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Noninvasive continuous positive airway pressure in elderly cardiogenic pulmonary edema patients

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Abstract *Objective:* To compare the physiological effects and the clinical efficacy of continuous positive airway pressure (CPAP) vs standard medical treatment in elderly patients ($\geq$75 years) with acute hypoxemic respiratory failure related to cardiogenic pulmonary edema. *Design:* A prospective, randomized, concealed, and unblinded study of 89 consecutive patients who were admitted to the emergency departments of one general, and three teaching, hospitals. *Intervention:* Patients were randomly assigned to receive standard medical treatment alone (n=46) or standard medical treatment plus CPAP (n=43). *Measurements:* Improvement in PaO_2/FIO_2 ratio, complications, length of hospital stay, early 48-h and overall mortality, compared between the CPAP and standard treatment groups. *Results:* Study groups were comparable with regard to baseline physiological and clinical characteristics (age, sex ratio, autonomy, medical history, cause of pulmonary edema). Within 1 h, noninvasive continuous positive airway pressure led to decreased respiratory rate (respiratory rate, 27±7 vs 35±6 breaths/min; p=0.009), and improved oxygenation (PaO_2/F_IO_2, 306±104 vs 157±71; p=0.004) compared with baseline, whereas no differences were observed within the standard treatment group. Severe complications occurred in 17 patients in the standard treatment group, vs 4 patients in the noninvasive continuous positive airway pressure group (p=0.002). Early 48-h mortality was 7% in the noninvasive continuous positive airway pressure group, compared with 24% in the standard treatment group (p=0.017); however, no sustained benefits were observed during the overall hospital stay. *Conclusion:* Noninvasive continuous positive airway pressure promotes early clinical improvement in elderly patients attending emergency departments for a severe pulmonary edema, but only reduces early 48-h mortality.

Keywords Cardiogenic pulmonary edema · Noninvasive ventilation · CPAP · Elderly patients

Introduction

The increase in life expectancy has led to a higher number of elderly patients seeking treatment for acute cardiogenic pulmonary edema over the past decades [1, 2, 3]. Congestive heart failure is by now the most common indication for hospital admission among older adults [4]. Although elderly patients constitute the majority of patients with acute cardiogenic pulmonary edema [5], they are often excluded from clinical trials of new therapeutic strategies [6, 7], or not always allocated optimal treatment if restrictions on health care resources are introduced [8]. As a result, the effectiveness of current therapies remains uncertain in this age group, which differs from younger patients with respect to sex ratio, underlying cardiomyopathy etiology, and precipitating

factors [6, 7, 9]. A combination of oxygen, furosemide, and nitrates is the standard treatment for pulmonary congestion, but the management of heart failure in elderly patients is also often complicated by associated illnesses as well as social and ethical concerns [8, 10].

Several studies have shown that noninvasive continuous positive airway pressure (CPAP) was beneficial for patients hospitalized in an intensive care unit (ICU) for acute cardiogenic pulmonary edema which failed to improve after conventional medical treatment, through improvement in gas exchange and decrease in the need for endotracheal intubation [11, 12, 13, 14]. Although the application of noninvasive CPAP, but also noninvasive pressure support ventilation, has received greater attention in recent years in such a setting of interest, serious drawbacks of such treatment are very few. Moreover, no studies have been adequately powered to address mortality [12, 15]. We therefore undertook a prospective, multicenter, randomized, and controlled study to compare the effectiveness of CPAP plus standard treatment with that of standard treatment alone, in elderly patients admitted to the emergency departments for acute cardiogenic pulmonary edema. The primary outcome variable was early 48-h mortality, i.e., mortality that could be directly related to emergency care, as we believed that for such patients, a rapid and short-term clinical improvement was the primary goal. Secondary outcome variables included clinical and physical parameters of respiratory distress improvement, the need for endotracheal intubation and/or mechanical ventilation, the occurrence of complications, the length of stay, and in-hospital mortality.

Methods

The appropriate review board ("Comité Consultatif de Protection des Personnes en Recherche Biomédicale"; CHU Brest) approved the study protocol, and all patients or their next of kin gave written informed consent.

Patient selection

The patients were enrolled from the emergency departments of one general and three teaching hospitals. Inclusion criteria were: (a) age $\geq$75 years; (b) acute hypoxemic respiratory failure, i.e., $PaO_2/F_IO_2 \leq$ 300 mm Hg despite oxygen $\geq$8 l/min for 15 min, respiratory rate $\geq$25 breaths/min, contraction of the accessory muscles of respiration; (c) clinical examination (systolic and/or diatolic hypertension; widespread crackles or wheezing), medical record (previous cardiomyopathy, and/or acute dyspnea with progressive orthopnea), electrocardiographic tracing (Q waves and/or abnormalities in the T wave and ST segment; left ventricular hypertrophy; bundle branch block; atrial fibrillation); and (d) chest radiography (cardiac enlargement with a cardiothoracic ratio>50%, and/or pulmonary congestion with Kerley B lines, alveolar filling, pleural effusions) compatible with the diagnosis of cardiogenic pulmonary edema. The combination of a normal electrocardiographic tracing and a normal chest radiography made a cardiac cause of dyspnea very unlikely. A cardiologist approved each diagnosis within a 15-min delay following admission, and an echocardiography was performed in cases of doubt to assess left ventricular ejection fraction calculation, regional contraction abnormalities, or diastolic dysfunction. Exclusion criteria were: (a) coma (Glasgow Coma Scale $\leq$7); (b) life-threatening hypoxemia (pulse oximetry $SpO_2 \leq$85% despite oxygen); (c) hemodynamic instability (systolic blood pressure $\leq$90 mm Hg despite optimal therapy); and (d) chronic respiratory insufficiency. F_IO_2 was measured using the same type of oxygen analyzer (MiniOX-I; Mine-Safety Appliances, Pittsburgh, Pa.) in all centers. The oxygen analyzer was introduced via a small hole in the oxygen mask.

The patients were assigned to standard treatment or CPAP by a phone call to a randomization center. The randomization protocol was computer generated and equalized in groups of ten patients.

Standard treatment

The investigators were not directly involved in the patients' treatment, but management guidelines were provided for both standard treatment and CPAP administration to ensure relatively uniform medical treatment. Oxygen was delivered through a face mask to achieve $SpO_2 \geq$92%, until the criteria for cessation were fulfilled ($SpO_2 \geq$92% without oxygen, respiratory rate $\leq$25 breaths/min). All patients received at least an initial 80 mg of intravenous furosemide and a continuous infusion of glyceryl-trinitrate (1 mg/h increase each 5 min, if systolic blood pressure $\geq$100 mm Hg). If the arterial carbon dioxide tension was $\leq$50 mm Hg, morphine could be given intravenously in 2-mg increments, up to 10 mg, as required for respiratory distress. After transfer to the general ward, patients were proposed to receive either 40 mg of furosemide, or twice the patient's normal dose daily; if any patient complaint of subsequent chest pain, sublingual nitroglycerin (600 µg) and orally isosorbide dinitrate (10–20 mg three times daily) were to be administered.

CPAP ventilation

The same type of CPAP device was used in all centers: (a) a Whisper-flow-1 (Caradyne, Galway, Ireland) delivering a high gas-flow (90–140 l/min), with adjustable F_IO_2 within the 35–100% range; (b) a 7.5-cm water-positive end-expiratory pressure valve (PEEP) [16, 17]; (c) a face mask; (d) a MR640 heated-humidifier (Fisher-Paykel, Auckland, New Zealand). The CPAP was given for at least 1 h, and as indicated, based on the patient's clinical response until the criteria for cessation were fulfilled (the same cessation criteria were used as applied for the oxygen group).

Parameters recording and follow-up

Physiological parameters, autonomy with regard to activities of daily living (ADL: 6=normal autonomy; 0: total dependence) [18], and baseline NYHA dyspnea evaluation were recorded on admission. Clinical and biological parameters, patient comfort, and dyspnea relief were recorded on admission, 1 h after inclusion, and between 12 and 24 h. Patients were queried about dyspnea relief (+2, marked improvement; +1, slight improvement; 0, no change; −1, slight deterioration; −2, marked deterioration) and their level of comfort under the mask (0: comfortable, 1: slightly uncomfortable, 2: uncomfortable, 3: intolerable). Facial skin necrosis, conjunctivitis, sinusitis, gastric distension, and pneumothorax, were also specifically monitored.

Criteria for endotracheal intubation

The criteria for endotracheal intubation requirement were predetermined: cardiac or respiratory arrest; severe hemodynamic instability

Table 1 Management decision after the occurrence of a serious complication in patients with acute cardiogenic pulmonary edema, during their emergency department stay, according to treatment randomization. Oxygen *standard treatment*, *CPAP* continuous positive airway pressure, *NIPSV* noninvasive pressure support ventilation

	Oxygen (n=46)	CPAP (n=43)	p value
Limitation of treatment	4 (9)	0	0.14
Endotracheal intubation	4 (9)	2 (5)	0.74
NIPSV	2 (4)	2 (5)	0.66
Switch to CPAP	8 (17)	–	–

Data are number of patients; numbers in parentheses are percentages

(defined as a systolic blood pressure <80 mmHg, and/or the administration of epinephrine or norepinephrine), refractory and/or progressive hypoxaemia (defined as a pulse oximetry SaO_2 of less than 92% despite oxygen mask), clinical signs of respiratory exhaustion (active contraction of the accessory muscles of respiration, with paradoxical abdominal motion), coma or seizures (Glasgow Coma Scale of 7 or less), and agitation requiring sedation.

Criteria for treatment failure: serious complications

The occurrence of criteria for endotracheal intubation, or death within the 48 h of admission (see above), where considered as serious complications and treatment failures. In such cases, the patient was withdrawn from the protocol and the decision to initiate life-sustaining resources (endotracheal intubation and mechanical ventilation) or to limit therapies, if presumed futile or non-beneficial, was left up to the treating physician. Cross-over to CPAP and NIPSV were not defined in the study protocol (Table 1).

Statistical analysis

A 180-patient sample size was chosen to detect a difference between 20% early 48-h mortality in the standard treatment group and 5% in the CPAP group (α=5%; 1-β=80%) [19]. Values are reported as mean±SD. All statistical analysis were performed on an intention-to-treat basis. Continuous variables were compared by repeated-measures analysis of variance (ANOVA). χ^2 or Fisher's tests were used to compare categorical variables. Kaplan-Meier curves for survival rate were plotted during the entire follow-up and compared with the log-rank test. The p values for statistical tests were two-tailed. Independent factors associated with outcome were analyzed by a Cox regression model and used to adjust treatment comparisons. In multivariate analysis, ADL index, NYHA evaluation, cardiomyopathy, and precipitating factors were assessed in addition to baseline physiological parameters. A value of $p \leq 0.05$ was considered significant [20], but the significance level for primary outcome was $p \leq 0.03$ owing to a planned interim analysis [21].

Results

The study was suspended after the interim analysis, as early 48-h mortality was significantly lower in the CPAP group, and the complication rate was higher in the standard treatment group. Eighty-nine patients were available for analysis (46 in the standard treatment group and 43 in the CPAP group). The follow-up was completed for all patients (Fig. 1). No differences in either baseline characteristics or outcome were observed within the enrollment centers. All patients received the assigned treatment.

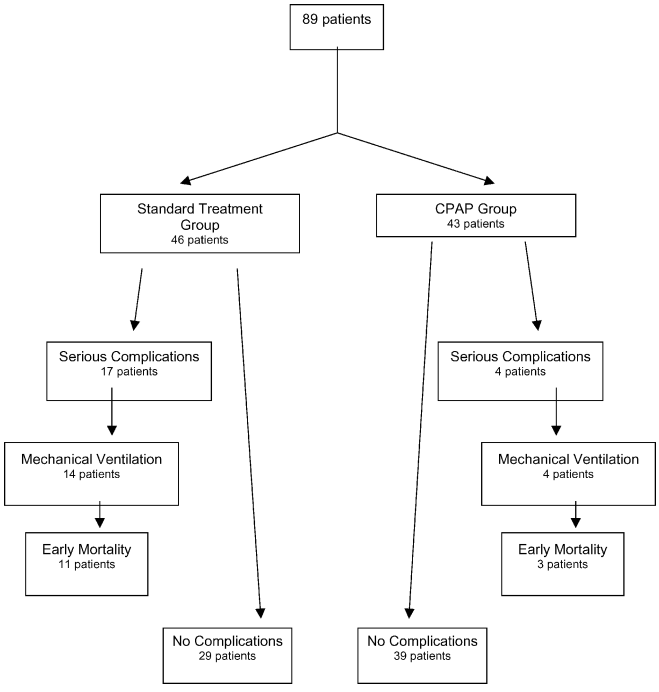

Fig. 1 Overview of enrollment and follow-up of elderly patients with acute cardiogenic pulmonary edema

Patient characteristics

The patients' baseline physiological and clinical characteristics are listed in Table 2. They were equally distributed among the two groups, except for the NYHA classification. Eighty percent of the patients already had a diagnosed cardiac insufficiency at the time of admission. Pre-existing cardiac diseases were mainly ischemic and mixed. When identified, the main precipitating cause of pulmonary edema was a respiratory tract infection. Initial echocardiographic findings from 59 patients were systolic heart failure in 69% cases and a predominant diastolic heart failure for the others. No patients had advanced directives and chose to stop medical treatment during their subsequent hospital stay. No patients were retrospectively found to be suffering from any other disease.

Table 2 Baseline characteristics of 89 elderly patients with acute cardiogenic pulmonary edema at inclusion, according to randomization. *NYHA* New York Heart Association functional classification

Patient characteristics	Oxygen (*n*=46)	CPAP+oxygen (*n*=43)	*p* value
Demographic age (years; mean±SD)	84±6	84±6	0.66
Males	18 (39)	19 (44)	0.63
Autonomy score (mean±SD)	5±1	5±1	0.16
History pre-existing heart disease			
Ischemic	15 (33)	17 (40)	0.50
Hypertensive	6 (13)	6 (14)	0.90
Valvular	3 (7)	1 (2)	0.34
Mixed	12 (26)	11 (26)	0.96
NYHA classification			
I–II	32 (70)	20 (47)	0.41
I–IV	7 (15)	16 (37)	0.02
Cause of plmonary eema			
Respiratory tract infection	19 (41)	11 (26)	0.12
Tachyarrhythmia	2 (4)	6 (14)	0.12
Acute ischemic heart disease	6 (13)	7 (16)	0.67
Other and miscellaneous	19 (41)	19 (44)	0.78
Echocardiographic findings			0.93
Systolic heart failure	21 (70)	20 (69)	
Diastolic heart failure	9 (30)	9 (31)	
Prior hospitalization for a 6-month period (mean±SD)	0.5±0.8	0.4±0.7	0.49

Data are mean±SD for continuous variables, and number of patients (numbers in parentheses are percentages) for discrete variables
Other and miscellaneous causes of pulmonary edema: fluid overload, hypertensive, etc., undiagnosed
Echocardiographic findings: data were available for 59 patients

Table 3 Evolution of physiological parameters, according to random assignment to treatment in elderly patients with acute cardiogenic pulmonary edema

	Baseline		1 h		12 h		24 h	
	Oxygen (*n*=46)	CPAP (*n*=43)	Oxygen (*n*=43)	CPAP (*n*=41)	Oxygen (*n*=36)	CPAP (*n*=37)	Oxygen (*n*=23)	CPAP (*n*=33)
Respiratory rate (mean±SD, breaths/min	36±7	35±6	31±8	27±7	26±7	25±7	22±6	23±7
p value	0.47		<0.001		0.17		0.78	
Heart rate (mean±SD, beats/min)	108±20	104±24	103±18	89±20	92±22	88±15	90±16	91±19
p value	0.67		0.004		0.69		0.53	
Mean blood pressure (mean±SD, mm Hg)	108±25	111±27	94±20	97±20	88±14	88±15	86±14	92±15
p value	0.59		0.61		0.99		0.17	
PaO_2/F_IO_2, (mean±SD)	167±73	157±71	199±85	306±104	215±103	238±103	251±94	244±94
p value	0.41		<0.001		0.41		0.53	
$PaCO_2$, (mean±SD, mm Hg)	51±19	49±13	47±16	42±10	43±11	43±11	42±11	43±9
p value	0.60		0.11		0.55		0.88	
Arterial pH, (mean±SD)	7.31±0.10	7.32±0.11	7.37±0.08	7.38±0.07	7.42±0.08	7.42±0.07	7.43±0.06	7.42±0.05
p value	0.93		0.36		0.95		0.71	

CPAP ventilation

The CPAP was applied for 8±6 h. All patients assigned to the CPAP group completed the first ventilation period of 1 h. Twelve hours or more of CPAP were required for 8 patients. There were no complications attributable to CPAP, and no patient felt any discomfort.

Evolution of physiological parameters

At 1 h, patients assigned to CPAP exhibited a higher PaO_2/F_IO_2 ratio than those assigned to standard treatment alone (306±104 vs 199±85; $p<0.001$). In 7 patients in the standard treatment group and 20 in the CPAP group, the PaO_2/F_IO_2 ratio returned to normal ($\geq$300) after 1 h of treatment ($p=0.001$; Table 3).

No differences were observed between the evolution of clinical and physiological parameters for hypercapnic

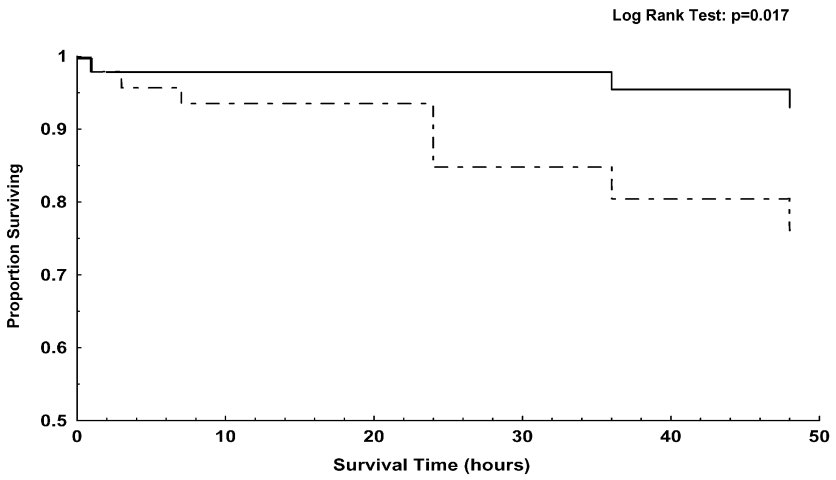

Fig. 2 Survival time, according to treatment randomization, of elderly patients with acute cardiogenic pulmonary edema. The percentage of patients who survived is expressed over time in each randomization group. Early 48-h mortality was significantly lower in the CPAP group (7 vs 24%; p=0.017)

Table 4 Outcome of treatment, according to randomization, in elderly patients with acute cardiogenic pulmonary edema

Outcome	Oxygen (n=46)	CPAP (n=43)	p value
Initial improvement in PaO_2/F_IO_2	24 (52)	34 (79)	0.008
PaO_2/F_IO_2 >300 at 1 h	7 (15)	20 (47)	0.001
Clinical improvement (dyspnea score)	24 (52)	36 (84)	0.002
Serious complications	17 (37)	4 (9)	0.002
Ventilatory assistance	14 (30)	4 (9)	0.01
48-h mortality	11 (24)	3 (7)	0.017
In-hospital mortality	14 (30)	12 (28)	0.8
Death within the emergency department	10 (22)	3 (7)	0.05
Death within the general ward	4 (9)	9 (21)	0.19
In-hospital length of stay (mean±SD, days)			
Among all patients	9±7	12±11	0.07
Among survivors	10±4	13±8	0.20
Among non-survivors	6±10	12±17	0.30

Data are number of patients (numbers in parentheses are percentages)

patients ($PaCO_2 \geq$45 mm Hg for 20 of 46 patients in the standard treatment group and in 22 of 43 in the CPAP group; p=0.13). Individual carbon dioxide arterial pressure on admission did not affect outcome.

At 1 h of CPAP, the patients assigned to this treatment had lower respiratory and heart rates than those assigned to oxygen therapy alone (p<0.001 and p=0.004).

Outcome of treatment

Early 48-h mortality was significantly lower in the CPAP group (7 vs 24%; p=0.0017; see Fig. 2; Table 4). Subjective clinical improvement (dyspnea score) was observed in 24 patients in the standard treatment group, and 36 in the CPAP group (p=0.002).

Seventeen patients in the standard treatment group and 4 patients in the CPAP group experienced serious complications (p=0.002), which mainly occurred during the first 12 h of management: cardiac arrest for 5 patients in the standard treatment group vs 2 patients in the CPAP group (p=0.3); neurological failure (coma) in 11 patients in the standard treatment group vs 1 patient in the CPAP group (p<0.003); acute hypoxemic respiratory failure worsening for 1 patient in each group. As a result, ventilatory support was initiated for 14 patients in the standard treatment group (4 were intubated, 2 were treated by noninvasive pressure support ventilation, and 8 were switched to CPAP), and 4 patients in the CPAP group (2 were intubated and 2 were treated by noninvasive pressure support ventilation; p=0.01). Five of the 8 patients switched to CPAP were improved clinically in less than 1 h. Four other patients in the standard treatment group whose treatment had failed were considered for treatment limitation, after discussion with both their relatives and the clinical staff from the different centers. One of these patients died subsequently in the emergency department, 1 patient died within a 72-h period in the general ward, and the 2 other patients survived. Overall mortality was not different in the two groups and mainly related to the initial pulmonary edema. From the multivariate analysis, no factors (neither baseline medical status and autonomy score, nor precipitating factors and physiological parameters on admission) were shown to affect outcome.

Discussion

The results of this study show that in elderly patients (mean age 84±6 years), noninvasive CPAP promotes early clinical and physiological improvement within the first hour of treatment, whereas no differences were observed in patients assigned to the standard treatment group within the same period. The CPAP also allowed a reduction in early 48-h mortality and in the occurrence of severe complications. Due to the significant drop in the complication rate and the achievement of our main objective (early mortality decrease), the study was suspended after the interim analysis.

Although ICU resources and intensive treatments are often denied to elderly patients [8], it is clear that age as such is a poor predictor of medical outcome [22, 23, 24], and that the effects on health cannot be assessed by mortality rates alone, especially in this age group. Improving the quality of life and obtaining a short-term clinical benefit such as dyspnea relief for example, are considered by many clinicians to be the main objectives in the management of elderly patients. In this study, CPAP was associated with a significantly greater improvement in PaO_2/F_IO_2 ratio and dyspnea within the first hour, than standard treatment alone (Table 3). Similar oxygenation and clinical benefits have already been observed with CPAP in other clinical or short-term physiological studies [12, 13, 14]. The early 48-h mortality (7 vs 24%; p=0.017), and serious complications rates were lower (4 vs 17%; p=0.002; Table 4). According to these results, we certainly believe that elderly patients with acute respiratory failure related to cardiogenic pulmonary edema should be supported by CPAP in early emergency medical care, while efforts should be undertaken to reverse the acute process and gather further information about the patient's preferences regarding life care.

Although early clinical improvement is a worthy goal in itself, these beneficial results must, however, be tempered by the lack of any sustained benefit, as also observed in other studies [12, 15]. A meaningful benefit should include both a decrease in mortality and morbidity, whereas a short-term mortality benefit that is ultimately erased by the time of discharge may just be a way of delaying the inevitable. As this study was not powered to detect a difference in overall mortality and was prematurely stopped, further larger studies are required to address this approach before recommending the routine use of CPAP in this setting.

As the precipitating cause of respiratory distress in this study was a respiratory tract infection in most patients, it could be argued that once the edema was resolved in the CPAP group, the underlying respiratory infection was the reason for the ongoing hypoxemia. In this case, CPAP has already been demonstrated by Delclaux et al. not to have any benefits on patients with hypoxemic respiratory failure [16]. This could be a sufficient reason for suggesting the use of a noninvasive pressure support ventilation (i.e., modes with an actively assisted inspiration), rather than CPAP alone, in such situations. Noninvasive pressure support ventilation could also be proposed as a first issue in hypoxemic patients with hypercapnia, and presumed respiratory muscle failure; however, initial $PaCO_2$ levels did not influence the final outcome in our study. In fact, $PaCO_2$ decreased in most hypercapnic patients, both in the CPAP and standard treatment groups (as already observed by Bersten et al. [2].

Our study has several important drawbacks; the main one is that the treatment was unblinded, with the possibility of a bias either on the part of the investigators, clinicians, or patients. As it was, of course, impossible to conceal the administered treatment, it was initially decided that the investigators would not be involved in the clinical decision of attempting to avoid such a bias. A cross-over of 8 patients from the oxygen group to CPAP was therefore observed, which may also have affected the late outcome and hospital mortality; thus, the sustained benefit for patients assigned to the CPAP group may have been missed. A second important drawback involves the potential difficulties and false diagnosis concerning the clinical definitions of the cause of acute pulmonary edema. Due to the particular setting of our study and the study population including elderly patients, no hemodynamic parameters measurements other than echocardiography were made available. As a result, guidelines were provided to clinicians for both diagnosis and medical treatment. Each cardiogenic pulmonary edema diagnosis was initially validated by a senior cardiologist with or without echocardiography, and the analysis was performed on an intention-to-treat basis. The overall diagnosis procedure among the patients included in the study, however, represents the "real-life" situation, which is the usual cardiogenic pulmonary edema management in the emergency department. The last important drawback of this study is that the patients were transferred to general wards after an initial 12–24 h treatment, and thus we did not have data on the treatment intensity and the in-ward decisions to sustain intensive therapies. As previously stated, the definitions of futility and benefit from treatments are subjective, and value-laden terms [25, 26], and may vary widely, according to the different goals of treatment in general wards; however, management guidelines were also provided after transfer from the emergency department and general wards physicians' were not involved in the study, to avoid discrepancy between both study groups.

Conclusion

In conclusion, the results of this multicenter, randomized study confirms that noninvasive CPAP improves early 48-h survival rate in elderly patients hospitalized in emergency wards for acute respiratory failure related to cardiogenic pulmonary edema. The CPAP also promotes early clinical and oxygenation improvement; however, the lack of sustained benefits may soften the enthusiasm when recommending the use of CPAP in routine practice.

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