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Оценка насыщения кислородом как показателя для интубации трахеи у пациентов с COVID-19: проспективное когортное исследование

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РЕЗЮМЕ

Введение. С началом пандемии COVID-19 возросла значимость клинических критериев для интубации трахеи у тяжелобольных пациентов с дыхательной недостаточностью, особенно в условиях ограниченных ресурсов.

Цель – оценить важность показателя насыщения гемоглобина кислородом как критерия для интубации трахеи у пациентов с COVID-19.

Материалы и методы. Многоцентровое проспективное обсервационное когортное исследование, включившее 117 пациентов с COVID-19, которые нуждались в респираторной поддержке в период с марта по июнь 2021 г. Пациенты были интубированы в соответствии с протоколом каждого участвовавшего в исследовании учреждения и клиническим заключением анестезиолога. Регистрировали признаки дыхательной недостаточности, методы респираторной поддержки и результаты лечения пациентов.

Результаты. Из 117 случаев у 100 пациентов насыщение гемоглобина кислородом составило 60–90%, 58 из них были интубированы. Во время госпитализации 56 интубированных пациентов и 14 неинтубированных пациентов умерли (96,6% против 33,3%).

Заключение. Насыщение гемоглобина артериальной крови кислородом в пределах 60–90% не может быть ключом к решению проблемы интубации у пациентов с COVID-19 и, следовательно, само по себе не может быть подходящим критерием для принятия решения об интубации.

Ключевые слова: COVID-19, интубация, насыщение кислородом, респираторная терапия

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Evaluation of oxygen saturation as an indicator for tracheal intubation in patients with COVID-19: a prospective cohort study

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ABSTRACT

Background. Since the beginning of COVID-19 pandemic, the importance of clinical criteria for tracheal intubation in critically ill patients with respiratory failure became more noteworthy, especially in resource limitations.

The objective was to evaluate the importance of hemoglobin oxygen saturation as a criterion for tracheal intubation in patients with COVID-19

Materials and methods. This is a multi-center, prospective, observational cohort study. We included 117 patients with COVID-19 who needed respiratory support between March to June 2021. Patients were intubated by the protocol of each institution participating in the study and the anesthesiologist's clinical judgement. Signs of respiratory failure, methods of respiratory support and patient outcome were recorded.

Results. Among 117 studied cases, 100 patients had hemoglobin oxygen saturation of 60–90% in whom 58 were intubated. During hospitalization, 56 intubated patients and 14 non-intubated patients died (96.6% Vs. 33.3%).

Conclusion. Arterial blood hemoglobin oxygen saturation of 60–90 could not be the correct key to unlock the problem of intubation decision in patients with COVID-19. Therefore, hemoglobin oxygen saturation should not be solely regarded as an indication for intubation in COVID-19.

Key words: COVID-19, intubation, oxygen saturation, respiratory therapy

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Introduction

In December 2019, in Wuhan (China) a previously unknown coronavirus, SARS-Cov-2 was identified that today is known as COVID-19. A virus with high level of contagion and high mortality rate of 2% due to respiratory distress in infected patients [7]. Despite massive effort to control viral transmission, it became an enormous worldwide pandemic.

The most common and severe manifestation of COVID is hypoxic respiratory failure that is also the

main reason of mortality [1, 8, 12]. Thus, these patients need respiratory support to maintain adequate oxygenation, ventilation, prevention of lung injury and decrease respiratory work. Respiratory support could be in various levels and it depends on the degree of alveolar damage and the severity of Acute Respiratory Distress Syndrome (ARDS). Oxygen can be delivered via different devices. Nasal cannula, simple face mask and reservoir bag increase FiO_2 by low flow oxygen. On the other hand, face mask with venturi valve and high flow nasal cannula (HFNC) provide high flow oxygen support. Non-invasive ventilation (NIV) including continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BiPAP) deliver oxygen to airway by applying positive pressure [5, 10]. In severe forms of respiratory failure, invasive mechanical ventilation by endotracheal tubes is inevitable.

The undetermined question is the time and criteria for using these supports, especially invasive mechanical ventilation that seems to be the last step of respiratory support in patient suffering from COVID-19. In general, there are heterogeneities between studies to determine intubation criteria in respiratory failure even before COVID-19 pandemic. Although various elements such as respiratory rate, heart rate, non-specific blood gas factors, dyspnea, hemodynamic instability and neurologic deterioration are suggested for decision making, but at last, there is lack of standard criteria for endotracheal intubation [4].

Certainly, this question would become more serious in CVOID-19 pandemic when scares of resources are accompanied by patients' abundant need for respiratory support. The decision of intubation may interfere with survival rate.

Materials and methods

This multi-center, prospective, observational cohort study was conducted in three tertiary public hospitals. Ethical Committee approved this study in February 2021 (Approval ID: IR.SBMU.MSP.REC.1399.677). Data were collected from March to June 2021. This time period was selected as peak of pandemic was risen and there was no consensus on intubation criteria. The questionnaire was designed to collect data. Patients with positive polymerase chain reaction (PCR) for COVID-19 or characteristic findings in Chest-CT scan who were consulted by anesthetist for airway management were included. In all centers, anesthesia consult was requested for patients who would need respiratory support during their hospital stay. Every institutes based on their skills and resources had their own intubation criteria. Patients who were transferred to other hospitals or those who were lost to follow-up or intubation after cardiopulmonary arrest were excluded from this study.

In this time period, detailed information of 117 patients were assessed by trained resident of anesthesiology under supervision of faculty members. Patients' detailed medical history, O_2 saturation, respiratory rate (RR), presence of cough (sporadic or heated), subjective dyspnea (mild or severe) and also signs of dyspnea (nasal flaring, rib retraction and abdominal breathing) were recorded in the questionnaire. We evaluated patient level of consciousness by using AVPU scale (Alert, Voice, Pain, Unresponsive) and patient outcome as discharged or deceased was also pursuit. Patients were intubated based on institute's criteria and also the faculty members' clinical judgement.

We intent to compare mortality rate among patients with severe symptoms who were intubated with those who are not intubated. Severe symptoms were defined by O_2 saturation of 60–90% with non-invasive oxygen support, respiratory rate of more than 30/minute, level of consciousness described by AVPU scale as P & U, heated cough, severe subjective dyspnea, presence of nasal flaring, rib retraction and abdominal breathing.

Qualitative data were shown by frequency and percentage, and analyzed by chi-squared and Fisher's exact tests. Quantitative data were shown by mean, and SD (standard deviation). The P-value less than 0.05 considered statistically significant difference. All statistically were analyzed. Analyses were conducted using the statistical software environment R, version 4.1.1.

Results

The study enrolled 117 critically ill patients who received anesthesia consultation during hospitalization from March to June 2020. COVID-19 infection was confirmed by PCR test (50.4%) or CT scan findings (49.6%). Of these patients, 48 were female and 69 were male (41% vs. 59%, respectively). The average age was 65.8 years, ranging from a minimum of 18 to a maximum of 95. Among the inpatients requiring anesthesia for respiratory assistance, 80 (68.4%) died and 37 were discharged (31.6%). In addition, 71% had at least one comorbidity. Hypertension (46.2%), diabetes (25.6%) and ischemic heart disease (20.5%) were the most common comorbidities. The most commonly used drug was angiotensin converting enzyme inhibitor (ACEI) (34.2%). Fifty patients (42%) were intubated during their hospitalization and there is not any significant relation in demographic data between intubated and non-intubated groups (Table 1).

At the time of consultation, the average O_2 saturation was 75.8% (30–96) and the respiratory rate was 26/minute (16–45). The most common respiratory symptoms were heated cough (70.1%), severe subjective dyspnea (56.4%), nasal flaring (48.6%), abdominal breathing (45.3%), and rib contraction (37.6%) (Table 2).

Of the 117 patients, 100 patients showed 60–90% O_2 saturation, of which 58 were intubated. During hospitalization, 56 intubated and 14 non-intubated patients died (96.6% vs. 33.3%). Among these patients, 56 patients had a respiratory rate of more than 30/minute, of which 87% were intubated and all died. Among 16 patients with fever cough, 13 were intubated and the mortality rate for these intubated patients was 92.3%. Ninety-six percent of patients with severe dyspnea died and two were discharged. Evaluating other symptoms of dyspnea, 3.9% of patients

Table 1. **Demographic Characteristics**

Parameter		Intubated (50)	Non-Intubated (67)	P-Value
Age, year		63.4±17.6	67.7±14.4	0.172 Mann–Whitney
Sex	Female	25 (50)	23 (34.3)	0.088 Chi-squared
	Male	25 (50)	44 (65.7)	
Diagnosis	PCR	23 (46)	36 (53)	0.408 Chi-squared
	Radiology	27 (54)	31 (47)	
Past Medical History	Diabetes Mellitus	16 (32)	14 (21)	0.174 Chi-squared
	Hypertension	23 (46)	31 (46)	0.977 Chi-squared
	Ischemic Heart Disease	11 (22)	13 (19)	0.731 Chi-squared
Drug History	ACEIs	18 (36)	22 (33)	0.433 Chi-squared

Data given as number (%) for nominal data and Mean±Standard Deviation for ordinal data

Table 2. Comparison of Clinical symptoms among intubated versus non-intubated patients

Parameter		Non-Intubated (50)	Intubated (67)	P-value
O_2 Saturation (%)		81.2±12.8	71.8±17.2	0.001 Mann–Whitney
Respiratory Rate (/min)		22.5±4.89	28.9±7.65	0.001 Mann–Whitney
Temperature (°C)		38.2±0.81	37.9±0.67	0.001 Mann–Whitney
Cough	Heated	3 (6)	8 (12.3)	0.335 Chi-squared
	Sporadic	33 (66)	35 (53.8)	
	Negative	14 (28)	22 (33.8)	
Subjective Dyspnea	Severe	1 (2)	31 (46.3)	0.001 Chi-squared
	Mild	37 (75.5)	31 (46.3)	
	Negative	11 (22.4)	5 (7.5)	
Nasal Flaring (positive)		2 (4)	23 (34)	0.001 Chi-squared
Rib Retraction		4 (8)	28 (41.8)	0.001 Chi-squared
Abdominal Breathing		4 (8)	28 (41.8)	0.001 Chi-squared
Decreased level of consciousness		3 (7)	43 (93)	0.001 Chi-squared
Outcome	Death	15 (30)	65 (97)	0.001 Fisher's exact test
	Discharge	35 (70)	2 (3)	

Data given as number (%) for nominal data and Mean±Standard Deviation for ordinal data

with nasal flaring, 4.9% of patients with rib contraction, and none of patients with abdominal breathing were discharged after intubation. In non-intubated patients, these statics were 16.7%, 33%, and 75%, respectively. Among 46 patients with decreased level of consciousness, all non-intubated patients had died whilst 3% of intubated ones had been discharged. Decreasing level of consciousness included nonresponsive patients and the ones that responsed to only painful stimulus.

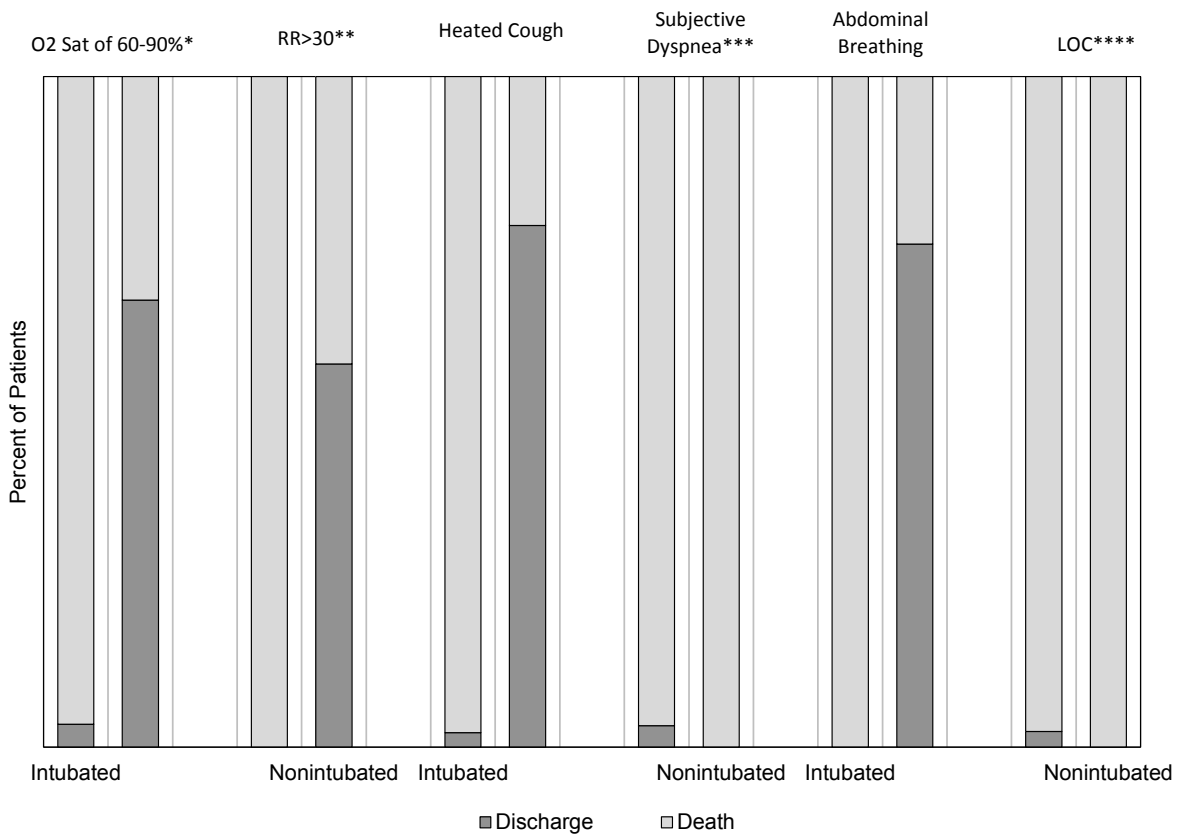
Fisher's exact test showed that intubation did not prolong survival in patients with heated cough, abdominal breathing, respiratory rate of more than 30/minute and oxygen saturation of 60–90% (p-value < 0.001).

Subjective severe dyspnea and decreased level of consciousness did not correlate with survival after intubation, although patients who were intubated discharged, whilst there were not any survivals in patients with severe dyspnea and decreased level of consciousness who were not intubated (P-value = 0.71) (Figure).

Discussion

The most appropriate time for intubation per se is a dilemma in hypoxic patients due to lack of standard endotracheal intubation criteria [8] and it became more challenging in a pandemic with huge number of patients with severe COVID-19 and worldwide resource limitation. Also, invasive ventilation in COVID patients is being between Scylla and Charybdis [2, 9]. It can be lifesaving by improvement in oxygenation and amelioration of virus spread, on the other hand, it could be life threatening by increasing ventilator induced lung injury (VILI) and resource consuming [3].

In COVID patients, it seems that the lower saturation could be better tolerated than the other hypoxic patients, so maybe just the percent of O_2 saturation should not be considered as a trigger for intubation [3]. Therefore, criteria for invasive ventilation in these patients is debatable. In this study, discharge rate of intubated and non-intubated patients who had severe respiratory symptoms at the time of decision making for intubation, were compared. We found that 96.6% of patients that had O_2 saturation of 60–90% and were intubated died, whilst in those who were not intubated with this range of O_2 saturation, mortality rate was 66.7%. This is obvious that mortality rate should be higher in intubated group due to their worse general condition as confirmed in table 2. They need more inva-



*Patient outcome with severe respiratory symptoms: * – Oxygen saturation between 60–90%; ** – Respiratory Rate of More than 30 Breaths/min; *** – Severe Subjective Dyspnea; **** – Loss of Consciousness by AVPU scale*

Table 3. **Intubation decision**

Clinical symptoms	Intubation criteria
O2 Saturation of 60–90%	Not a good criteria
Respiratory Rate > 30/min	Not a good criteria
Heated cough	Not a good criteria
Abdominal breathing	Not a good criteria
Severe subjective dyspnea	Could be a criteria
Decreased level of consciousness	Could be a criteria

sive respiratory support, but the interesting part in this result is discharge rate of 33.3% in patients with low O_2 saturation that were not intubated in compare to less than 4% in intubated group. It could show us maybe decreasing O_2 saturation below 90% even to 60% is not good criteria for starting mechanical ventilation of patients with COVID infection. The findings of Yong Hoon et al in 2020 can be in favor of ours that show early intubation is not associate with improvement in survival. In their study, early intubation was defined as intubation in the first day of meeting ARDS criteria in patients with COVID-19 [6].

In evaluation of other signs and symptoms for intubation, we found limited studies that mostly suggested their own clinical criteria and the lack of evidence based guidelines for the best time to start mechanical ventilation was noticeable. In an observational cohort study by Ahmad et al in 2020 on 150 intubated patients, association between early intubation and improvement in outcome was shown. As they mentioned, their data was not a definitive evidence for early vs late intubation, but they suggested that if tracheal intubation was considered based on following criteria, they could have better clinical outcome and staff safety. Their criteria were : O_2 saturation $< 92\%$, FiO_2 requirement of more than 60%, respiratory rate of more than 25/minute, increase work of breathing and failure adequate oxygenation in 4-hour prone position [1]. In another study, severity of respiratory failure, multi-organ failure, hemodynamic shock and multiple high risk condition are suggested as institutional intubation criteria. Of course, all these conditions depend on availability of ventilators and intensive care capacity [11]. In our study, we tried to detect respiratory distress in detailed. Among various respiratory symptoms, we found that mortality rate in patients with respiratory rate $\geqslant 30$/min and abdominal breathing who were intubated were signifi-

cantly higher than patients with these symptoms who were not intubated. We found that intubation did not decrease mortality in patients with respiratory rate ⩾ 30/min and abdominal breathing and could not be suitable criteria for intubation.

In our cases with severe subjective dyspnea and decreased level of consciousness, we had patients who were discharged after intubation but all of the non-intubated patients died. It was not statistically significant but clinically could be important. Therefore, evaluating patients' subjective dyspnea and decreased level of consciousness could be considered as valuable variables for future studies (Table 3).

Our limitation in this study was limited number of patients, because data gathering during pandemic situation was difficult. Also, in pandemic situation, mortality rate can be affected by resource limitations. For defining a guideline for intubation in COVID patients, aggregation of more study with huge number of data could be helpful.

Conclusion

In conclusion, our data showed that oxygen saturation of 60–90% could not be the correct key to unlock the problem of intubation decision in patients with COVID-19.

Конфликт интересов. Авторы заявляют об отсутствии у них конфликта интересов.
Conflict of Interests. The authors state that they have no conflict of interests.

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От редакции

В настоящее время вопрос об эффективности применения неинвазивной вентиляции легких при ОРДС является дискутабельным. В свете современных рекомендаций по респираторной поддержке при ОРДС использование неинвазивной вентиляции легких целесообразно только при легком ОРДС (pO_2/FiO_2 более 200–250). При традиционном подходе к терапии гипоксемической дыхательной недостаточности считается, что снижение SpO_2 ниже 88–90% на фоне проводимой оксигенотерапии требует экстренной коррекции вплоть до применения инвазивной ИВЛ. Собственно, во временных рекомендациях по лечению пациентов с COVID-19 такой подход и декларируется. Однако сложившиеся на практике подходы к проведению респираторной поддержки были несколько иными. Проявления гипоксемической дыхательной недостаточности у пациентов с COVID-19 имеют определенные особенности, по крайне мере в начальной стадии заболевания, когда, как правило, объем легких сохранен и нет нарушения выведения CO_2, отсутствуют выраженные тахипноэ, диспноэ и пр. Как выяснилось, ранняя интубация и проведение инвазивной ИВЛ катастрофически повышали риск присоединения бактериальной инфекции, что в большинстве случаев оказывалось фатальным событием для пациентов с тяжелым течением COVID-19. Кроме того, использование неинвазивных методов респираторной терапии могло быть более выгодным в условиях массового поступления пациентов в стационар и высокой нагрузки на медицинский персонал. Все эти обстоятельства в значительной степени и повлияли на широкое использование неинвазивных методов респираторной поддержки у пациентов с тяжелым течением COVID-19. Впрочем, какого-то единого подхода к проведению респираторной поддержки, несмотря на немалое количество исследований и публикаций, выработать так и не удалось, также как и не удалось сформулировать четкие показания к проведению инвазивной ИВЛ. В этой связи цель представленного авторами исследования является актуальной, поскольку изучение взаимосвязи между выраженностью симптомов ОДН, методом респираторной поддержки и исходом заболевания, возможно, позволит более точно определить показания к проведению инвазивной ИВЛ у этой категории больных. Авторам удалось показать, что вне ОРИТ (это важно подчеркнуть) такой традиционный критерий для эскалации респираторной поддержки, как снижение насыщения артериальной крови менее 90%, является неочевидным ориентиром для принятия решения об интубации трахеи.

Вместе с тем следует отметить наличие ряда спорных моментов в построении исследования и интерпретации его результатов. В частности, обратила на себя внимание неоднородность сравниваемых групп: состояние интубированных пациентов, как следует из представляемых результатов, было более тяже-

Editorial Note

Currently, the question of the effectiveness of the use of non-invasive ALV in ARDS is debatable. In the light of current recommendations on respiratory support for ARDS, the non-invasive lung ventilation is advisable only for mild ARDS (p_aO_2/FiO_2 more than 200–250). With the traditional approach to the treatment of hypoxemic respiratory failure, it is considered that a decrease in SpO2 below 88–90% against the background of ongoing oxygen therapy requires emergency correction, up to the use of an invasive ALV. Actually, in the temporary recommendations for the treatment of patients with COVID-19, this approach is declared. However, the approaches to respiratory support developed in practice were somewhat different. Manifestations of hypoxemic respiratory failure in patients with COVID-19 have certain features at least in the initial stage of the disease when, as a rule, lung volume is preserved and there is no disorders of CO2 excretion, there are no pronounced tachypnea, dyspnea, etc. As it turned out, early intubation and invasive ALV dramatically increased the risk of bacterial infection, which in most cases turned out to be a fatal event for patients with severe COVID-19. In addition, the use of non-invasive methods of respiratory therapy could be more profitable in conditions of mass admission of patients to the hospital and high workload on medical personnel. All these circumstances have significantly influenced the widespread use of non-invasive methods of respiratory support in patients with severe COVID-19. However, despite a considerable number of studies and publications, it was not possible to develop a single approach to respiratory support, as well as it was not possible to formulate clear indications for invasive ALV. In this regard, the purpose of the study presented by the authors is relevant, since the study of the relationship between the severity of symptoms of ARF, the method of respiratory support and the outcome of the disease may make it possible to more accurately determine the indications for invasive ALV in this category of patients. The authors managed to show that outside the ICU (it is important to emphasize this), such a traditional criterion for the escalation of respiratory support, as a decrease in arterial blood saturation of less than 90%, is an unobvious guideline for making a decision on tracheal intubation.

At the same time, it should be noted that there are a number of controversial points in the construction of the study and the interpretation of its results. In particular, the heterogeneity of the compared groups drew attention to itself: the condition of intubated patients, as follows from the presented results, was more severe, clinical manifestations of respiratory distress in these patients were more pronounced. It is not at all obvious that the refusal of invasive ALV could somehow affect the results of treatment. The single criterion for the diagnosis of oxygenation disorders actually turned

лым, клинические проявления респираторного дистресса у этих пациентов были более выраженными. Совершенно неочевидно, что отказ от инвазивной ИВЛ мог как-то повлиять на результаты лечения. Единым критерием для диагностики нарушений оксигенации фактически оказалось снижение SpO_2 менее 90%, хотя этот показатель варьировал в очень широком диапазоне значений (60–90%), т. е. скорее традиционный подход оказался не очень пригодным для определения показаний к инвазивной ИВЛ, а не оценка оксигенации в целом, как посчитали авторы публикации. Следует отметить, что критическое значение показателя степени насыщения артериальной крови до сих пор является предметом дискуссий. Кроме того, у большинства интубированных пациентов также наблюдали нарушения сознания (до уровня сопора), что традиционно считается важным аргументом для выполнения интубации трахеи. При этом, несмотря на выраженные расстройства сознания, трем пациентам интубация трахеи так и не была выполнена. В то же время результаты данной работы интересны тем, что они акцентировали внимание на недопустимости шаблонного подхода к переводу на инвазивную вентиляцию легких больных COVID-19, которых при массовом потоке вынуждены госпитализировать в отделения общего профиля, а не в ОРИТ. Такое решение должно приниматься с учетом комплексной оценки клинической ситуации и с обязательным участием анестезиолога-реаниматолога или иного специалиста по респираторной терапии, знакомого с особенностями течения данного коварного заболевания.

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out to be a decrease in SpO_2 of less than 90%, although this indicator varied in a very wide range of values (60–90%), i.e. rather the traditional approach was not very suitable for determining indications for invasive ALV, and not an assessment of oxygenation as a whole, as the authors of the publication considered. It should be noted that the critical value of the indicator of the degree of saturation of arterial blood is still a subject of discussion. In addition, most intubated patients also had impaired consciousness (up to the level of sopor), which is traditionally considered an important argument for performing tracheal intubation. At the same time, despite pronounced disorders of consciousness, tracheal intubation was not performed in three patients. Equally, the results of this work are interesting because they focused attention on the inadmissibility of a template approach to the transfer to invasive lung ventilation of patients with COVID-19, who, with a mass flow, are forced to be hospitalized in general departments, and not in the ICU. Such decision should be made taking into account a comprehensive assessment of the clinical situation and with the mandatory participation of intensivist or other specialist in respiratory therapy who knows the peculiarities of the course of this insidious disease.

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