



Is disposable continuous positive airway pressure system effective for the management of acute hypercapnic respiratory failure?

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Abstract

Aim This study aimed to investigate the effectiveness of disposable continuous positive airway pressure (DCPAP) system in decreasing the partial pressure of carbon dioxide (P_aCO_2) levels in patients with acute hypercapnic respiratory failure (AHRF).

Material and methods This retrospective observational study included patients treated in the emergency department (ED) with respiratory distress and $P_aCO_2 > 45$ mmHg. Patients were divided into two groups (DCPAP and non-DCPAP), depending on the treatment received to treat AHRF. The difference between the baseline P_aCO_2 levels in the first blood gas obtained from patients at the time of admission and the follow-up blood gas after treatment. Then, the calculated P_aCO_2 decrease was divided by the time elapsed to obtain the rate of decrease in P_aCO_2 levels in mmHg/min. The statistical analyses were performed using SPSS version 18.0 software. A p value of < 0.05 was considered statistically significant.

Results A total of 61 patients were included in the study, 31 patients in the DCPAP group and 30 patients in the non-DCPAP group. The mean age of the patients was 74.03 ± 10.04 , and the male/female was 23/38. The study demonstrated a statistically significant difference between the DCPAP and non-DCPAP groups in terms of P_aCO_2 decreasing rate, and it was found to be twice higher in the DCPAP group (0.11 ± 0.07 mmHg/min) than in the non-DCPAP group (0.05 ± 0.06 mmHg/min).

Conclusion The study demonstrated that the treatment of AHRF patients with a DCPAP provides a faster decrease in P_aCO_2 levels in hypercapnic patients compared to standard medical therapy alone.

Keywords Carbon dioxide · Continuous positive airway pressure · Dyspnea · Hypercapnia · Noninvasive ventilation

Introduction

Hypercapnia is defined as partial pressure of carbon dioxide (P_aCO_2) level over 45 mmHg (6 kPa), and it has a close relationship with respiratory acidosis ($pH < 7.35$) and increased mortality. Acute-on-chronic obstructive pulmonary disease

(COPD) exacerbation and acute cardiogenic pulmonary edema (ACPE) are critical life-threatening conditions encountered in the emergency department (ED) and are the leading causes of CO_2 retention [1]. Acute hypercapnic respiratory failure (AHRF) is caused by the increased dead space ventilation fails to meet the CO_2 emission.

Treatment options for the management of AHRF include standard medical therapy, supplemental oxygen, noninvasive ventilation (NIV), and endotracheal intubation. Supplemental oxygen is the primary component of standard medical therapy along with pharmacological treatment. However, if the patient does not respond to the standard medical therapy, including supplemental oxygen targeted to a saturation level of 88–92% within 1 h, additional therapeutic measures shall be considered if $PaCO_2$ persists > 45 mmHg [2].

Beyond the delivery of supplemental oxygen via a nasal cannula, NIV, or intubation are the options to be considered according to the patient's clinical condition. Similar to invasive mechanical ventilation (IMV), NIV increases alveolar

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ventilation, improves gas exchanges, and unloads the respiratory muscles, thus, reducing the work of breathing. NIV also reduces PaCO₂ levels and improves respiratory acidosis in patients with acute respiratory failure [3]. Including the NIV application to treat acute-on-chronic COPD exacerbations at home with persistent hypercapnia has been reported to reduce readmission and mortality rates [4]. Therefore, NIV has been recently used in AHRF treatment rather than invasive approaches. In addition to O₂ and medical therapy, NIV has been reported to reduce mortality, intubation rates, and hospitalization in patients with COPD and ACPE [1].

The NIV is a mechanical ventilation technique that does not require invasive airway management and includes two main modes: continuous positive airway pressure (CPAP) and biphasic positive airway pressure (BiPAP) [5]. Current literature has emphasized the clinical value of CPAP in the immediate treatment of type 1 (ACPE) and type 2 (AHRF) respiratory failure [6]. It has also been reported that CPAP reduces treatment costs and the risk of developing complications by reducing the need for endotracheal intubation and risks associated with the known complications of mechanical ventilation, in particular [7]. Therefore, CPAP mask application has been reported to be beneficial for the patients with ACPE or COPD exacerbations, but the number of studies on NIV in the use of ED is limited. [4, 8]

Several types of electronic equipment are available on the market to deliver NIV. But more recently, disposable CPAP (DCPAP) systems manufactured using a special valve system are also used successfully in the treatment of patients with CO₂ retention. The main important advantage of a DCPAP system over the conventional NIV electronic equipment is that it does not need an additional equipment; it can deliver CPAP therapy with only one oxygen gas source from an oxygen gas cylinder or the hospital oxygen system. With this feature, it enables the treatment of AHRF patients in the ED without requiring additional equipment. However, the number of ED-based studies investigating the effect of DCPAP system on hypercapnic AHRF patients is limited.

This study aimed to evaluate the decreasing rate in PaCO₂ levels by using a disposable DCPAP mask in patients with AHRF.

Materials and methods

This retrospective study included patients who were admitted to the ED of the Tertiary Care Training and Research Hospital between September 1, 2016, and April 30, 2019, for respiratory distress and hypercapnia. This study was conducted in accordance with the 1989 Declaration of Helsinki and was approved by the local ethics committee. Study protocol was approved by the local Gulhane Training and Research Hospital Clinical Research Ethics Committee on

June 11, 2019 (approval number 19/255). The ethics committee waived the requirement for patient informed consent because no patient recontact was established for the study and data were anonymized.

Ventilator support medical devices to be used to treat hypercapnia in patients with AHRF are selected according to the clinical evaluation of the emergency consultant, and DCPAP is one of these treatment methods. The standard medical therapy is initiated as a routine treatment protocol for patients with AHRF, and in cases where there is no response to the standard medical treatment and supplemental oxygen, NIV therapy is initiated in addition to medical treatment. In the hosting institution, electronic NIV devices are not routinely used, and a disposable CPAP system is our treatment of choice (Flow-Safe®, Mercury Medical Inc., FL, USA) for NIV routine treatment protocol.

For the treatment, DCPAP system is connected to an oxygen source (cylinder or wall), and then the CPAP mask is applied to the patient. The DCPAP system is based on fluid mechanics, with oxygen gas molecules accelerated through microchannels, generating turbulence and, hence, CPAP pressure. The desired CPAP pressure (5–13 cm H₂O) applied to the patient is proportional to the gas flow (8–15 LPM) and, therefore, titratable to the clinical needs.

Within the scope of hospital protocol, DCPAP application is started with 8 L/min O₂ support. At this flow rate, 5 cmH₂O pressure is created, and the pressure is titrated by progressively increasing the O₂ flow rate according to the clinical needs of the patient. This process is continued until the patient's P_aCO₂ level reaches the target value.

Patient selection

A retrospective chart review of patients who presented to the ED with dyspnea and whose PaCO₂ level in blood gas was above 45 mmHg was performed. Exclusion criteria were as follows: patients unable to tolerate DCPAP, those under the age of 18, pregnant women, patients with myocardial infarction, hypotension (blood pressure < 100/60 mmHg), hospital admission for trauma, patients with cardiorespiratory arrest, and those with missing data.

Patients who met the inclusion criteria were identified through a retrospective scan made using the electronic hospital information management system (eHIMS). All history, physical examination, diagnostic codes, treatment, and expenditures in the hosting ED were handled through HIMS. Among the patients who were admitted to the ED during the study period, those who were diagnosed with dyspnea (R06.0) were screened. Patients with PaCO₂ of > 45 mmHg at the time of admission and those whose control blood gas sample was analyzed in the ED were included. The treatments that patients received and status whether DCPAP was applied were also evaluated via HIMS. Patients who met the

criteria during the retrospective screening were included in the study, and the screening was ended when the number of patients required for the study according to power analysis was reached. Demographic data (age, gender, complaints of admission, comorbidities), complete blood count at the time of admission and controls, routine and cardiac markers, and blood gas parameters of the patients were recorded.

The difference between the baseline PaCO₂ levels in the first blood gas obtained from patients at the time of admission and PaCO₂ levels in the follow-up blood gas was recorded in mmHg, and PaCO₂ change was divided by the time elapsed (minutes) to calculate the primary outcome of the study. According to the hospital protocol, blood gas sample is collected from patients who are followed in the ED due to shortness of breath before starting DCPAP treatment, and these are ordered via HIMS. In addition to the vital signs of the patients, blood gas is monitored at regular intervals, and the course of treatment is decided according to the decrease in pH and PaCO₂ levels in the blood gas. This study was based on the blood gas levels obtained when DCPAP was initiated, and the first control blood gas values during the treatment period as the duration may vary according to the patient. All the patients in the DCPAP group received the CPAP therapy with standard devices (Flow-Safe®, Mercury Medical Inc., FL, USA).

Statistical analysis

Demographic data were expressed as frequency and percentage. Continuous variables were reported as means with standard deviation for normally distributed continuous variables, while non-normally distributed continuous variables were presented as medians with interquartile ranges (IQR). A chi-square test was used for the comparison of two groups in terms of categorical variables. Mann–Whitney *U* test was used for pairwise comparison of continuous data that did not follow a normal distribution, whereas Student's *t*-test was used for pairwise comparison of continuous data following a normal distribution. The statistical analyses were performed using SPSS version 18.0 software. A *p* value of <0.05 was considered statistically significant.

Results

A total of 61 patients were included in the study and retrospectively divided in 2 groups depending on whether they received medical therapy and oxygen alone or in conjunction with CPAP therapy. Thirty-one patients were included in the DCPAP group and 30 patients in the non-DCPAP group. The flowchart of the study is shown in Fig. 1. A total of 23 (37.7%) patients were male, and 38 (62.3%) were female with a mean age of 74.03 ± 10.04 years. There

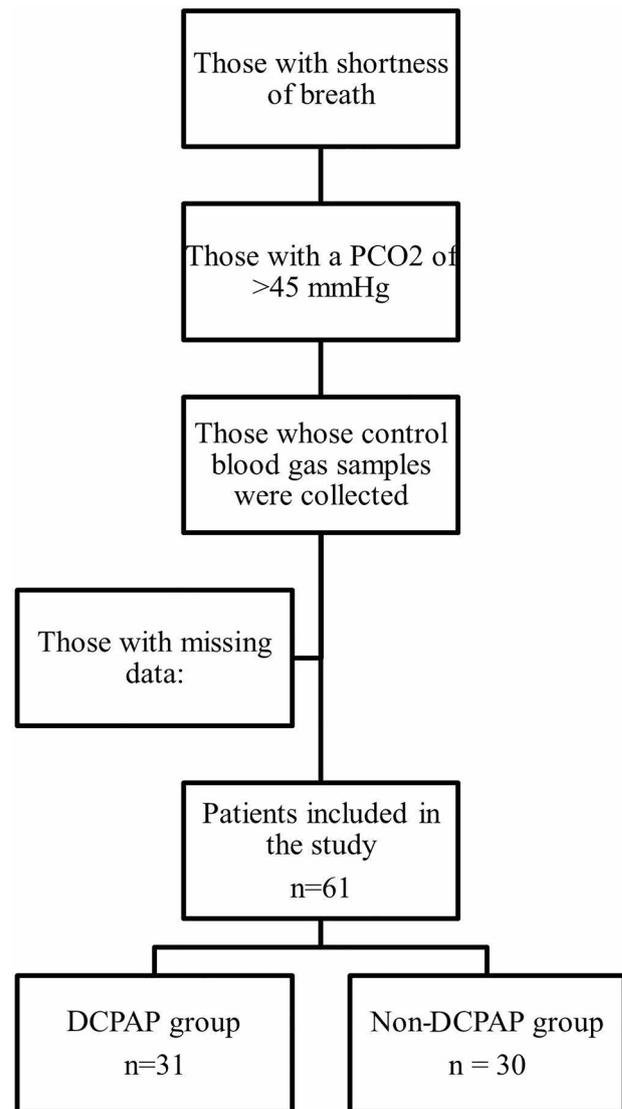


Fig. 1 Flowchart of the study (DCPAP: disposable continuous positive airway pressure mask system)

was no difference between the groups in terms of age and gender (Table 1).

There was no difference between the groups in terms of known cardiac comorbidities ($P = 0.202, 0.731, \text{ and } 0.795$, respectively; chi-square test). A total of 41 (67.2%) were hospitalized, whereas 20 (32.8%) patients were discharged after treatment in ED. No significant difference was observed between the groups in terms of hospitalization rates. Length of stay in the ED was found to be 7 h (IQR: 5–8) for the DCPAP group, whereas it was 8 h (IQR: 5–8) for the non-DCPAP group. The length of hospital stay was 6 days (IQR: 4–7) for the DCPAP group and 5 days (IQR: 4–7) for the non-DCPAP group. Table 2 presents the vital signs of patients and their intergroup

Table 1 Comparison of demographic data of groups

Parameter	DCPAP	n	Mean \pm SD	95% CI	p
Age	Non-DCPAP group	30	74.07 \pm 9.86	-5.12–5.26	0.067*
	DCPAP group	31	74.00 \pm 10.38		
Sex (male/female)	Non-DCPAP group	9/21	N/A	N/A	0.169*
	DCPAP group	14/17	N/A		
Hospitalization/discharge	Non-DCPAP group	20/10	N/A	N/A	0.572*
	DCPAP group	21/10	N/A		
Heart rate	Non-DCPAP group	30	96.87 \pm 15.35	-10.59–2.07	0.183*
	DCPAP group	31	101.13 \pm 8.54		
Systolic blood pressure (mmHg)	Non-DCPAP group	30	129.67 \pm 23.43	-1.46–18.08	0.094*
	DCPAP group	31	121.35 \pm 13.56		
Diastolic blood pressure (mmHg)	Non-DCPAP group	30	82.03 \pm 12.83	-8.89–2.18	0.230*
	DCPAP group	31	85.39 \pm 8.39		
SaO ₂	Non-DCPAP group	30	80.17 \pm 19.72	0.17–20.66	0.047*
	DCPAP group	31	69.76 \pm 20.26		
Respiratory rate	Non-DCPAP group	30	20.83 \pm 1.66	-4.69–(-2.67)	<0.001*
	DCPAP group	31	24.52 \pm 2.25		
Left ventricle ejection fraction	Non-DCPAP group	30	49.30 \pm 12.71	-2.11–10.07	0.196*
	DCPAP group	31	45.32 \pm 11.03		
CO ₂ decreasing rate (mmHg/minute)	Non-DCPAP group	30	0.05 \pm 0.06	-0.09–(-0.03)	<0.001*
	DCPAP group	31	0.11 \pm 0.07		

DCPAP disposable continuous positive airway pressure mask system, CI confidence interval, SD standard deviation

*Student's *t*-test

*Chi-square test

Table 2 Comparison of laboratory findings at the time of admission of patients with acute hypercapnic respiratory failure in DCPAP and non-CPAP groups

Parameter	DCPAP	n	Mean \pm SD	95% CI	p*
White blood cell count (10 ³ cells/mL)	Non-DCPAP group	30	12.17 \pm 5.96	-2.36–2.98	0.820
	DCPAP group	31	11.87 \pm 4.37		
Hemoglobin (g/dL)	Non-dCPAP group	30	12.94 \pm 1.87	-1.77–0.36	0.192
	BCPAP group	31	13.65 \pm 2.26		
Hematocrit (%)	Non-DCPAP group	30	41.99 \pm 6.16	-3.37–2.99	0.903
	DCPAP group	31	42.19 \pm 6.25		
Platelets (10 ³ cells/mL)	Non-DCPAP group	30	252.93 \pm 89.06	-13.02–75.41	0.163
	dCPAP group	31	221.74 \pm 83.51		
Glucose (mg/dL)	Non-BCPAP group	30	176.07 \pm 76.09	-27.09–49.35	0.562
	DCPAP group	31	164.94 \pm 73.09		
Urea (mg/dL)	Non-DCPAP group	30	69.30 \pm 34.57	-3.26–24.63	0.131
	DCPAP group	31	58.61 \pm 17.26		
Creatinine (mg/dL)	Non-DCPAP group	30	1.15 \pm 0.44	-0.15–0.24	0.660
	DCPAP group	31	1.10 \pm 0.33		
Sodium (mmol/L)	Non-DCPAP group	30	136.83 \pm 4.14	-3.88–0.45	0.118
	DCPAP group	31	138.55 \pm 4.29		
Potassium (mmol/L)	Non-DCPAP group	30	4.81 \pm 0.74	-0.22–0.49	0.449
	DCPAP group	31	4.68 \pm 0.65		

DCPAP disposable continuous positive airway pressure mask system, CI confidence interval, SD standard deviation

*Student's *t*-test

Table 3 Comparison of liver functions at the time of admission, coagulation markers, and length of stay in the ED, and hospital of the patients with acute hypercapnic respiratory failure in DCPAP and non-DCPAP groups

Parameter	DCPAP	n	Median rank	Z	p-value
AST (U/L)	Non-DCPAP group	30	29.57	-0.621	0.535
	DCPAP group	31	32.39		
ALT (U/L)	Non-DCPAP group	30	31.65	-0.282	0.778
	DCPAP group	31	30.37		
INR	Non-DCPAP group	30	31.32	-0.137	0.891
	DCPAP group	31	30.69		
PTT	Non-DCPAP group	30	29.20	-0.780	0.436
	DCPAP group	31	32.74		
Troponin	Non-DCPAP group	30	31.72	-0.310	0.756
	DCPAP group	31	30.31		
ProBNP	Non-DCPAP group	30	30.75	-0.108	0.914
	DCPAP group	31	31.24		
Emergency department Length of stay (hours)	Non-DCPAP group	30	31.63	-0.295	0.789
	DCPAP group	31	30.39		
Length of stay in hospital (days)	Non-DCPAP group	20	18.05	-0.290	0.772
	DCPAP group	16	19.06		

DCPAP disposable continuous positive airway pressure mask system, BNP brain natriuretic peptide, AST aspartate aminotransferase, ALT alanine aminotransferase, INR international normalized ratio, PTT prothrombin time

comparison. No difference was observed between the groups in terms of waiting time in ED and length of hospital stay (Table 3).

In both groups, it was observed a significant improvement in pH and PaCO₂ values after treatment ($P < 0.001$; paired samples *t*-test), whereas no statistically significant difference was observed for HCO₃ ($P = 0.190$; paired samples *t*-test). Noteworthy, there was a statistically significant difference between the two groups in terms of PaCO₂ decreasing rate, which was found to be higher in the DCPAP group (0.11 ± 0.07 mmHg/min) than in the control group (0.05 ± 0.06 mmHg/min) (Table 4) (Fig. 2).

Discussion

This study demonstrated that NIV performed using DCPAP system significantly improved hypercapnia levels and twice more rapidly in patients with AHRF compared to the patients that received standard medical therapy alone. To the best of our knowledge, this is the first study in the literature that primarily investigates the efficacy of DCPAP in the decreasing rate of PaCO₂ levels in the acute phase in patients with AHRF.

Emergency physicians should immediately perform an emergency evaluation and initiate medical treatment for

Table 4 Comparison of blood gas test results at the time of admission and control of patients with acute hypercapnic respiratory failure in DCPAP and non-DCPAP groups

Groups	Admission				Control				
	n	Mean ± SD	CI 95%	p*	n	Mean ± SD	CI 95%	p*	
pH	Non-DCPAP group	30	7.27 ± 0.09	-0.05-0.08	0.673	30	7.31 ± 0.08	-0.07-0.03	0.358
	DCPAP group	31	7.25 ± 0.15			31	7.33 ± 0.10		
PaCO ₂	Non DCPAP group	30	67.72 ± 10.80	-10.77-4.14	0.377	30	58.09 ± 11.16	-2.49-12.21	0.191
	DCPAP group	31	71.04 ± 17.4			31	53.23 ± 16.87		
HCO ₃	Non-DCPAP group	30	27.32 ± 6.26	-5.06-1.81	0.349	30	27.82 ± 6.52	-2.98-3.49	0.874
	DCPAP group	31	28.94 ± 7.11			31	27.56 ± 6.11		

DCPAP disposable continuous positive airway pressure mask system, CI confidence interval, SD standard deviation

*Student's *t*-test

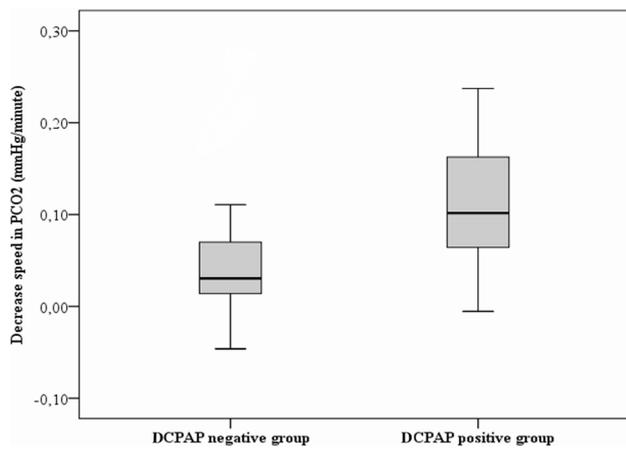


Fig. 2 Comparison of PaCO₂ decreasing rate (mmHg/minute) of patients with acute hypercapnic respiratory failure in DCPAP and non-DCPAP groups. (DCPAP: disposable continuous positive airway pressure mask system)

a patient diagnosed with hypercapnia. However, it is recommended to keep the target SaO₂ levels within the range of 88–92% since there is a risk of hypoxemia and oxygen-induced hypercapnia in such cases [1]. Therefore, mechanical ventilation should be evaluated if the response to the initial treatment is insufficient [9]. The efficacy of NIV in patients with ACPE has been reported to be similar to CPAP. [10] According to the results of the present study, it was concluded that DCPAP could be used as a practical NIV approach to treat patients with AHRF, improving PaCO₂, SaO₂, and pH.

In a recent study by Uz et al., DCPAP was compared to a conventional electronic NIV equipment in patients with hypoxemic respiratory failure. [11] The study concluded that the DCPAP system can be as effective as NIV in patients with ACPO, considering the overall improvement observed in the physiological blood gas and other parameters as well as the mortality and cost-related considerations. Due to its lightweight and ease of use, the DCPAP could be a treatment of choice in the emergency and prehospital settings where electronic NIV devices may not be available especially in lower-income countries.

In a study by Murphy et al., the mean age of patients presenting to the hospital with COPD attack has been reported to be 67 ± 10 years, with a male sex ratio of 53% and PaCO₂ levels of 59 mmHg [4]. The cohort in the current study is compatible with the literature in terms of demographic data. Patients with AHRF have been seen to apply to the ED in the fifth and seventh decades with a PaCO₂ level of about 60 mmHg.

The main component of DCPAP is a CPAP valve, whereby O₂ molecules from the O₂ system are accelerated through micro-channels to provide positive pressure. The

pressure that is titrated by the flow from the O₂ system using the mask and CPAP pressure at 10 cmH₂O can be created when oxygen is delivered at a rate of 15 L/min. In a study on this topic, end-expiratory pressure levels of patients receiving DCPAP have been reported to be 9.3 ± 0.3 cmH₂O. [12] In another study, it has been reported that an airway pressure of 2.5 to 12.5 cmH₂O can be achieved using DCPAP in healthy adults [13]. DCPAP titrates the positive end-expiratory pressure (PEEP) levels with O₂ flow and shows the numerical PEEP without any electronic part.

The NIV requirement in COPD exacerbation has been reported to be associated with poor prognosis [4]. Noteworthy, CPAP application above 15 cmH₂O may reduce cardiac output by 20–30% [3]. Therefore, the addition of NIV to standard oxygen and medical therapy in the early period is beneficial for patients with AHRF. It may be associated with a poor prognosis when not given in appropriate indications and appropriate doses. However, the standard NIV settings (median home ventilator settings) in electronic BiLevel CPAP devices can be recommended as follows: an inspiratory positive airway pressure (IPAP) of 24 cmH₂O (IQR: 22–26), an expiratory positive airway pressure (EPAP) of 4 (IQR: 4–5) cmH₂O, and a backup rate of 14 (IQR: 14–16) breaths per minute, which may seem relatively complicated to users [4]. The use of DCPAP in patients with AHRF in emergency settings can be an effective option as the pressure can be titrated via the oxygen gas flow (portable cylinder or stationary wall source), and it can be applied immediately and efficiently in an emergency medical intervention without requiring any additional equipment other than the oxygen source and DCPAP.

DCPAP can also be integrated into prehospital systems. In a study by Spijker et al., DCPAP has been reported to be used successfully in the prehospital management of patients with ACPE [8]. In this study, a significant increase (from 88 to 95%) has been reported to occur in the mean SaO₂ values in the prehospital period, whereas there was a slight decrease in pulse, systolic blood pressure, and diastolic blood pressure values. The median length of hospital stay was reported to be 4.6 (min–max: 1.5–20) and 5.1 (1.5–34) days in DCPAP and non-DCPAP groups, respectively [8]. Another interesting finding of this study was that DCPAP was applied in only 16% of patients. The authors have attributed the reason for this to the fact that the hospital staff prefers to use the mask in more severe cases. The median SaO₂ values of the DCPAP group were lower than that of the non-DCPAP group. Compatible with the literature findings, the vital signs of the patients in the DCPAP group at the time of admission were worse, and the respiratory rate was significantly higher in the present study. The reason for this difference has been attributed to the fact that DCPAP was applied for patients with poor clinical status and unresponsive to primary treatment.

In a recent study, DCPAP has been reported to be quickly and successfully applied by nurses working in the ambulance without the need of a physician [14]. In patients with ACPE, median SaO₂ values have been reported to increase from 79% (69–94%) to 96% (89–98%) within 20 min using DCPAP adjusted to a standard 15 L/min flow and 5 cmH₂O pressure, and ambulance staff has been reported to be satisfied with DCPAP treatment [14]. Similarly, in another study by Dieperink et al. involving patients in the coronary care unit, it has been reported that the SaO₂ values of the DCPAP group are lower than that of the non-DCPAP group, and the DCPAP system is a simple, effective, and cost-effective treatment approach [15]. These data suggest that DCPAP may be a useful device in the treatment of patients with acute respiratory failure, particularly in the ED as well as prehospital settings.

Limitations

Our study was a single-center study done with a small sample size, and it was a retrospective study. This study lacked a regular CPAP group. There is a need for large, multicentric, prospective ED-based studies.

Conclusion

This study showed that DCPAP is a method that can be used in the ED as it is easy to apply and lightweight, does not require additional equipment, and can provide rapid improvement of PaCO₂ levels.

Declarations

Ethics approval This study was conducted in accordance with the 1989 Declaration of Helsinki and was approved by the local ethics committee. Study protocol was approved by Gulhane Training and Research Hospital Clinical Research Ethics Committee on June 11, 2019 (approval number 19/255).

Conflict of interest The authors declare no competing interests.

Prior publication This manuscript has not been published and is not under consideration for publication elsewhere. The manuscript has not been presented in any congress.

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