A New ARDS Early Noninvasive Screening Protocol： Potential Value of SpO_2 and FiO_2 as a Diagnostic Tool

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Research

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Abstract

Background: A large number of recent studies have confirmed that the pulse oximetric saturation (SpO_2)/fraction of inspired oxygen (FiO_2) ratio (SFR) correlate well with PaO_2/FiO_2 ratio (PFR). However, whether SFR can replace PFR for the diagnosis and evaluate the severity of ARDS patients is unclearly. The purpose of this study is to explore potential value of SFR as a new diagnostic tool for ARDS, and establish a diagnostic process.

Methods: 341 patients were included in this study, SFR and PFR values were recorded in the same time. 161 patients were used to establish the model, and 180 patients were used to verify the validity of the model. 161 groups of data were divide into hypoxic group (group H) and non-hypoxic group (group N) according to whether SpO_2 was greater than 97%. For group H, the regression equation was established to describe the relationship between SFR and PFR. and calculated the value of SFR when PFR is 300. For group N, the correlation between each observation data and PFR were analyzed. Receiver operating characteristic (ROC) curve analysis was used to determine the diagnostic value of the index. Finally, a new diagnostic process was established for ARDS based on these results, and the reliability was verified with Berlin definition set as the gold standard for diagnosis and classification.

Results: For group H the diagnostic linear equation is PFR = 0.9162*SFR-21.39 (R^2=0.66 , P<0.0001). After calculation, when PFR is 300, SFR is 352. For group N, There is a significant negative correlation between FiO_2 and PFR((R= -0.521,P<0.0001)). The AUC of using FiO_2 to diagnose ARDS was 0.694 (95%CI 0.571~0.817, P□0.005). When the cutoff value of FiO_2 was 39%, the sensitivity was 0.838 and the specificity was 0.545. Therefore, in this new diagnosis progress, when $SpO_2 \leq 97\%$, if SFR≤352, ARDS may exist; when SpO_2>97%, if FiO_2min>39%, there may be ARDS. The sensitivity, specificity, NPV, PPV, and accuracy of the new diagnosis progress for ARDS were 91.1%, 76.7%, 89.6%, 79.6%, and 83.9%, respectively.

Conclusions: There are potential value of SpO_2 and FiO_2 as a noninvasive diagnostic tool for ARDS.

Background

Acute respiratory distress syndrome (ARDS) is devastating clinical syndromes with associated mortality more than 40%[1], which can be caused by a variety of etiologies. Although ARDS is a common fatal disease, In the LUNG SAFE study, the largest international cohort of patients with ARDS, however, the diagnosis of ARDS was delayed or missed in two-thirds of patients, with the diagnosis missed entirely in 40% of patients[2]. In the absence of accurate identification of ARDS, effective ARDS treatment has not been fully applied, including protective mechanical ventilation, fluid restriction, and prone positioning. The P:F ratio is the center of understanding, describing, and treating ARDS. The PFR is not only used in the definition of ARDS, but also used to grade the severity of ARDS[3].

In the absence of significant progress in the recognition and treatment of ARDS, An arterial blood gas analysis is required to determine the P:F ratio of a patient, but patients who are not suspected of having ARDS may not undergo ABG examination, and frequent blood gas monitoring are also questioned, In addition, Bellani et al[4]. confirmed that even though the P:F ratio reached the standard, clinicians still could not recognize ARDS timely, due to ABG testing is too rare and discontinuous in one day, and parts of ARDS patients with contraindications of arterial puncture or in institutions without blood gas analysis conditions. Therefore, the development of approaches to enable more timely recognition has the potential to save lives. Recent studies have shown that it is of great significance to improve the early diagnosis of ARDS by using the universally accessible and continuously updated SaO_2/FiO_2 (S:F) ratio based on pulse peripheral oxygen saturation. especially in resource constrained situations. Brown et al.[5, 6] used the method of non-linear calculation to obtain accurate P:F ratio in ARDS patients based on the S:F ratio. However, the inclusion criteria for SpO_2 in this study was less than 96%, but, $SpO_2 \leq 96\%$ at the time of enrollment will result in patients who use ventilator or oxygen therapy often not being includes. And, previous studies have also shown that for patients with $SpO_2 > 97\%$, there may still be an early lung risk. If ignored, it may cause the disease to worsen[4]. At the same time, It is difficult to identify ARDS early when $SpO_2 > 96\%$ in patients with non-pulmonary causes of oxygen therapy. Therefore, The purpose of this study is to explore potential value of SFR ratio as a new diagnostic tool for ARDS, and establish a diagnostic process. in this study, we found when $SpO_2 \leq 97\%$, if SFR ≤ 352, ARDS may exist; when $SpO_2 > 97\%$, if FiO_2min > 39%, there may be ARDS. The sensitivity, specificity, NPV, PPV, and accuracy of the new diagnosis progress for ARDS were 91.1%, 76.7%, 89.6%, 79.6%, and 83.9%, respectively.

Methods

Study Design and Study Population

This study is a prospective observational studies, and was conducted in Yijishan Hospital Affiliated to Wannan Medical College. This is an observational study, arterial blood samples and vital signs monitoring are parts of its standard treatment and the study was approved by the First Affiliated Hospital of Wannan Medical College and participating institution ethics committees (approval number: 2019-97).

The inclusion critera is that patients who are admitted to the Department of Critical Care Medicine in our hospital from August to October 2019 and require arterial blood gas analysis and ECG monitoring due to their condition. Patients with contraindications to arterial puncture, methemoglobinemia and other reasons that affect data collection are excluded. All the arterial blood samples were analyzed using the blood gas analyzer (Danish Raydu ABL800 FLEX)within one minute after the blood collection, and the monitor (China Mindray iPM-12) was used to record the SpO_2 and vital signs data immediately after the blood collection. To ensure the accuracy of the data, the blood oxygen saturation sensor is placed on a clean thumb; the blood oxygen saturation waveform is stable; there is no posture change or sputum suction operation at least 10 minutes before the measurement.

Data Collection

Demographic and clinical data of the included patients were collected: gender, age, etc. Immediate percutaneous peripheral blood oxygen saturation (SpO_2), inspired oxygen concentration (FiO_2), arterial oxygen partial pressure (PaO_2), respiratory rate (RR) were recorded , SpO_2/FiO_2 ratio (SFR) and PaO_2/FiO_2 ratio (PFR) values were calculated according to the above information.

Statistical Analysis

All normal distribution measurement data are represented by (`x±s), non-normal distribution count data are represented by median (P25, P75), and count data are represented by example(%).The two independent sample t test was used for the comparison between the normal distribution measurement data, the Mann-Whitney U test was used for the comparison between the nonnormal distribution measurement data, and the χ^2 test was used for the comparison between the count data. The test level is two-sided $\alpha=0.05$, $P<0.05$, which indicates that the difference is statistically significant.

Establishment of the New Diagnosis Tool: 341 patients were included in this study, SFR and PFR values recorded in the same time. 161 patients were used to establish the model, and 180 patients were used to verify the validity of the model. 161 groups of data were divide into hypoxic group (group H) and non-hypoxic group (group N) according to whether SpO_2 was greater than 97%. For group H, the regression equation was established to describe the relationship between SFR and PFR. and calculated the value of SFR when PFR is 300. For group N, the correlation between each observation data and PFR were analyzed and choose the value index. Receiver operating characteristic (ROC) curve analysis was used to determine the diagnostic value of the index. Finally, use SFR and the index to establish a new diagnostic process for ARDS. After determining the new diagnostic process, the Berlin definition is used as the gold standard to calculate the NPV, PPV, accuracy, sensitivity and specificity of the new diagnostic method.

Verify the Reliability of the New Diagnosis Tool: At the same time, another group of 180 ICU patients requiring blood gas analysis were collected to verify the reliability of the diagnosis tool. The Berlin definition is used as the gold standard to diagnose the presence or absence of ARDS. According to the Berlin definition grading standard, the corresponding SFR values were calculated with PFR of 100, 200 and 300 as the cutoff values, and the accuracy of the new method used for grading was verified.

Results

Of the 375 patients who needed arterial blood gas analysis in the Department of Intensive Care Medicine of our hospital, 34 were excluded due to their inaccurate data collection. Finally, there were 341 patients included in this study, including 160 males (46.9%) and 181 females (53.1%). The subjects were randomly divided into two cohort(Fig. 1). The basic information of the research objects is shown in Table 1.

Table 1
Characteristics of subjects

Characteristics	n = 341
Sex, n (%)	
Male	160(46.9)
Female	181(53.1)
Mean body weight (range), kg	57 ± 10.11
Age(range),years old	48(19–78)
Mean FiO_2 (range),%	45.7(20–100)
Mean PaO_2 (range), mmHg	93.84(35.4–230)
Mean SpO_2 (range), %	94.82(63–100)
Mean PFR (range)	226.57(48.9–540)
Mean SFR (range)	226.40(73.8–456)

Establishment of a New Diagnosis Process

1. Linear Equations Of Group H

1.1 The correlation between SFR and PFR Finally,there are 87 cases in group H. because the data is not normally distributed, Spearman correlation is used to evaluate the correlation between SFR and PFR. SFR and SFR have a strong positive correlation ($R^2 = 0.66$, $P < 0.001$),the results are shown in Table 2.

Table 2
Spearman correlation study table of SFR and PFR

	R^2	*P*	N
SFR & PFR	0.66	0.0001	87

1.2 Establishment Of Linear Regression

To further clarify the correlation between SFR and PFR. The Linear regression between SFR and PFR was performed. linear regression equation indicated that there is a strong linear relationship between SFR and PFR ($R^2 = 0.66$, $P < 0.0001$). the linear regression equation as fellows:

PFR = 0.9162*SFR − 21.39

The linear relationship diagram is shown in Fig. 2.

2. The correlation between FiO_2 and PFR in group N There are 74 cases in group N. All the SpO_2 more than 97%. correlation analysis shows than only the FiO_2 and PFR have a a significant negative correlation (R= -0.521,P < 0.0001). Next, receiver operation characteristic curve(ROC curve) was used to investigate the value of FiO_2 in diagnosis of ARDS,The AUC of using FiO_2 to diagnose ARDS was 0.694 (95%CI 0.571 ~ 0.817, P□0.005). the best cutoff value of FiO_2 was 39%, the sensitivity was 0.838 and the specificity was 0.545. The ROC curve is shown in Fig. 3.

3. Establish a New Diagnosis Tool Based on the above results, we set up a new diagnosis process as follows (Fig. 4): when a patients with suspicious ARDS, the $SpO_2 \leq 97\%$, calculate SFR according to the formula: $SFR = SpO_2/FiO_2$, if $SFR \leq 352$, ARDS may exist; when $SpO_2 > 97\%$, if high concentration inhaled oxygen is required, ie $FiO_{2min>}39\%$, ARDS may exist.

Reliability Of The New Diagnostic Method

A total of 180 patients in the intensive care medicine department of our hospital who needed arterial blood gas analysis due to their condition were included in the verification group, There are both 90 cases with $SpO_2 \leq 97\%$ and $SpO_2 > 97\%$. 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%.

The Utility Of Different Spo2/fio2 Cutoffs For Ards Prediction

According to the established linear regression equation (PFR = 0.9162*SFR − 21.39) ,when PFR is 300, SFR is 352, when PFR is 200, SFR is 241, and when PFR is 100, SFR is 132. ROC curves were used to investigate the value of different SFR cut-off value in diagnosis of ARDS, The 3 presented cutoffs demonstrated good specificity (98.5%, 62.8%, and 93.1%, respectively) and sensitivity (61.1%, 89.2%, and 63.4%, respectively). And the PPV and NPV were also high. The utility of the new method for ARDS classification was verified in Table 3.

Table 3
Utility of SFR for ARDS classification ($SpO_2 \leq 97\%$)

SFR	Sensitivity(%)	Specificity(%)	PPV(%)	NPV(%)	+LR,-LR
< 132	61.1	98.5	84.6	95	40.73[a],0.39
< 241	89.2	62.8	74.2	83	2.39,0.17
< 352	63.4	93.1	82.5	83.3	9.18,0.04[b]

[a]:The likelihood of diagnosing ARDS is significantly increased when the positive likelihood ratio is greater than 10. [b] The likelihood of excluding ARDS is significantly increased when the negative likelihood ratio is less than 0.1.

Discussion

Our study reinforce the value of using SpO_2 and FiO_2 as an noninvasive diagnostic tool for ARDS, We also set up a new diagnosis process base on SpO_2 and FiO_2, when a patients suspicious with ARDS, the $SpO_2 \leq 97\%$, calculate SFR according to the formula: $SFR = SpO_2/FiO_2$, if $SFR \leq 352$, ARDS may exist; when $SpO_2 > 97\%$, if high concentration inhaled oxygen is required, ie $FiO_2min > 39\%$, ARDS may exist. Meanwhile, We verified the accuracy of the model, The model has a very high sensitivity and specificity. Our finding could to enable clinicians to recognize ARDS timely and accurately, especially in developing countries which lacking sufficient medical resources. However, saturation-based measurements are easily available

in relatively resource-poor settings.

The establishment of the Berlin definition in 2012 made the diagnosis and classification of ARDS more accurate and standardized[7]. However, repeated blood draws in the ICU environment may lead to iatrogenic anemia, the need for blood transfusions, an increased risk of infection, and an increase in hospital costs[8]. In addition, as mentioned earlier, many underdeveloped regions and countries may lack the conditions for arterial blood gas. Therefore, a large number of recent studies[5, 9, 10] have confirmed that SFR can be used to evaluate ARDS patients. For example, in 2015 Kigali University Teaching Hospital proposed that if arterial blood gas and chest X-ray are difficult to achieve, SpO_2/FiO_2 ratio and lung ultrasound Can be used as a substitute for diagnosis of ARDS[11].

This study confirmed that there is a strong correlation between SFR and PFR, and it is statistically significant ($r = 0.873$, $P < 0.0001$),which means that this non-invasive methods can be used to estimate PaO_2 and oxygenation index in clinical work. This is similar to the results of Katherine DesPrez, BA[9]. They proposed that SFR can be used as a substitute for PFR and provide noninvasively prognostic information and assess the severity of ARDS. The linear regression equation of the relationship between SFR and PFR calculated in this study is PFR = 0.9162*SFR-21.39, which has a higher correlation

coefficient, which shows that the formula in this study may be more in line with the linear relationship between SFR and PFR. The oxygenation index calculated by this formula may be more accurate. When $SpO_2 > 97\%$, statistical analysis shows that FiO_2 is significantly correlated with PFR((R= -0.521,P < 0.0001)). In clinical applications,if the blood oxygen saturation is within the normal range due to the excessively high inspired oxygen concentration ,there maybe ARDS too[12].

In the oxygen dissociation curve[13], it can be seen that the curve drawn by the arterial blood oxygen saturation with the change of the arterial blood oxygen partial pressure is divided into three sections: upper, middle and lower. In the middle and lower part of the curve, the curve is steep, and SaO_2 changes greatly with PaO_2, which is conducive to hemoglobin releasing oxygen for tissue utilization. Therefore, separating the data with $SpO_2 \leq 96\%$ for linear regression, the correlation between the two is higher than before. In the upper part, the curve is flat, and SaO_2 changes little with PaO_2. Therefore, when $SpO_2 > 97\%$, the PFR calculated by the linear formula is not accurate. Through statistical analysis, there is a significant correlation between FiO_2 and PFR at this time. when FiO_2 more than 39%. The sensitivity of using FiO_2 to diagnose ARDS is high, which is conducive to the early warning of ARDS. In the early research of Rice TW et al.[14], they also explored the relationship between SpO_2 and PaO_2 and concluded that it is similar to this experiment, but they only analyzed the data of $SpO_2 \leq 97\%$. They pointed out in the discussion 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. So it excludes patients' data with high oxygen saturation. However, in clinical work, patients who rely on high concentration oxygen support,even though the monitor indicates that the blood oxygen saturation is normal, they may already have ARDS[15]. In this case, if they are not detected and treated early, which may cause illness deterioration. In our research, if the minimum FiO_2 ($SpO_2 > 97\%$) is greater than 39%, the patient may have early ARDS. The results of this study are of great significance to avoid ignoring the occurrence and development of ARDS. On the basis of the research results, a flow chart was drawn for the rapid diagnosis tool of high-risk patients (Fig. 3). Taking Berlin's definition as the gold standard for diagnosis, the diagnosis of the new diagnostic process has high sensitivity and specificity, indicating that the new diagnostic tool is suitable for early recognition of ARDS. However, a large sample of multiple centers is still needed for further verification.

However, it is worth mentioning that not all patients are suitable for condition assessment using this method. For example, in the case of carbon monoxide poisoning, peripheral circulatory failure, etc., it may not be possible to use finger pulse oxygen to monitor blood oxygen saturation, and blood gas analysis is the only way to rule out this disease[16].Transcutaneous blood oxygen saturation technology transmits two wavelengths of light (usually 660mm and 940mm) through the tissue to measure the absorbance change of each wavelength over time. The absorption of light by the tissue is cyclic, which is due to the circulation of the heart and the resulting pulsation of arterial blood into the tissue bed. However, COHb and O_2Hb have similar absorption characteristics at 660mm. Therefore, the percutaneous oxygen saturation (SpO_2) of patients with carb monoxide and peripheral circulatory failure must not be an

accurate measurement of O_2Hb[17]. A recent observational study also confirmed that in patients using VV-ECMO, transcutaneous oxygen saturation is a poor oxygenation test. Due to the increase in COHb levels, as the VV-ECMO support time increases, Its reliability is reduced[18].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 will increase by 15%[19]. Recent study has shown that carboxyhemoglobin saturation (SpCO) baseline levels are significantly higher in long-term smokers than in nonsmokers[20].Under these above circumstances, only blood gas analysis and percutaneous carbon monoxide analyzer can judge the patient's true oxygenation situation comprehensively.

There are some shortcomings in this study. First of all, it is a single-center observational study with a small sample size, so the new diagnostic tool needs to be verified by a multi-center large-sample study. In addition, we explored the linear relationship between SFR and PFR without considering the influence of other factors on the oxygen dissociation curve, such as pH, CO_2, etc..This is because the purpose of this study is to explore the general relationship between the two, so that diagnostic tools can be used even when these confounders are unknown. Similarly, we did not conduct separate studies on different ventilation modes, such as ventilation mode and PEEF,etc.. 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.

Conclusion

Measurement of the SpO_2 and FiO_2 performed as well as PaO_2 in diagnosis of ARDS and grade the severity, while avoiding invasive arterial blood gas monitoring. Meanwhile, Continuous monitor SpO_2 and FiO_2 could enable clinicians to recognize ARDS timely and accurately.

Supplementary information

Abbreviations

ARDS
acute respiratory distress syndrome; SFR = SpO2/fraction of inspired oxygen ratio; PFR = PaO2/fraction of inspired oxygen ratio

Declarations

Authors' contributions

W. Lu, the corresponding author, was responsible for the conceptualization of the study and the revision and approval of this manuscript.Q. Xu and Y. Xia participated in the design and drafted the manuscript. Z. Guo and H. Zhang collected data and were responsible for its accuracy.Y. Cao, P. Qi and Q. Chen helped to

revise the manuscript. All authors contributed to the data analysis and interpretation. All authors read and approved the final manuscript.

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Availability of data and materials

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

Ethics approval and consent to participate

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

Trial registration

ChiCTR.ChiCTR2000029217. Registered 19 January 2020-Retrospectively registered, http://www.chictr.org.cn/showproj.aspx?proj=43364

Consent for publication

All authors have approved the manuscript and its publication.

Competing interests

The authors have no competing interests.

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Figures

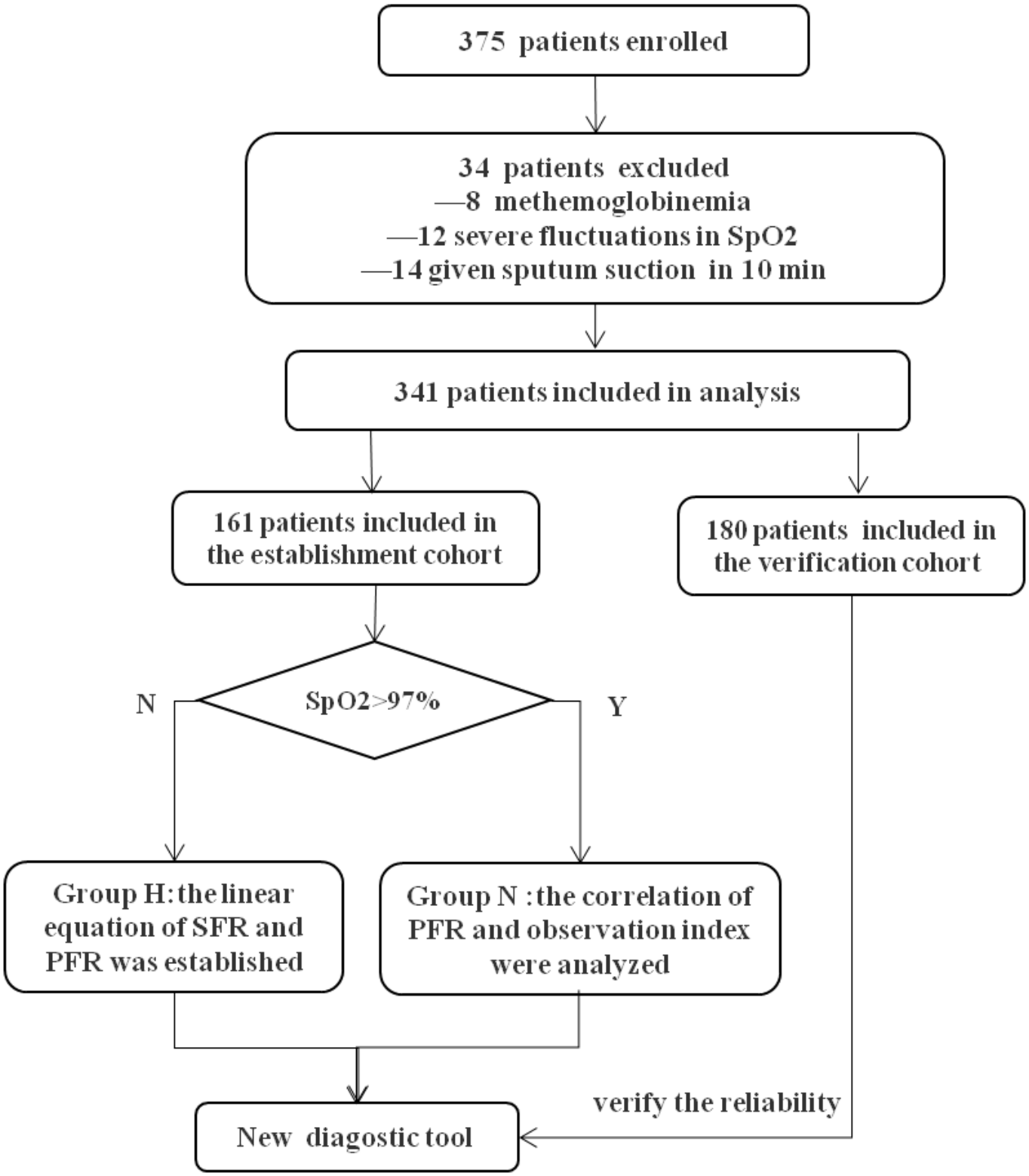

Figure 1

Flow chart of the experiment

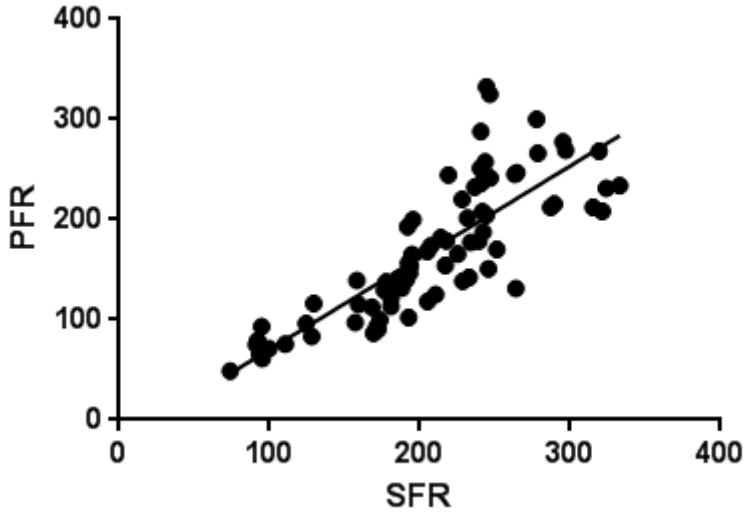

Figure 2

Linear relationship between SFR and PFR in group H (PFR= 0.9162*SFR-21.39, P< 0.0001, R2=0.66)

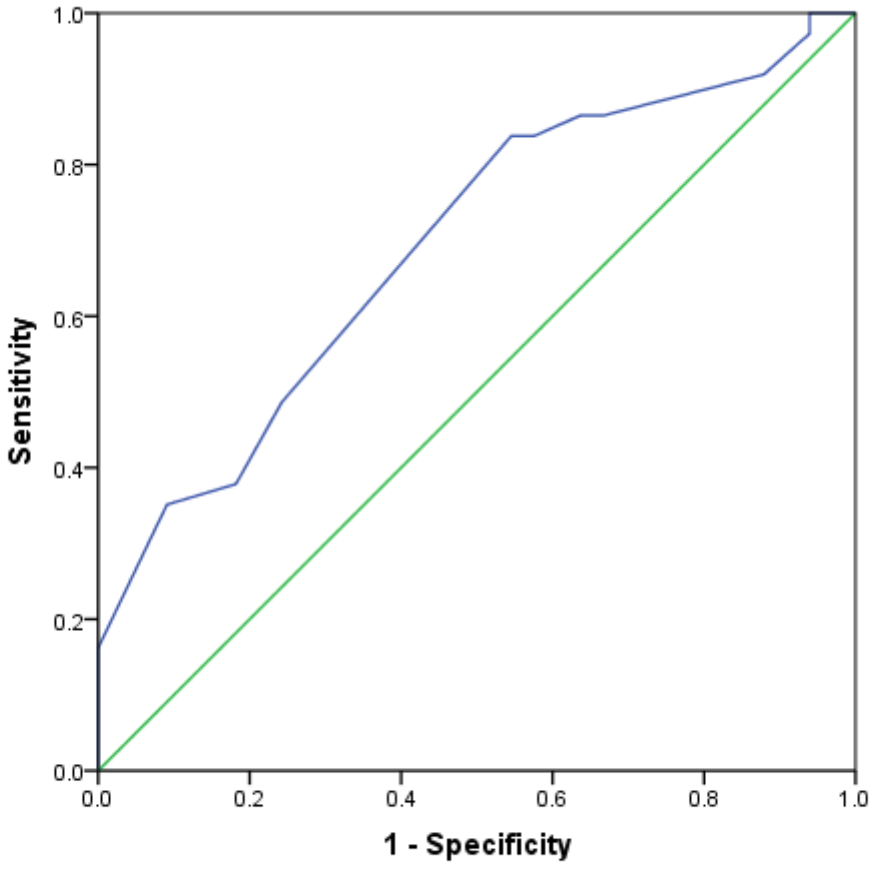

Figure 3

ROC curve of FiO2 in diagnosing ARDS (group N)

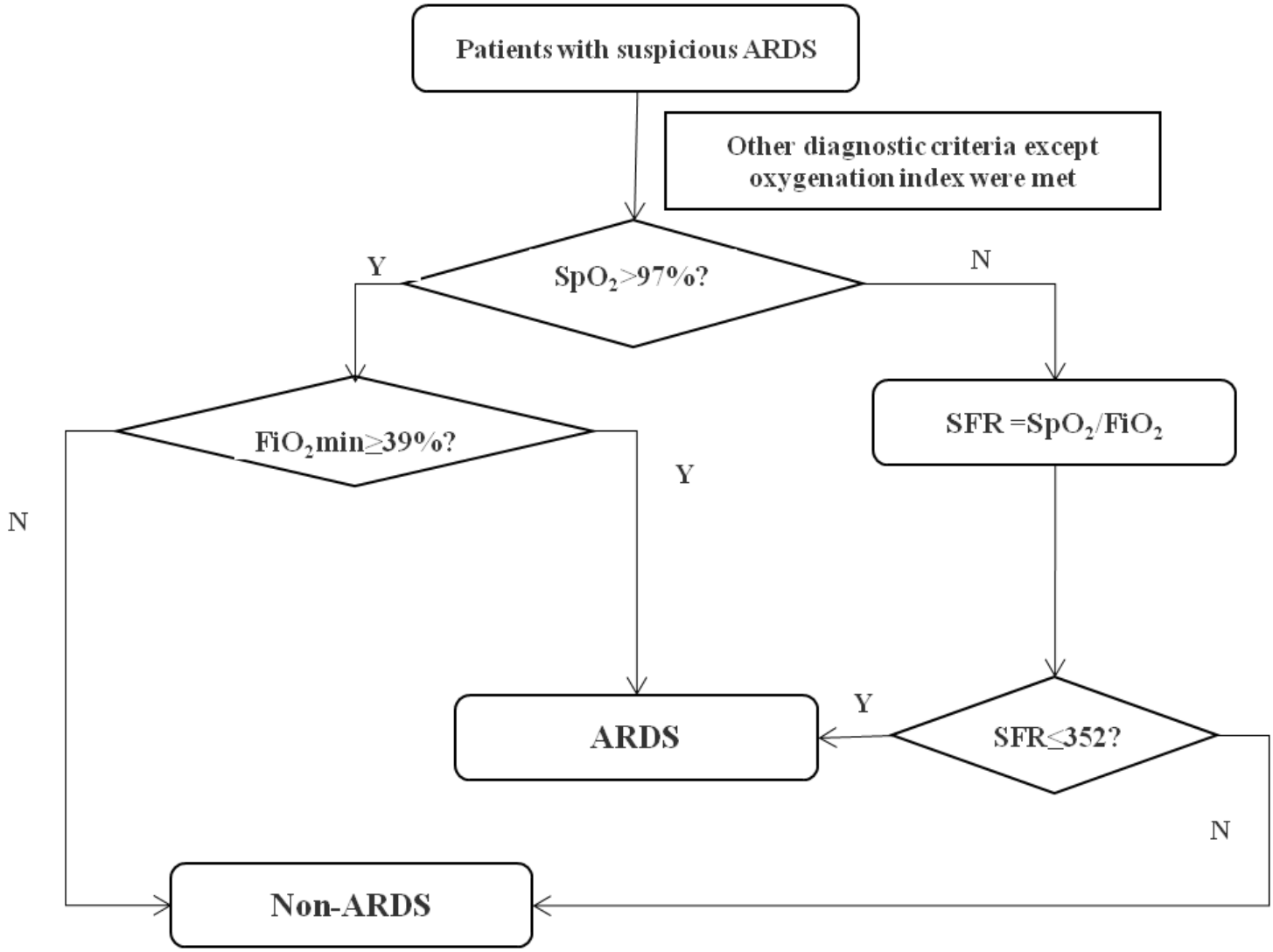

Figure 4

New Diagnostic Tool Chart of ARDS

Supplementary Files

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