

# Effectiveness of OxyMask™ vs. Simple Oxygen Mask Against Chronic Obstructive Pulmonary Disease Exacerbation

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## Abstract

**Aim:** In our study, it was aimed to compare the effectiveness of a diffuser mask (OxyMask™) and a simple nebulizer set oxygen mask on the blood gas values of patients with the diagnosis of chronic obstructive pulmonary disease (COPD) exacerbation who presented to the emergency department.

**Materials and Methods:** Our research is a prospective, single-blind, randomized controlled study conducted in the Emergency Department of Atatürk University Medical Faculty Hospital. Our study was completed with 213 patients after the exclusion criteria were applied. Of these patients, 93 were administered breathing treatment with a diffuser mask, and 120 were given treatment with a simple nebulizer set oxygen mask.

**Results:** After the treatment with COPD exacerbation, the  $SO_2$  and  $PO_2$  values of the diffuser mask group were found to be significantly higher than those in the simple oxygen mask group ( $p<0.05$ ). After the treatment, the  $PCO_2$  values of the diffuser mask group were significantly lower than those in the simple oxygen mask group ( $p<0.05$ ). The diffuser mask also reduced the hospitalization rate of the patients.

**Conclusion:** We suggest that a diffuser mask, which provides better oxygenation in the blood and lowers the carbon dioxide concentration in the blood to a higher extent, can be used in administering breathing treatment to COPD patients with exacerbation who presented to the emergency department with dyspnea.

**Keywords:** Breathing treatment, chronic obstructive pulmonary disease, diffuser, OxyMask™, simple oxygen mask

## Introduction

Chronic obstructive pulmonary disease (COPD) is a common, preventable, and treatable disease characterized by chronic respiratory symptoms and airflow restrictions in the airways and lung parenchyma, mostly caused by the significant exposure of the airways to hazardous particles and gasses and/or alveolar abnormalities (1). There are 2 groups of risk factors for COPD, genetic risk factors (alpha-1 antitrypsin deficiency) and environmental risk factors (smoking, occupational exposure, air pollution, and infections). The most significant risk factor is active smoking (2).

COPD should be considered a diagnosis in individuals with chronic cough, sputum production, dyspnea complaints, and/or a history of exposure to risk factors, and spirometry is required for diagnosis in these patients.  $FEV_1/FVC$  values smaller than 0.70 after bronchodilator therapy in patients with clinically relevant symptoms and exposure to harmful excitants indicated a permanent airflow restriction, and therefore, the presence of COPD (1,3).

COPD exacerbation is defined as an acute increase and worsening in the symptoms of COPD that may require additional treatment (4). COPD exacerbations are usually associated with increased



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airway inflammation and increased mucus production (5). Exacerbations are mainly triggered by viral respiratory infections, but factors such as bacterial infections, environmental pollution, and ambient temperature can also trigger or worsen this condition (6).

Beta agonists and anticholinergic drugs are the first choice for treating COPD-exacerbated patients admitted to the emergency department. Oxygen therapy and the types of masks used while administering these drugs are critical for the effectiveness of the treatment. The diffuser mask is a face mask that delivers oxygen to the mouth and nose through a small diffuser. With the low current passing through the jet inside, a high concentration of oxygen is provided. Owing to the small holes on it, carbon dioxide trapping is reduced to a minimum (7). In this study, the effectiveness of a diffuser mask and a simple oxygen mask with a chamber in patients with COPD who applied to the emergency department with shortness of breath will be evaluated objectively by blood gas values. In this way, it will be evaluated which treatment method is effective for the patients.

## Materials and Methods

Our study was approved by the Atatürk University Faculty of Medicine Clinical Research Ethics Committee (decision number: 08-11, date: 26.12.2019). The patients participating in this study signed an informed consent form. This is a single-blind, randomized-controlled study conducted in the Emergency Department of Atatürk University Faculty of Medicine Hospital between 01.01.2020 and 31.05.2020. Patients with a diagnosis of COPD who presented to the Emergency Department of Atatürk University Faculty of Medicine Hospital with complaints of dyspnea and displayed signs of COPD exacerbation according to the 2020 Global Initiative for Obstructive Lung Disease (GOLD) COPD guidelines were included in this study.

Patients who were older than 18 years, diagnosed with COPD, had an exacerbation of COPD (according to the GOLD 2020 COPD guidelines), and volunteered to participate in the study were included in the study. Patients who did not volunteer to participate in the study, patients younger than 18 years, pregnant patients, patients with mental deficiencies, uncooperative patients, patients with anatomical barriers to wearing masks, patients with shortness of breath after trauma, and patients with unexpected comorbidities or exitus during the study were excluded.

Two hundred and sixty patients with COPD who presented to the Emergency Department of Atatürk University Faculty of Medicine Hospital with complaints of dyspnea and were diagnosed with COPD exacerbation were screened as potential participants. They were divided into two groups: 130 patients treated with a simple

nebulizer set oxygen mask (group 1) and 130 patients treated with a diffuser mask (group 2). For various reasons, 10 patients in group 1 and 37 patients in group 2 could not complete the study. The study was completed with 120 patients in group 1 and 93 patients in group 2, constituting 213 patients.

Two hundred and thirteen patients were divided into two groups: 93 patients treated with a diffuser mask (OxyMask™, Southmedic Inc, Canada) (Figures 1, 2, 3) and 120 patients treated with a simple nebulizer set oxygen mask (nebulizer set mask®, CGR Medical) with the same pharmacological agents. Beta agonist and anticholinergic treatment as inhaler treatment (Iprasal® 0.5+2.5 mg/2.5 mL) was administered. During the treatment of COPD exacerbation, a diffuser mask was used in one group, and a simple nebulizer set oxygen mask was used in the other group. Arterial blood samples taken from the patients before and after their COPD exacerbation treatments were compared in terms of their blood gas values. Among the blood gas parameters, the values of pH,  $SO_2$ , carboxyhemoglobin (COHb), MethHb, lactate,  $HCO_3$ , SBE,  $PCO_2$ , and  $PO_2$  were evaluated. Additionally, the demographic characteristics of the patients and their values, including vital signs, chronic diseases, hospitalization status (determined according to the GOLD 2020 COPD guidelines), a type of mask used during COPD exacerbation treatment, symptom onset time, history of smoking, biomass exposure history, and whether they used an oxygen concentrator at home were recorded (Table 1).

## Statistical Analysis

The IBM Statistical Package for the Social Sciences 20.0 statistical analysis program was used to analyze the data. The data are



Figure 1. Diffuser mask (OxyMask™, Southmedic Inc, Canada)

presented with mean, standard deviation, median, minimum, maximum, percentage, and frequency values. According to the Kolmogorov-Smirnov test results, the data were normally distributed. Then, the numeric variables were analyzed by paired-samples t-test, and the categorical variables were analyzed with Pearson's chi-squared test. A p value of <0.05 was considered significant for all the statistical analysis results.

## Results

Two hundred-thirteen patients who met the criteria were included in the study. Of the patients participating in our study,

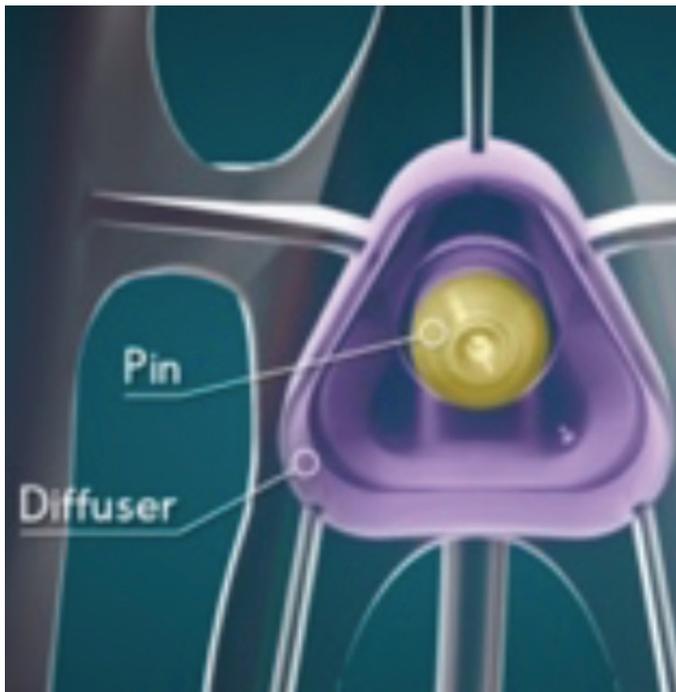


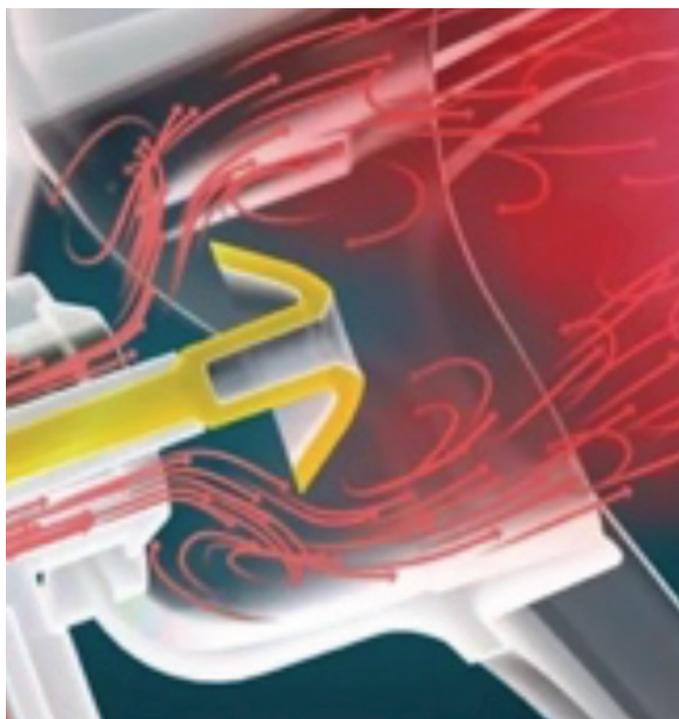
Figure 2. Diffuser mask pin and diffuser technology

65.7% (n=140) were male and 34.3% (n=73) were female. Patients were divided into two groups as patients who used simple chamber oxygen masks for treating attacks (group 1, n=120) and patients who used diffuser masks (group 2, n=93). The mean age of all patients participating in the study was 64.39±8.9 years. The mean age of the patients in group 1 was 63.95±8.46 years, of which 61.7% (n=74) were male and 38.3% (n=46) were female. The mean age of the patients in group 2 was 64.96±9.37 years, of which 71% (n=66) were male and 29% (n=27) were female. The statistical results of the groups using a diffuser mask and a simple chambered oxygen mask, except for blood gas, are shown in Table 1.

While 75.1% of all patients participating in the study had a history of home oxygen concentrator use, 24.9% of them did not use oxygen concentrators at home. When the hospitalization status of all patients after COPD attack treatment was examined, it was found that 32.9% (n=70) were hospitalized and 67.1% (n=143) were discharged from the emergency department. The mean age of the patients who were admitted to the clinic was found to be 4.02 years higher than the mean age of the patients who were discharged from the emergency department with COPD attack treatment. When the patients who used a diffuser mask were admitted to the clinic after COPD attack treatment, it was seen that 22.5% (n=21) were hospitalized and 77.5% (n=72) did not need to be admitted to the clinic. When the hospitalization status of the patients who used a simple oxygen mask with a chamber was examined after COPD attack treatment, it was seen that 40.8% (n=49) were hospitalized and 59.2% (n=71) did not need to be hospitalized. The most common comorbidity was hypertension (38%). Subsequently, she had a history of diabetes mellitus (30.5%), congestive heart failure (17.8%),

Table 1. Statistical results of the parameters, except for blood gas, of the groups using diffuser mask and simple oxygen mask with chamber

	Group 1	Group 2	p
Gender (male/female)	74/46	66/27	0.190
Age	63.95 (8.46)	64.96 (9.37)	0.412
Complaint start time (hours)	44.74	44.98	0.969
Duration of smoking (pack-years)	41.29 (33.36)	38.14 (37.38)	0.420
Chronic biomass exposure (%)	37.5	33.3	0.566
Oxygen concentrator usage at home (%)	73.3	76.3	0.638
Systolic blood pressure (mmHg)	134.33 (18.96)	131.65 (20.37)	0.322
Diastolic blood pressure (mmHg)	89.88 (19.20)	91.27 (19.15)	0.599
Fingertip oxygen saturation (%)	76.65	75.53	0.506
Respiratory rate (/min)	21.88	22.35	0.198
Pulse rate (/min)	102.11	100.74	0.536
Body temperature (°C)	37.02	36.93	0.3



**Figure 3.** Cork-shaped pin directing the oxygen flow (accessed date: 17.02.2022. Available from: <http://thebetteroxygenmask.com/oxy-mask-technology/>)

coronary artery disease (16.9%), chronic kidney disease (8.9%), cancer (8.9%), and cerebrovascular accident (8%).

After COPD exacerbation treatment, 22.5% of the patients in group 2 were admitted to the clinic, whereas 40.8% of the patients in group 1 were admitted to the clinic. The frequency of hospitalization in group 2 was significantly lower than that in group 1 ( $p < 0.05$ ).

Having compared the parameters in the arterial blood gas analyses of the patients in groups 1 and 2, after the COPD exacerbation treatments, the  $SO_2$  values in group 2 were found significantly higher compared with those in group 1 ( $p < 0.05$ ), the  $PO_2$  values in group 2 were significantly higher than those in group 1 ( $p < 0.05$ ), and the  $PCO_2$  values in group 2 were significantly lower compared with those in group 1 ( $p < 0.05$ ) (Table 2).

## Discussion

COPD is a disease that progress with exacerbations and whose emergency applications are frequently seen. While effective treatment improves the prognosis of the disease, it will decrease the hospitalization rates and the frequency of admission (8). A retrospective study was conducted by Russell et al. (9) on 537 patients who presented to the emergency department with a

**Table 2.** Statistical results of the blood gas parameters of the groups using diffuser mask and simple oxygen mask with chamber

	Group 1 average	Group 2 average	p
<b>Before COPD attack treatment</b>			
pH	7.401	7.398	0.706
$SO_2$ (%)	76.973	77.313	0.855
COHb (%)	2.601	2.831	0.259
MetHb (%)	1.553	1.494	0.292
Lactate (mmol/L)	2.293	2.367	0.755
$HCO_3$ (mmol/L)	25.394	24.453	0.191
SBE (mmol/L)	1.678	0.544	0.327
$PCO_2$ (mmHg)	42.169	41.355	0.567
$PO_2$ (mmHg)	50.338	50.727	0.844
<b>After COPD attack treatment</b>			
pH	7.392	7.398	0.502
$SO_2$ (%)	83.278	87.30	0.010*
COHb (%)	2.523	2.840	0.092
MetHb (%)	1.498	1.613	0.462
Lactate (mmol/L)	2.040	1.869	0.291
$HCO_3$ (mmol/L)	25.317	24.539	0.236
SBE (mmol/L)	0.878	0.322	0.381
$PCO_2$ (mmHg)	43.496	40.346	0.024*
$PO_2$ (mmHg)	57.406	61.856	0.020*

\*Data that were found statistically significant at the  $p < 0.05$  level.

COPD: Chronic obstructive pulmonary disease, SBE: Standard base excess, COHb: Carboxyhemoglobin

COPD exacerbation. Of these patients, 57% were hospitalized for COPD exacerbation, and 43% were treated in the emergency department and discharged. Additionally, it was observed that the average age of the patients who were hospitalized was 2.4 years higher than the average age of the patients treated in the emergency department. In our study, 32.9% of the patients were hospitalized due to COPD exacerbation, and 67.1% were treated in the emergency department and discharged. Similarly, it was observed that the average age of the patients who were hospitalized was 4.02 years higher than the average age of the patients treated in the emergency department. This difference was statistically significant ( $p < 0.05$ ).

COPD can be associated with many systemic diseases. The most common comorbid diseases in COPD are hypertension, coronary artery disease, and diabetes mellitus. The risk factors in COPD are well known, and if they are controlled in the early period, the natural course of the disease is positively affected (10). In a study by Garcia-Gutierrez et al. (11), 34.6% of 2841 patients had previously used oxygen concentrators at home. In addition to the diagnosis of COPD exacerbation, 21.66% of these patients have diabetes mellitus and 21.6% have cardiac disease. In our study, it was learned from the anamnesis of the patients that 75.1% of the patients had previously used oxygen concentrators at home. It was thought that this situation was due to the better oxygen concentrator supply conditions applied in our country. Additionally, the most common accompanying chronic diseases were hypertension (38%), followed by diabetes mellitus (30.5%) and congestive heart failure (17.8%).

The diffuser mask is an open oxygen mask developed in 2005, which can provide various oxygen concentrations from 24% to 90% between the flowrate values of 1 and 15+ liters per minute. It provides a very high  $\text{FiO}_2$ , especially in patients with COPD with chronic hypoxemia, and it can be used safely without causing carbon dioxide retention thanks to its diffuser feature. The diffuser mask features innovative technology designed to concentrate and direct the flow of oxygen. The mushroom-shaped pin creates an organized pattern of vortices and a cloud of concentrated oxygen molecules. The triangular diffuser corrects the shape of the oxygen vortices and directs the flow to the patient's nose and mouth (12-14).

In the literature, there are few studies on diffuser masks. In a study by Lamb and Piper (15) in which a non-rebreather mask and a diffuser mask were compared in a laboratory environment, a low flowrate (2 L/min) was provided in one group, and a high flowrate (15 L/min) was provided to the other group. At respiratory rates of 15/min, 20/min, and 24/min in each flow group, the percentages of decrease in the values of  $\text{etCO}_2$ ,  $\text{FiO}_2$ , inspired  $\text{CO}_2$  fraction, and  $\text{CO}_2$  were compared. As a result, the diffuser

mask performed significantly better in each category than the non-rebreather mask. Especially at very low flowrate with the diffuser mask, higher inspiratory oxygen levels, lower inspiratory  $\text{CO}_2$  levels, and more efficient  $\text{CO}_2$  clearance were achieved. In a single-blind, randomized, crossover study by Beecroft and Hanly (13), 13 of 26 chronic oxygen-dependent patients were treated with oxygen with a venturi mask, and the remaining 13 were treated with a diffuser mask for 60 min. Oxygen flowrate were lower when the diffuser mask was being used, whereas inspired  $\text{PO}_2$  values were higher, and expired  $\text{PO}_2$  values were lower. Thus, the diffuser mask provided a higher  $\text{PO}_2$  concentration compared to the venturi mask at a lower flowrate without causing carbon dioxide retention.

Hocagil et al. (16) investigated the COHb lowering capabilities of a diffuser mask and a simple mask used to deliver oxygen therapy in a patient group without an indication for hyperbaric oxygen therapy in carbon monoxide poisoning cases. After their treatments, patients who received oxygen therapy with the diffuser mask had significantly lower COHb (mg/dL) levels [9.6 (5.0) vs. 12.8 (6.2),  $p = 0.0203$ ] and higher  $\text{PaO}_2$  (mmHg) levels [224.4 (56.5) vs. 183.4 (63.7)] ( $p = 0.0046$ ) compared with those in the simple mask group. Iscanli et al. (17) compared the effectiveness of diffuser masks and simple oxygen masks in reducing carbon dioxide levels and increasing peak expiratory flow (PEF) values in patients who presented to the emergency department with asthma and COPD attacks. It was shown to provide a good PEF value for COPD and asthma attacks.

In our study, after the COPD exacerbation treatments of the patients with used diffuser masks and simple nebulizer set oxygen masks, the blood gas analyses results of the patients revealed that the  $\text{SO}_2$  values in the diffuser mask group were significantly higher than those in the simple oxygen mask group ( $p < 0.05$ ), the  $\text{PCO}_2$  values in the diffuser mask group were significantly lower than those in the simple oxygen mask group ( $p < 0.05$ ), and the  $\text{PO}_2$  values in the diffuser mask group were significantly higher than those in the simple oxygen mask group ( $p < 0.05$ ).

In the literature review conducted for this study, it was seen that the number of studies on the use of diffuser masks in patients with COPD was limited, and the patient populations of the available studies were also small. Likewise, most studies conducted with diffuser masks were those performed under simulation in a laboratory environment. The fact that our study was conducted with a large population and real patients differs from other studies.

### Study Limitations

There may be some possible limitations in this study. The main limitation of our study is that it is single-centered. Additionally,

our study does not show a homogeneous distribution in terms of gender, socioeconomic level, and education levels.

## Conclusion

In our study, the diffuser mask significantly increased  $SO_2$  and  $PO_2$  values and significantly reduced  $PCO_2$  values compared to the simple nebulizer set oxygen mask. It was determined that the patients who received COPD exacerbation treatment with a diffuser mask were discharged more frequently and hospitalized less frequently. Consequently, we suggest that the diffuser mask can be used as a successful adjunctive therapy method for treating patients with acute exacerbation of COPD who presented to the emergency department with dyspnea, considering its advantages such as high patient compliance.

## Ethics

**Ethics Committee Approval:** The study was approved by the Atatürk University Faculty of Medicine of Clinical Research Ethics Committee (decision number: 08-11, date: 26.12.2019).

**Informed Consent:** The patients participating in this study signed an informed consent form.

**Peer-review:** Externally peer-reviewed.

## Authorship Contributions

Surgical and Medical Practices: T.S.M., A.O.K., Concept: T.S.M., Z.Ç., M.B.K., Design: T.S.M., Z.Ç., Data Collection or Processing: T.S.M., Z.Ç., Analysis or Interpretation: T.S.M., B.M., Literature Search: T.S.M., B.M., Writing: T.S.M., M.B.K., A.O.K.

**Conflict of Interest:** No conflict of interest was declared by the authors.

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