as FiO_2 (0.5 mm Hg vs 0.4 mm Hg), SpO_2 (95.0% vs 96.0%), PaO_2 (82.0 mm Hg vs 77.0 mm Hg), SF ratio (188.0 vs 235.0), and PF ratio (183.3 vs 241.0) at admission and 24 hours; (E) a significant correlation between SF ratio and PF ratio in the overall population, in patients invasive and noninvasive mode of oxygen therapy, in patients with alkalosis and acidosis; (F) the ROC curve analysis of SF ratio at PF ratio above 200 and at PF ratio above 300.

About 40% of the participants in this study were older than 60 years. Among the participants, 68.8% were men. Similar findings were reported in other studies. Another study conducted by Catoire P et al. observed a median age of 60 years and 48.9% men among 395 participants.[16] Sheetal Babu et al. found that 62% of participants were men, with the majority falling within the 40–60 age range.[12] In a study conducted in the USA, Pandharipande P et al. found that participants' mean age was 50.8 years, with 41% of them being women.[17]

In our study, 71.2% of patients with respiratory failure had hypertension, and 66.4% had diabetes mellitus.

In the current study, median respiratory investigations like FiO_2 (0.5 mm Hg vs 0.4 mm Hg), SpO_2 (95.0%) PaO_2 (82.0 mm Hg), SF ratio (188.0), and PF ratio (183.3) at admission. No significant difference in respiratory investigations was observed across invasive and noninvasive modes of oxygen therapy. Similar findings were reported by Sheetal Babu et al., where the median SpO_2 value was 99% and the median PaO_2 value was 82 mmHg. The PF and SF ratios had median values of 256 and 312, respectively ($p > 0.05$).[12]

In our study, a significant correlation was identified between the SF ratio and PF ratio ($r = 0.622$). This favorable association was also reported in other studies ($r > 0.6$, $p < 0.05$).[9,10,12,15] The SF ratio threshold values for PF ratio of 200 and 300, respectively, in different studies, were as follows: In our study, 252 and 321; in Sheetal Babu et al., 285 and 323; in Rice TW et al., 235 and 315; in Catoire P et al., 370 and 450 at PF ratio of 300 and 400; in Nemat Bilan et al., 181 and 235; in Tripathi et al., 235 and 310; and in Khemani et al., 201 and 263.[10,12–14,16,18]

An SF ratio of 252 in our current study correlated with a PF ratio of 200, indicating a 68.9% sensitivity and a 95% specificity, according to ROC curve analysis. Moreover, an SF ratio of 235 had 85% sensitivity and 85% specificity, whereas an SF ratio of 315 had 91% sensitivity and 56% specificity for ARDS prediction, according to a different study conducted by Rice et al.[13] In a study conducted by Pierre Catoire et al., the areas under the ROC curves for the SF ratio were 0.918 (CI 95%: 0.885–0.950) and 0.901 (CI 95%: 0.872–0.930) for PF ratio thresholds of 300 and 400 mmHg, respectively.[16] A SF ratio threshold of 350 had a positive predictive value (PPV) of 0.88 (CI 95%: 0.84–0.91) for PF ratio lower than 300 mm Hg, whereas a threshold of 470 had a negative predictive value (NPV) of 0.89 (CI 95%: 0.75–0.96) for PF ratio lower than 400 mm Hg. In a study conducted by Tripathi et al., the SF ratio was found to be a trustworthy substitute for the PF ratio in surgical patients ($r = 0.46$), particularly in those who needed PEEP levels higher than 9 cm H_2O ($r = 0.68$) and those who had a PF ratio of ≤ 300 ($r = 0.61$).[14]

Riviello ED et al.[9] conducted a study utilizing the modified Berlin definition, referred to as Kigali, and employing different cut-off values for the SF ratio. The findings indicated that 4.0% of hospital admissions met the criteria for ARDS, with infection being the predominant risk factor. The median age of ARDS patients was 37 years, and only 30.9% were admitted to an ICU, with a hospital mortality rate of 50.0%. The study concluded that the Berlin definition likely underestimates the impact of ARDS in low-income countries, emphasizing the need for validation of the Kigali modification before widespread use.[9]

The newly proposed diagnostic criteria for ARDS, known as the Matthay modification, include the SF ratio ≤315 as an oxygenation criterion to define ARDS, which correlates closely to our study; additionally, the criteria involve a PEEP/continuous positive airway pressure (CPAP) of ≥5 cm H_2O or high-flow nasal cannula (HFNC) ≥30 L/min, and the presence of opacities in two quadrants (bilateral or unilateral) on chest radiograph or the use of lung ultrasonography to diagnose opacities.[9,19]

A study conducted by Sonali Vadi showed the oxygenation index and oxygen saturation index are good indicators for oxygenation, thus noninvasively monitored SpO_2 can be considered a surrogate to PaO_2 in monitoring continuously in mechanically ventilated patients.[20]

Limitations

This study has some limitations, including a limited focus on a single center and a small sample size that may restrict the generalizability of the findings. The relatively short study duration and observational design prevent the establishment of causal relationships. Furthermore, while the study suggests the utility of the Kigali modification in ARDS diagnosis, its applicability necessitates further validation in diverse healthcare settings to ensure broader relevance and reliability.

Conclusion

In summary, this study offers significant insights into the potential utility of the SF ratio as a substitute for the PF ratio in the diagnosis of AHRF in adults who are critically ill. The findings reveal a significant positive correlation between the SF ratio and PF ratio, supporting the feasibility of using the SF ratio for AHRF diagnosis. Significantly, the study illustrates that the SF ratio and PF ratio can be employed interchangeably in diverse oxygen therapy modalities, as well as in acidosis and alkalosis. Our study findings underscore the potential utility of the noninvasive SF ratio, especially in resource-constrained settings, offering a valuable tool for clinicians in the early identification of AHRF in critically ill patients.

Authors' Contributions

Conceptualization: SSI, JNS. Data curation: RA, PJ. Formal analysis: RA, JNS. Methodology: SSI, JNS. Project administration: VP. Visualization: SK, VP. Writing – original draft: RA. Writing – review & editing: RA, SSI, JNS.

Orcid

Rakesh Alur T https://orcid.org/0009-0009-4538-5630
Shivakumar S Iyer https://orcid.org/0000-0001-5814-2691
Jignesh N Shah https://orcid.org/0000-0002-8812-8791
Sampada Kulkarni https://orcid.org/0000-0002-1445-747X
Prashant Jedge https://orcid.org/0000-0002-9655-159X
Vishwanath Patil https://orcid.org/0000-0002-0103-2210

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