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Original Article

A modified screening protocol for ARDS in patients with respiratory support based on SpO_2 and FiO_2: A single-center prospective, observational study

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ABSTRACT

Background: The purpose is to formulate a modified screening protocol for acute respiratory distress syndrome (ARDS) in patients with respiratory support based on saturation of pulse oximetry (SpO_2) and inspired oxygen concentration (FiO_2).

Methods: This prospective observational study was conducted from August to October 2020 at the Department of Critical Care Medicine of Yijishan Hospital Affiliated with Wannan Medical College. All patients admitted during the study period and required arterial blood gas analysis and electrocardiogram monitoring were included in this study. Patients with contraindications to arterial puncture, methemoglobinemia, carbon monoxide poisoning, and other factors that could affect data collection were excluded. The demographic and clinical data, immediate percutaneous SpO_2, FiO_2, arterial oxygen partial pressure (PaO_2), and respiratory rate were recorded; and the SpO_2/FiO_2 ratio (SFR) and PaO_2/FiO_2 ratio (PFR) values were calculated according to the above information. The patients were divided into two cohorts by random number table: the establishment cohort and the verification cohort. In the established part, data were divided into group H and group N according to whether SpO_2 >97 %. For group H (SpO_2 ≤97 %), the regression equation was established between SFR and PFR. For group N (SpO_2 >97 %), the correlation between each observation data and PFR was analyzed. Then, a new diagnostic process was established, and the reliability was verified with the Berlin definition set as the gold standard for diagnosis and classification.

Results: There were 341 patients were included. Among them, 161 patients were used to establish the model, and 180 patients were used to verify the validity of the model. In this new diagnosis progress, when SpO_2 ≤97 %, if SFR ≤352, ARDS may exist; when SpO_2 >97 %, if FiO_{2min} >39 %, there may be ARDS. The sensitivity, specificity, negative predictive value, positive predictive value, and accuracy of the new diagnosis progress for ARDS were 91.1 %, 76.7 %, 89.6 %, 79.6 %, and 83.9 %, respectively.

Conclusion: The SpO_2/FiO_2 ratio demonstrates notable sensitivity and specificity in diagnosing ARDS, presenting as a credible alternative to PFR.

Trail Registration Chinese Clinical Trial Registry Identifier: ChiCTR2000029217

Introduction

Acute respiratory distress syndrome (ARDS), which is a devastating clinical syndrome with an associated mortality rate of more than 40 %,[1] can be caused by various etiologies. In the LUNG SAFE study, the largest international cohort of patients with ARDS, two-thirds of the patients had a delayed or missed diagnosis of ARDS, even though ARDS is a common fatal disease.[2] In light of the absence of comprehensive and readily applicable methodologies for the identification of ARDS, the implementation of efficacious treatments, such as protective mechanical ventilation, fluid management strategies, and prone positioning, has not been fully realized. The arterial oxygen partial pressure (PaO_2)/ inspired oxygen concentration (FiO_2)

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ratio (PFR) is central to understanding, describing, and treating ARDS. The PFR is used not only in the definition of ARDS but also to grade the severity of ARDS.[3]

In the absence of significant progress in the recognition and treatment of ARDS, arterial blood gas (ABG) analysis is required to assess the PFR of a patient. However, patients who are not suspected to have ARDS may not undergo ABG examination, and frequent blood gas monitoring is questionable. In addition, Bellani et al.[4] confirmed that even when the PFR reached the standard, clinicians were still unable to recognize ARDS in a timely manner because ABG testing is too uncommon and is not continuous over the course of a day. In addition, some ARDS patients have contraindications to arterial puncture, and some institutions do not have the resources for blood gas analysis. Therefore, the development of approaches that enable more timely recognition has the potential to save lives.

In 2017, Riviello et al.[5] proposed that a saturation of pulse oximetry (SpO_2)/FiO_2 ratio (SFR) ≤315 can be used as the oxygenation standard under resource constraints. The latest global definition of ARDS also mentions the use of SFR instead of PFR in the diagnosis of ARDS when SpO_2 ≤97 %.[6,7] However, in clinical practice, maintaining SpO_2 >97 % in non-ARDS patients is more common. Therefore, failure to promptly recognize ARDS may result in poor outcomes associated with elevated SpO_2 targets.[4] At the same time, it is difficult to identify ARDS early when SpO_2 is >97 % in patients with non-pulmonary conditions requiring oxygen therapy. In particular, high-flow nasal cannula oxygen therapy (HFNC) is currently widely used as an effective therapy to support acute respiratory failure in patients with ARDS, such as those with coronavirus disease 2019.[8,9] Studies have shown that clinicians should focus on the severity of lung injury in patients who require high levels of oxygen support, suggesting that the diagnosis of ARDS should not depend on the presence of an endotracheal tube or positive-pressure ventilation in adults.[10] Recently, Matthay et al.[11] recommended that the Berlin definition of ARDS be broadened to include patients treated with HFNO (at least 30 L/min) who fulfill the other criteria for the Berlin definition of ARDS and proposed that this would be an improvement for patients with lung injury who require high levels of oxygen support. In this case, from an epidemiological perspective, the inclusion of such patients would more comprehensively identify individuals with ARDS at an earlier stage and would include more patients in resource-limited settings, as recommended by the Kigali modification of the Berlin definition of ARDS. Therefore, the purpose of this study was to explore the potential value of the SFR as a new diagnostic tool for ARDS by establishing a new process in patients who require high levels of oxygen support.

Methods

Study design and study population

This is a prospective observational study that was conducted at the Department of Critical Care Medicine, Yijishan Hospital Affiliated with Wannan Medical College from August to October 2020. The study was approved by the First Affiliated Hospital of Wannan Medical College and participating institutional ethics committees (approval number: 2019–97). Arterial blood samples and vital sign monitoring are part of the standard treatment for patients. The requirement for written informed consent was waived by the Institutional Review Board (IRB). This clinical trial was registered in the Chinese Clinical Trial Registry (ChiCTR2000029217) by Weihua Lu on 19 January 2020, which was prior to patient enrollment.

All patients admitted during the study period and required for ABG analysis and ECG monitoring were included in this study. Patients with contraindications to arterial puncture, methemoglobinemia, carbon monoxide poisoning, and other factors that could affect data collection were excluded.

All arterial blood samples were analyzed using a blood gas analyzer (Danish Raydu ABL800 FLEX,Shanghai Langyi Medical Equipment Co., LTD, China) within 1 min after blood collection, and a monitor (China Mindray iPM-12) was used to record the SpO_2 and vital sign data immediately after blood collection. To ensure the accuracy of the data, a blood oxygen saturation sensor was placed on a clean thumb; the blood oxygen saturation waveform was stable; and there was no posture change or sputum suction procedure for at least 10 min before the measurement.

Previous literature indicates an intensive care unit (ICU) hypoxemia incidence of approximately 53 %.[12] Based on preliminary trial data showing a 75 % hypoxemia incidence, according to the sample size of the non-inferiority test between the single-group rate and the baseline rate, the sample size was calculated as 46 cases. Sample size calculations justified our cohort size.

Data collection

The demographic and clinical data of the included patients were collected, such as sex, age, etc. Immediate SpO_2, FiO_2, PaO_2, and respiratory rate (RR) were recorded; and the SFR and PFR values were calculated according to the above information.

Statistical analysis

All normally distributed measurement data are represented as mean±standard deviation, non-normally distributed count data are represented as the median (interquartile range), and count data are represented as the number (%). The specific statistical methods are as follows. P values <0.05 are statistically significant.

Establishment of the new diagnostic tool

The enrolled patients were divided into the model establishment cohort and the model verification cohort by random number table. The patients of the model establishment cohort were divided into group H and group N according to whether SpO_2 >97 %. For group H (SpO_2 ≤97 %), a regression equation was established to describe the relationship between the SFR and PFR and was used to calculate the value of the SFR when the PFR was 300. For group N (SpO_2 >97 %), Pearson correlation analysis was used to explore the correlation between each observed variable and the PFR, and the valueable index was chosen. Receiver operating characteristic (ROC) analysis was used to assess the diagnostic value of the index. Finally, the SFR and index were used to establish a new diagnostic process for ARDS.

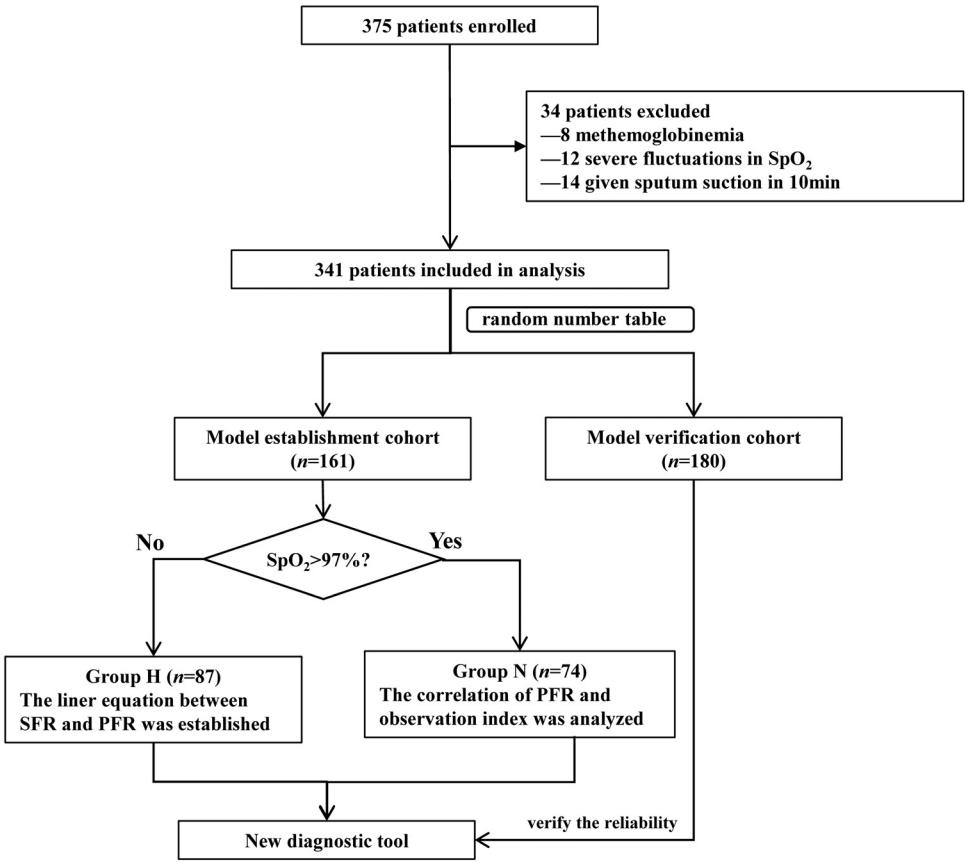

Figure 1. Flow chart of the experiment.
FiO_2: Inspired oxygen concentration; PaO_2: arterial oxygen partial pressure; PFR: PaO_2/FiO_2 ratio; SFR: SpO_2/FiO_2 ratio; SpO_2: Saturation of pulse oximetry.

Verification of the reliability of the new diagnostic tool

The patients of the model verification cohort were collected to verify the reliability of the diagnostic tool. The Berlin definition was used as the gold standard to diagnose or exclude ARDS. According to the Berlin definition grading standard, the corresponding SFR values were calculated with PFRs of 100, 200, and 300 as the cut-off values.The negative predictive value (NPV), positive predictive value (PPV), accuracy, sensitivity, and specificity of the new method were calculated to verify the accuracy of the new method.

Results

Of the 375 patients enrolled in this study during the study period, 34 were excluded due to inaccurate data collection. Finally, 341 patients, comprising 160 males (46.9 %) and 181 females (53.1 %), were included in this study. The patients were randomly divided into two cohorts (Figure 1). The basic information on the research objects is shown in Table 1.

Establishment of a new diagnostic process

Ultimately, there were 87 patients with SpO_2 ≤97 % in group H. Because the data were not normally distributed, Spearman correlation analysis was used to evaluate the correlation between the SFR and PFR. The SFR and PFR were found to have a strong positive correlation (r=0.873, P <0.001).

Table 1
Characteristics of patients (n=341).

Characteristics	Data
Sex	
Male	160 (46.9)
Female	181 (53.1)
Mean body weight (kg)	57 ± 10
Age (years)*	48 (19–78)
Potential risk factors	
pneumonia	45 (13.2)
Non-pneumonia sepsis	66 (19.4)
pancreatitis	35 (10.3)
Severe trauma†	138 (40.5)
Other‡	57 (16.7)
Respiratory support modes	
None	10 (2.9)
Nasal catheter	41 (12.0)
High-flow nasal oxygen	55 (16.1)
Non-invasive ventilator	79 (23.2)
Invasive ventilator	156 (45.8)
Mean PaO_2 (mmHg)	93.8 (35.4–230.0)
Mean SpO_2 (mmHg)	94.8 (63.0–100.0)
Mean PFR	226.6 (48.9–540.0)
Mean SFR	226.4 (73.8–456.0)

Data were expressed as mean±standard deviation, median (interquartile range), and n (%).
FiO_2: Inspired oxygen concentration; PaO_2: Arterial oxygen partial pressure; PFR: PaO_2/FiO_2 ratio; SFR: SpO_2/FiO_2 ratio; SpO_2: Saturation of pulse oximetry.
* Data were expressed as median (rang).
† Severe trauma: including major surgery, high-risk surgery, multiple injuries.
‡ Other: including massive blood transfusion, drug overdose, ischemia-reperfusion injury, etc.

Linear regression between the SFR and PFR was performed, which indicated that there was a strong linear relationship between the SFR and PFR (r=0.873, P <0.0001). The linear regression equation is as follows:

$$PFR = 0.9162 \times SFR - 21.39$$

The linear relationship diagram is shown in Figure 2.

There were 74 patients with SpO_2 >97 % in group N. Correlation analysis showed that only FiO_2 and the PFR had a significant negative correlation (r=−0.521, P <0.0001). A ROC curve was used to investigate the value of FiO_2 in the diagnosis of ARDS. The area under the curve (AUC) of FiO_2 for diagnosing ARDS was 0.694 (95 % CI: 0.571 to 0.817, P <0.005). The best cut-off value of FiO_2 was 39 %, the sensitivity was 0.838, and the specificity was 0.545. The ROC curve is shown in Figure 3.

Based on the above results, we set up a new diagnostic process as follows (Figure 4): when a patient is suspected to have ARDS and has an SpO_2 ≤97 %, the SFR is calculated according to the formula SFR=SpO_2/FiO_2; an SFR is ≤352 may indicate ARDS. An SpO_2 is >97 % and the requirement for a high concentration of inhaled oxygen (i.e., FiO_{2min} >39 %) may be indicative of ARDS.

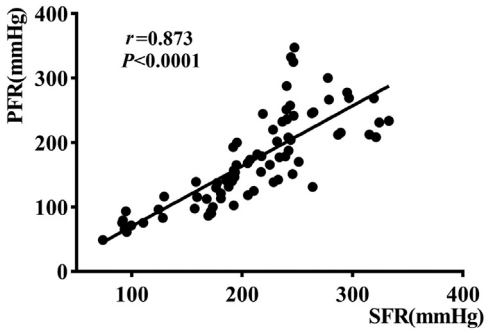

Figure 2. Linear relationship between the SFR and PFR in group H.
FiO_2: Inspired oxygen concentration; PaO_2: arterial oxygen partial pressure; PFR: PaO_2/FiO_2 ratio; SFR: SpO_2/FiO_2 ratio; SpO_2: Saturation of pulse oximetry.

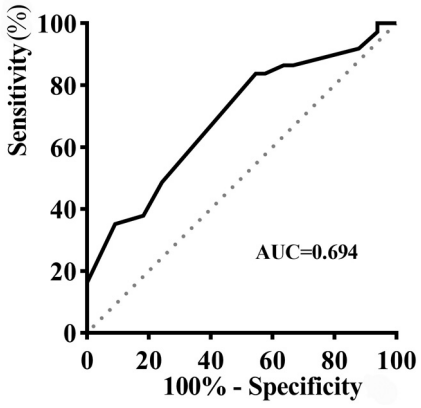

Figure 3. ROC curve of FiO_2 in diagnosing ARDS in patients with SpO_2 ≤97 %.
ARDS: Acute respiratory distress syndrome; ROC: Receiver operating characteristic.

Reliability of the new diagnostic method

Of the 180 patients in the verification group, there are 90 patients with a SpO_2 ≤97 %, and 90 patients with a SpO_2 >97 %. With the Berlin definition as the gold standard, the sensitivity, specificity, NPV, PPV, and accuracy of the new diagnostic tool were 91.1 %, 76.7 %, 89.6 %, 79.6 %, and 83.9 %, respectively.

According to the established linear regression equation (PFR=0.9162 × SFR−21.39), when the PFR is 300, the SFR is 352; when the PFR is 200, the SFR is 241; and when the PFR is 100, the SFR is 132. ROC curves were used to investigate the value of different SFR cut-off values in the diagnosis of ARDS. The three presented cut-off values demonstrated good specificity (98.5 %, 62.8 %, and 93.1 %, respectively) and sensitivity (61.1 %, 89.2 %, and 63.4 %, respectively). In addition, the PPVs

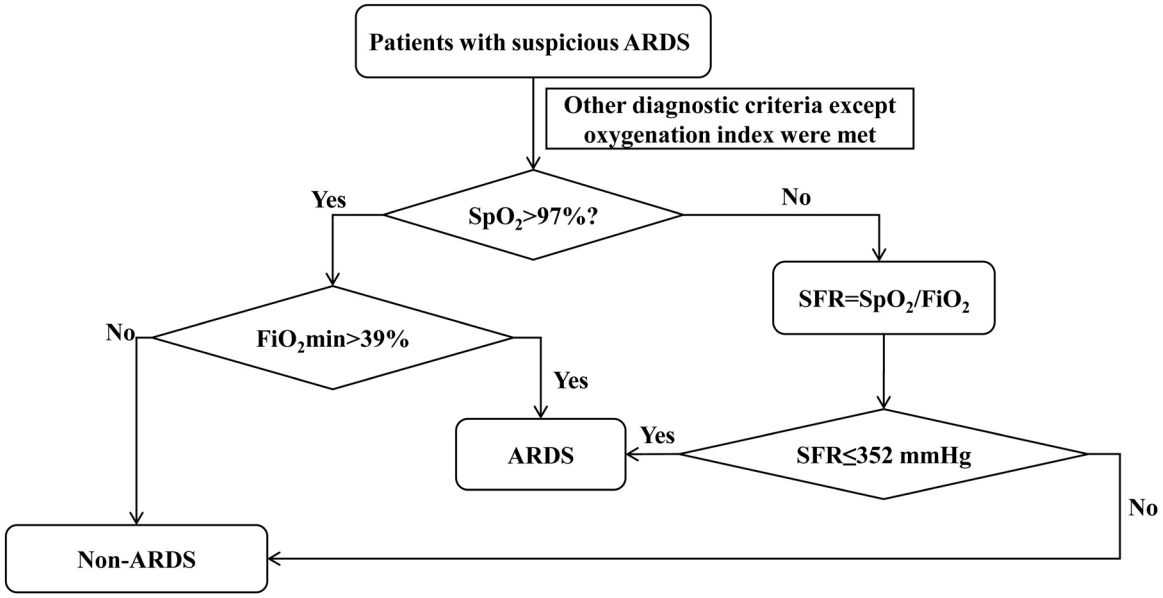

Figure 4. Flow chart of the new diagnostic tool for ARDS.
ARDS: Acute respiratory distress syndrome; FiO_2: Inspired oxygen concentration; SFR: SpO_2/FiO_2 ratio; SpO_2: Saturation of pulse oximetry.

Table 2
Use of the SFR for ARDS classification (SpO_2 ≤97 %, *n*=87).

SFR	Corresponding PFR	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	+LR	-LR
<132 (*n*=15)	<100	61.1	98.5	84.6	95.0	40.73*	0.39
<241 (*n*=55)	<200	89.2	62.8	74.2	83.0	2.39	0.17
<352 (*n*=17)	<300	63.4	93.1	82.5	83.3	9.18	0.04†

ARDS: Acute respiratory distress syndrome; FiO_2: Inspired oxygen concentration; -LR: Negative likelihood ratio; +LR: Positive likelihood ratio; NPV: Negative predictive value; PaO_2: Arterial oxygen partial pressure; PPV: Positive predictive value; PFR: PaO_2/FiO_2 ratio; SFR: SpO_2/FiO_2 ratio; SpO_2: Saturation of pulse oximetry.

* The likelihood of diagnosing ARDS is significantly increased when the +LR is >10.

† The likelihood of excluding ARDS is significantly increased when the -LR is <0.1.

and NPVs were also high. The use of the new method for ARDS classification is shown in Table 2.

Discussion

Our study reinforces the value of a non-invasive diagnostic tool that uses SpO_2 and FiO_2 for ARDS. We also set up a new diagnostic process based on SpO_2 and FiO_2. When a patient was suspected of having ARDS and had an SpO_2 ≤97 %, we calculated the SFR according to the formula SFR=SpO_2/FiO_2. An SFR ≤352 may indicate ARDS; an SpO_2 >97 % and the requirement for a high concentration of inhaled oxygen (i.e., FiO_{2min} >39 %) may be indicative of ARDS. Moreover, we verified the accuracy of the model and found that it has a very high sensitivity and specificity. Our findings could enable clinicians to recognize ARDS in a timely and accurate manner, especially in developing countries that lack sufficient medical resources given that saturation-based measurements can easily be obtained in relatively resource-poor settings.

The establishment of the Berlin definition in 2012 made the diagnosis and classification of ARDS more accurate and standardized.[13] The oxygenation index is one of the important factors in the diagnosis and treatment of ARDS, which is closely related to the prognosis of ARDS patients.[14] A large number of studies have confirmed the reliability of the oxygenation index, and the clinical treatment of ARDS patients depends on it.[15] However, repeated blood draws in the ICU environment may lead to iatrogenic anemia, a need for blood transfusions, an increased risk of infection, and an increase in hospital costs.[16] In addition, as mentioned earlier, many underdeveloped regions and countries may lack the conditions for ABG analysis. Therefore, a large number of recent studies[6,17,18] have confirmed that the SFR can be used to evaluate ARDS patients. For example, Kigali University Teaching Hospital proposed that if ABG analysis and chest X-ray are difficult to obtain, the SFR and lung ultrasound can be used as a substitute in the diagnosis of ARDS.[19]Therefore, the latest global definition of ARDS emphasizes the importance of SFR in diagnosing ARDS.[7]However, this new definition ignores the difficulty of diagnosing ARDS patients who use devices to maintain oxygen saturation >97 %. In clinical practice, to correct hypoxemia, it is tempting to use HFNO, non-invasive ventilators, and other oxygen therapy devices to provide high inhaled oxygen concentrations to maintain an adequate oxygen supply. However, this new diagnostic tool effectively addresses the difficulty of diagnosing patients with ARDS who have an oxygen therapy device that maintains their SpO_2 >97 %.

This study confirmed that there is a strong significant correlation between the SFR and PFR (r=0.873, P <0.0001), which means that these non-invasive methods can be used to estimate PaO_2 and the oxygenation index in clinical work. This finding is similar to the results of DesPrez et al.[17] They proposed that the SFR can be used as a substitute for the PFR, provide non-invasive prognostic information, and be used to assess the severity of ARDS. The linear regression equation of the relationship between the SFR and PFR calculated in this study is PFR=0.9162 × SFR−21.39, which has a higher correlation coefficient, demonstrating that the formula in this study may be more in line with the linear relationship between the SFR and PFR than other formulas. Moreover, the oxygenation index calculated by this formula may be more accurate. When SpO_2 was >97 %, statistical analysis showed that FiO_2 was significantly correlated with the PFR (r=−0.521, P <0.0001). In clinical applications, a blood oxygen saturation value is within the normal range due to an excessively high inspired oxygen concentration may indicate ARDS.[20]

The oxygen dissociation curve[21] shows that the curve drawn by the arterial blood oxygen saturation with the change in the arterial blood oxygen partial pressure is divided into three sections: upper, middle, and lower. The curve is steep in the middle and lower sections, and SaO_2 changes considerably with PaO_2, which is conducive to the release of oxygen from hemoglobin for tissue utilization. Therefore, when the data are separated at an SpO_2 ≤97 % for linear regression, the correlation between SaO_2 and PaO_2 is higher than before. For SpO_2 is >97 %, the PFR calculated by the linear formula is not accurate. Statistical analysis revealed a significant correlation between FiO_2 and the PFR at this point when FiO_2 was >39 % (r=−0.521, P <0.0001). The sensitivity of FiO_2 for diagnosing ARDS is high, which is conducive to early identification of ARDS. In their early research, Rice et al.[22] explored the relationship between SpO_2 and PaO_2, and their conclusions were similar to those of this experiment; however, they analyzed only the data at which SpO_2 was ≤97 %. In the discussion, they pointed out that in the oxygen dissociation curve, the slope of SpO_2 and PaO_2 in the saturated state is almost zero, and a large change in PaO_2 may cause little or no change in SpO_2. Therefore, patients' data with high oxygen saturation would be excluded. However, in clinical work, patients who rely on high-concentration oxygen support may already have ARDS, even though the monitor indicates that their blood oxygen saturation is normal.[23] In this case, if such patients are not identified and treated early, their condition may deteriorate. In our research, a minimum FiO_2 (SpO_2 >97 %) >39 % indicates that the patient may have early ARDS. The re-

sults of this study are of great importance to prevent missing the occurrence and development of ARDS. Based on our research results, a flow chart was drawn to illustrate the rapid diagnostic tool for high-risk patients (Figure 4). With Berlin's definition as the gold standard for diagnosis, the new diagnostic process has high sensitivity and specificity, indicating that the new tool is suitable for early recognition of ARDS. However, a study with a large sample from multiple centers is still needed for further verification.

However, it is worth mentioning that not all patients are suitable for assessment using this method. For example, in cases of carbon monoxide poisoning, methemoglobinemia, and peripheral circulatory failure, it may not be possible to use finger pulse oximetry to monitor blood oxygen saturation, and blood gas analysis is the only way to rule out such conditions.[24] The transcutaneous blood oxygen saturation method transmits two wavelengths of light (usually 660 mm and 940 mm) through the tissue to measure the absorbance change at each wavelength over time. The absorption of light by the tissue is cyclic, which is caused by the circulation and the resulting pulsation of arterial blood into the tissue bed. However, Carboxyhemoglobin (COHb) and oxyhemoglobin (OxyHb) have similar absorption characteristics at 660 mm. Therefore, SpO_2 in patients with carbon monoxide poisoning or peripheral circulatory failure is not an accurate measurement of O_2Hb.[25] A recent observational study also confirmed that in patients using venovenous-extracorporeal membrane oxygenation (VV-ECMO), transcutaneous oxygen saturation is not an ideal oxygenation test. Due to the increase in COHb levels, the reliability of the method is reduced as the VV-ECMO support time increases.[26] This situation can also be seen in long-term smokers. Early studies have confirmed that the COHb content in the blood of long-term smokers is increased by 15 %.[27] A recent study showed that carboxyhemoglobin saturation (SpCO) baseline levels are significantly higher in long-term smokers than in non-smokers.[28] Under these circumstances, only blood gas analysis and percutaneous carbon monoxide analysis can comprehensively assess the patient's true oxygenation situation.

Moreover, the new procedure should not obscure the need to exclude left heart failure or primary lung disease (such as autoimmune disease or acute eosinophilic pneumonia). The expanded definition will enable the diagnosis of ARDS to be more widely applicable and help to identify patients in the early stages of the syndrome as well as patients with severe clinical lung injury who are already receiving high levels of oxygen support. The implementation of the new process may improve clinical practice and clinical outcomes of patients.

There are some shortcomings in this study. First, it is a single-center observational study with a small sample size, so the new diagnostic tool needs to be verified by a multicenter study with a large sample size. In addition, we explored the linear relationship between the SFR and PFR without considering the influence of other factors, such as pH and CO_2, on the oxygen dissociation curve. This is because the purpose of this study is to explore the general relationship between the SFR and PFR so that a diagnostic tool can be used even when the values of confounders are unknown. Similarly, we did not conduct separate studies on different ventilation modes, such as positive end-expiratory pressure (PEEP). Finally, this study only verified the efficacy of this new diagnostic tool and did not explore its correlation with the prognosis of ARDS patients, which could be explored in later studies.

Conclusions

The measurement of SpO_2 and FiO_2 was performed as well as PFR in the diagnosis of ARDS and grading of disease severity while avoiding the need for invasive ABG monitoring. Continuous monitoring of SpO_2 and FiO_2 may help clinicians to identify ARDS in a timely and accurate manner.

CRediT Authorship Contribution Statement

Weihua Lu was responsible for the conceptualization of the study and the revision and approval of this manuscript. **Qiancheng Xu** and **Yan Xia** participated in the design and drafted the manuscript. **Zhiyuan Guo** and **Huijuan Zhang** collected the data and were responsible for its accuracy. **Yingya Cao**, **Yupeng Qi**, and **Qun Chen** helped to revise the manuscript. All authors contributed to the data analysis and interpretation.

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Ethics Statement

The study was approved by the First Affiliated Hospital of Wannan Medical College and participating institution ethics committees (approval number: 2019-97).

Conflict of Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

The data used to support the findings of this study are available from the corresponding author upon reasonable request.

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