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Performances of CPAP Devices With an Oronasal Mask

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BACKGROUND: The aim of this bench study was to investigate the performances of 8 devices for noninvasive CPAP. METHODS: Eight devices for noninvasive CPAP with an orofacial mask were studied: Ventumask, Ventumask 30, EasyVent, EasyVent Emergency, Compact Model II, Flowone, Superflow, Boussignac CPAP valve. Each device was tested at oxygen input flows from 5 to 20 L/min, and the output gas flow was measured in static conditions. Each device was evaluated during a eupneic and a tachypneic simulated breathing test. RESULTS: The gas output flow generated by each device increased with higher oxygen input flow; EasyVent and Flowone produced the highest output flow ($P < .001$). At the simulated eupneic breathing test, Superflow and EasyVent showed a more stable pressure swing at different PEEP levels, whereas the other masks had a greater swing, between 10 and 15 cm H_2O PEEP ($P = .002$ for all pairwise comparisons). During the tachypneic breathing test, the pressure swing was stable with Flowone and EasyVent ($P = .055$), whereas it had increased with other masks ($P = .002$ for all pairwise comparisons). CONCLUSIONS: We found a significant variation in the performances of the 8 CPAP devices examined in this study. The technical characteristics and limitations of different CPAP devices should be considered when using in patients with hypoxemic acute respiratory failure. *Key words: CPAP; mechanical ventilation; respiratory failure; hypoxemia; orofacial mask; effectiveness; efficacy.* [Respir Care 0;0(0):1–•. © 0 Daedalus Enterprises]

Introduction

Noninvasive CPAP is a widely used ventilation technique to improve oxygenation.[1,2] CPAP devices provide a specific level of positive pressure during the respiratory cycle to prevent alveolar collapse and increase lung volume.[3] Recently, several devices for short-term use have been made available; these are capable of delivering CPAP at different pressure levels while only requiring a gas source to be operated. These devices are ideal for use in settings such as extra-hospital or intra-hospital emergencies, which allows positive-pressure respiratory assistance in patients who are not intubated.[4] The level of CPAP is determined in most devices by an adjustable or fixed PEEP valve, and the total gas flow is essential to ensure a stable pressure level throughout the respiratory cycle,[3] with a minimum flow of 60 L/min generally required in patients with an increased respiratory demand.[4] This study compared 8 devices for noninvasive CPAP with an orofacial mask. Seven devices used the Venturi effect to generate flow: Ventumask (Starmed, Mirandola, Italy), Ventumask 30 (Starmed), EasyVent (Dimar, Mirandola, Italy), EasyVent Emergency (Dimar), Compact Model II (Harol, San Donato Milanese, Italy); Flowone (Deas, Castelbolognese, Italy), and Superflow

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Dr Servillo discloses a relationship with Deas. The other authors have disclosed no conflicts of interest.

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(Deas). One device, the Boussignac CPAP valve (Vygon, Ecouen, France), used the Bernoulli principle with a virtual valve effect.[3]

The aim of this study was to investigate the performances of these 8 CPAP devices in terms of effectiveness, defined as evaluation of output flow generation in static conditions, and of efficacy, defined as airway pressure swing, namely the difference between inspiratory and expiratory pressures during simulated spontaneous breathing with eupneic and tachypneic respiratory patterns. We hypothesized that the effectiveness and efficacy were different in the tested devices. The work was performed at the University of Naples Federico II, Naples, Italy.

QUICK LOOK

Current knowledge

Noninvasive CPAP is the most commonly used ventilation technique in prehospital and emergency settings; its benefits in patients with hypoxemic acute respiratory failure are well known.

What this paper contributes to our knowledge

The results of the static and dynamic tests performed indicated that the Dimar and Deas devices showed the best performance in terms of output flow generation and pressure swing around the imposed PEEP level compared with the Starmed, Harol, and Boussignac CPAP devices. The characteristics and the limitations of different CPAP devices should be considered when used in patients with hypoxemic acute respiratory failure.

Methods

Devices

Eight devices for noninvasive CPAP with orofacial mask were studied (Fig. 1): Ventumask, Ventumask 30, EasyVent, EasyVent Emergency, Compact Model II, Flowone, Superflow, and Boussignac CPAP valve. These devices operate with a single external oxygen source, and some also have an additional oxygen source, located downstream from the air-entrainment valve, that may be used to increase F_{IO_2}. The characteristics of the masks evaluated in the present study are shown in Table 1. The Boussignac CPAP valve system is the only commercially available device that does not incorporate an air-entrainment Venturi system: this device consists of a small cylinder that, when receiving the oxygen, the flow generates a turbulence, which thus acts as a virtual PEEP valve and results in a positive airway pressure. All other CPAP systems use the Venturi effect to entrain room air and generate a high output flow, and an adjustable or calibrated mechanical PEEP valve is used to set the desired positive pressure level.

Experimental Setting

Output Flow Generation. An oxygen source was connected to the devices and a flow meter, which measures the air flow generated by the CPAP device, was positioned downstream from the air-entrainment valve. A rapid response oxygen analyzer ($MaxO_2$+AE; Maxtec, Salt Lake City, Utah) was placed at the side port of the devices to evaluate the delivered F_{IO_2}. Each device was tested at increasingly higher oxygen source flows, from 5 L/min up to 20 L/min in 4 steps. The primary outcome was the output-flow generation (effectiveness) of the different CPAP devices; the secondary outcome was the airway inspiratory-expiratory pressure swing (efficacy) during simulated spontaneous eupneic and tachypneic respiratory patterns. Pressure swing (Δp) was defined as the difference between inspiratory and expiratory airway pressure around the CPAP level and was considered as an indicator of the work of breathing.[2]

Static Test. Each mask was evaluated at 4 increasing levels of PEEP (5, 10, 15, and 20 cm H_2O) obtained with adjustable valves and a pressure manometer that measured the actual pressure inside the device. Each device was evaluated for generated output flow with a flow meter analyzer (Fluke Biomedical, Cleveland, Ohio), F_{IO_2} and with pressure that started from 5 L/min of oxygen to 20 L/min, according to the recommendations of the manufacturer.

Simulated Breathing Test. Each device was evaluated during simulated spontaneous breathing by using a lung model (Deas). Each mask was connected to a pneumatic lung simulator with a preset respiratory frequency, volume and inspiratory-expiratory ratio while generating a sinusoidal flow. A pressure transducer, F_{IO_2} analyzer, and flow analyzer were serially connected. Two breathing patterns were investigated: (1) eupneic breathing with a volume of 500 mL, rate of 20 breaths/min, minute volume of 10 L/min, and inspiratory-expiratory ratio 1:2; (2) tachypneic breathing with volume size of 800 mL, rate of 30 breaths/min, minute volume of 24 L/min, and inspiratory-expiratory ratio 1:1. Each device was tested for 2 min of uninterrupted simulated breathing.

Statistical Analysis

Data were reported as mean ± SD. All data were analyzed by averaging 3 replicates from each experiment. Normality was assessed with the D'Agostino-Pearson omnibus test. The total gas flow generated by different devices was compared with a 2-way analysis of variance.

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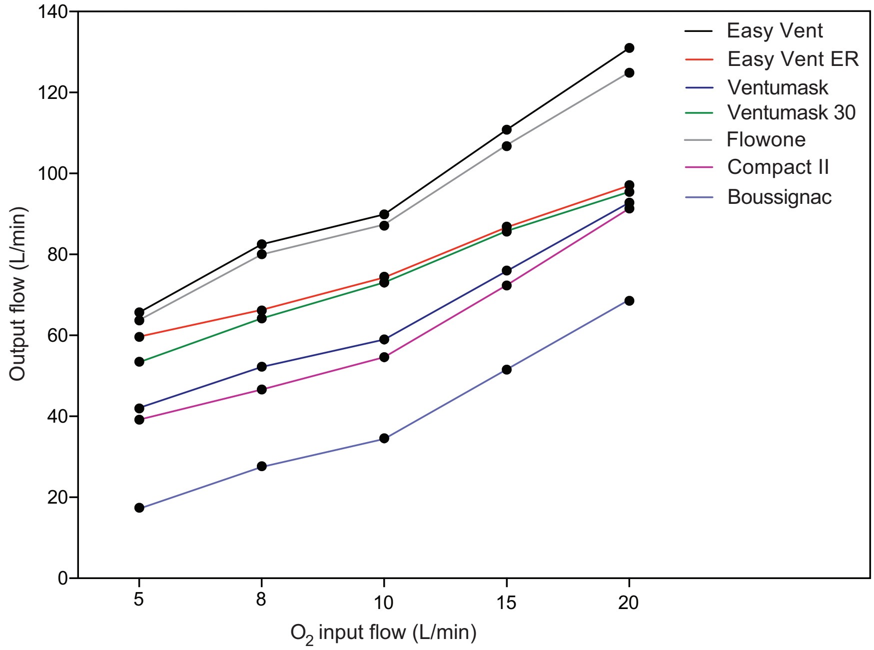

Fig. 1. Output flow generated by each device according the O_2 input flow.

Table 1. Characteristics of Different CPAP Devices Included in the Study

Device	Venturi Device	Concentration of O_2 (%)*	Feed With Flow A + Flow B	Maximum Flow Delivered (L/min)†	Adjustable PEEP Valve	PEEP Level (cm H_2O)
Easy Vent	+	33–100	+	120	+	5, 10, 15, 20
Easy Vent Emergency	+	33	– (only flow A)	120	+	5, 10, 15, 20
Ventumask	+	40, 50, 60, 100 (with a minimum O_2 flow of 42 L/min)	+	60	+	5, 7.5, 10, 12.5
Ventumask 30	+	30, 40, 50, 60, 100 (with a minimum O_2 flow of 40 L/min)	+	80	+	5, 7.5, 10, 12.5, 15, 20
Flowone	+	30	+	122	–	
Superflow	+	30–60	+	122 L/min	+	5, 10, 15, 20
Compact Model II	+	40–70	+	77 L/min	+	5, 10, 15
Boussignac	–	30, 50, 100	–	NA	–	2, 4, 5, 7, 10 (according to the delivered flow)

* Concentration of O_2 approximately reached.
† As declared by the manufacturer.
NA = not applicable
+ = present
− = absent
Flow A = Main flow
Flow B = Adjunctive flow

The relationship between the oxygen input flow and generated air-flow output of each device was investigated with a linear regression analysis. Pressures obtained at the static and dynamic tests were compared by using the Kruskal-Wallis test with Dunn post hoc analysis. All statistical analyses were performed by using SPSS version 21 (IBM, Armonk, New York), and significant at $P < .05$.

Results

Output Flow Generation

The gas output flow generated by each device increased with higher O_2 flow input (Fig. 1). The results of the linear regression are reported in Table 2. The Dimar EasyVent

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Table 2. Output Flow Generation Performance of Each Tested Device

Device	Slope (95% CI)	Intercept	r^2
Easy Vent	0.219–0.238	−10.4	0.99
Ventumask	0.292–0.306	−7.6	0.99
Ventumask 30	0.334–0.418	−16.3	0.98
Flowone	0.231–0.259	−11.1	0.99
Superflow	0.331–0.456	−9.4	0.98
Easy Vent Emergency	0.357–0.435	−19	0.98
Compact Model II	0.27–0.3	−5.6	0.99
Boussignac	0.287–0.293	0.008	1

Results are from the linear regression of the output flow generated vs the input flow.

and Deas Flowone produced the greatest output flow at each O_2 input flow compared with the other devices (Dimar Easy Vent output flow generation 5, 10, 15, and 20 L/min input flow: 65.6, 8.71, 90.6, 110.9, and 132.1 L/min. Deas Flowone output flow generation 5, 10, 15, and 20 L/min input flow: 63.7, 80.5, 86.4, 107.1, and 125.7 L/min).

Static Test

The masks evaluated at 4 levels of PEEP (5, 10, 15, and 20 cm H_2O) with oxygen input flow of 20 L/min are shown in Figure 2. At 20 L/min, the Dimar EasyVent and Deas Flowone generated the highest output flow at each PEEP level (output flows at each PEEP level of Dimar EasyVent vs Deas Flowone, $P = .99$), even if Deas Flowone output flow decreased at 40 L/min with 20 cm H_2O of PEEP level. The Deas Flowone had the highest increase of F_{IO_2} at 15 and 20 cm H_2O of PEEP (F_{IO_2} 39.3% and 55%, respectively). The performances of all the masks evaluated at 4 levels of PEEP (5, 10, 15, and 20 cm H_2O) with oxygen source flows of 10 and 30 L/min are shown in the supplementary materials (see http://www.rcjournal.com).

Simulated Breathing Test

The airway pressure swing (Δp) during simulation of eupneic and tachypneic breathing patterns is shown in Figure 3. During the eupneic breathing pattern test, the Deas Superflow and Dimar EasyVent showed a more stable Δp at different PEEP levels (Deas Superflow Δp: 2.38, 2.98, and 4.33 cm H_2O; and Dimar EasyVent Δp: 2.80, 3.03, 4.03, and 3.68 cm H_2O at 5, 10, 15 and 20 cm H_2O PEEP, respectively), whereas the other masks had a greater swing between 10 and 15 cm H_2O of PEEP (Dimar EasyVent Emergency Δp: 9.9 and 7.3 cm H_2O; Starmed Ventumask Δp: 6.6 and 4.3 cm H_2O; Starmed Ventumask 30 Δp: 3.9 and 6.1 cm H_2O; Deas Flowone Δp: 4.3 and 2.9 cm H_2O; Harol Compact Model II Δp: 6.3 and 7 cm H_2O; Vygon Boussignac Δp: 0.8 and 1.1 cm H_2O at 5, 10, 15, and 20 cm H_2O PEEP, respectively) ($P = .002$ for all pairwise comparisons).

With the tachypneic breathing pattern test, Δp was stable between the Deas Flowone and Dimar EasyVent (Deas Flowone Δp: 13.7, 14.8, 14.7, and 16.6 cm H_2O; and Dimar EasyVent Δp: 6.3, 7.1, 7.9, and 10.8 cm H_2O at 5, 10, 15, and 20 cm H_2O PEEP, respectively) ($P = .055$ for all pairwise comparisons), whereas Δp increased with other masks ($P < .001$ for all pairwise comparisons). The inspiratory and expiratory pressures during eupneic and tachypneic breathing pattern simulations are shown in the supplementary materials (see http://www.rcjournal.com). During the eupneic breathing pattern test, Flowone had the highest inspiratory pressure than the other devices (Deas Flowone inspiratory pressure: 3.3, 7.2, 11.4, and 13.9 cm H_2O at 5, 10, 15, and 20 cm H_2O PEEP, respectively) ($P < .001$ for all paired comparison), whereas, with tachypnea breathing, the Deas Flowone and Dimar EasyVent Emergency had the highest inspiratory pressure Deas Flowone inspiratory pressure: 1.1, 5.5, 9.2, and 14.7 cm H_2O; and Dimar EasyVent Emergency inspiratory pressure: 12.4, 15.5, 16.8, and 16.6 cm H_2O at 5, 10, 15, and 20 cm H_2O PEEP, respectively) ($P < .001$ for all paired comparison). The expiratory pressures were not different during both breathing pattern simulations.

Discussion

Main Findings

In this bench study, we found that (1) the capability to deliver an adequate output flow was different among the CPAP devices, and (2) the devices showed different performances in eupneic and tachypneic simulated breathing conditions. CPAP devices are compact and easy-to-use systems[5] that have been shown to delay or avoid intubation in acute respiratory failure due to cardiac and noncardiac conditions, in both prehospital and hospital settings.[5,6] A recent meta-analysis that included 8 randomized trials showed that the prehospital use of CPAP reduced mortality and the risk for intubation compared with standard care, whereas the effectiveness of prehospital bi-level inspiratory positive airway pressure was uncertain.[7,8]

From this perspective, CPAP may play a major role for the treatment of acute respiratory failure.[4,7] Because different CPAP devices have recently been marketed, it is important for the medical staff to know the individual performance of different brands, and thus identify the best tools to be applied in specific populations of patients. The strength of our study was that, to our knowledge, this was the first bench comparison of the effectiveness and efficacy of 8 different CPAP devices, including the Boussignac system. The Boussignac system is the most studied

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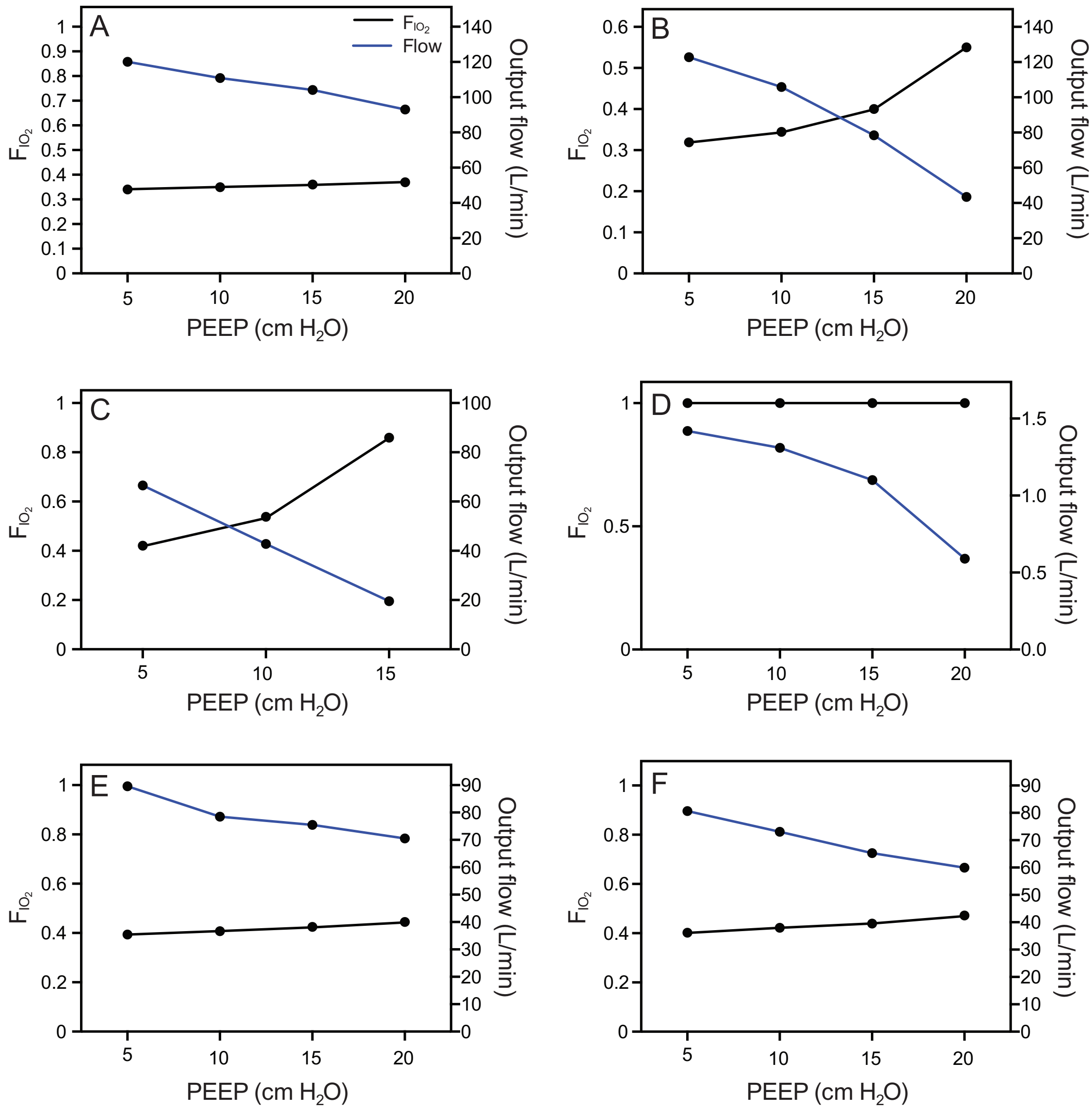

Fig. 2. Static test for each device performed with 4 levels of PEEP (5, 10, 15, and 20 cm H_2O) with oxygen source flows of 20 L/min. (A) Easy Vent. (B) Flowone. (C) Compact II. (D) Boussignac. (E) Ventumask 30. (F) Ventumask.

CPAP device.[3] There is limited literature that compares different devices based on the Venturi system. One study compared 3 CPAP masks,[9] whereas our study evaluated 8 devices.

In the present study, the efficiency of the devices was compared based on oxygen flow needed to generate a minimum air flow of 60 L/min at each CPAP setting, generally required in patients with an increased respiratory demand.[4,8] In this study, the Dimar EasyVent and Deas Flowone generated an output flow of 60 L/min with 5 L/min of O_2 input flow and an output flow of 120 L/min with 20 L/min of input flow. Probably because of the different experimental setting, these results are slightly different from those reported by Brusasco et al[9] in which the Dimar EasyVent generated an output flow of <60 L/min with 5 L/min of O_2 input flow.

The static test aimed to evaluate the performances of the devices in developing adequate output flow by using the Venturi system; the generated flow linearly decreased, whereas F_{IO_2} increased at higher PEEP.[10] According to Brusasco et al[9], at increased PEEP levels, from 5 to 20 cm H_2O at 15 L/min of O_2 input flow, the O_2 output flow of the Starmed devices dramatically decreased, and F_{IO_2} increased up to 45%, whereas the Dimar EasyVent mask kept a stable F_{IO_2} of 40%, with a decreasing O_2 output flow.[9]

The devices were tested with 10, 20, 30 L/min of O_2 input flow and CPAP levels from 5 to 20 cm H_2O. Inter-

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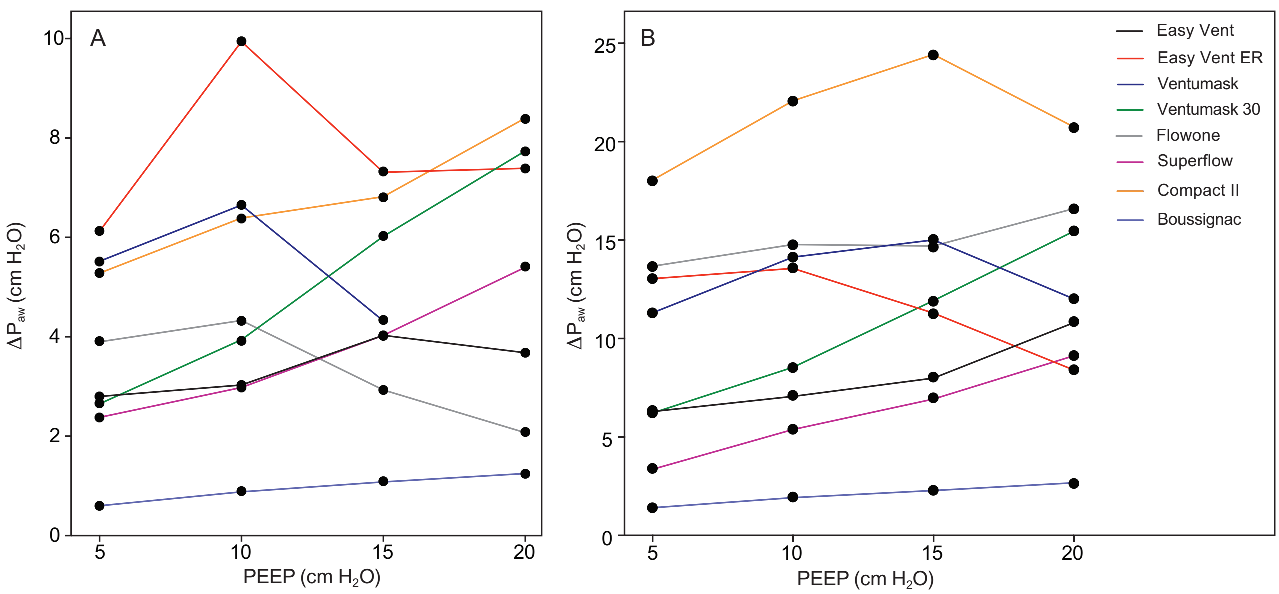

Fig. 3. The change in airway pressure (ΔP_{aw}) during the eupneic breathing (A) and tachypneic breathing (B).

estingly, at 10 L/min of O_2 input flow, we found that all devices, except the Boussignac system, markedly decreased the output flow, from 60 to 20 L/min. At 20 L/min, only the Dimar devices and the Starmed Ventumask kept the O_2 output flow of >60 L/min for all PEEP, whereas the Deas Flowone kept the O_2 output flow at >60 L/min only with PEEP of <15 cm H_2O.

Clinical Implications

A good CPAP device should maintain constant positive pressure during the respiratory cycle to be able to reduce the work of breathing.[10] The respiratory muscles activity during CPAP results in fluctuations in the airway pressure around the imposed PEEP level, therefore, a greater pressure swing is associated with increased respiratory effort.[11] Moreover, the additional work of breathing may induce respiratory muscle fatigue and discomfort in patients with acute respiratory failure.[12] With regard to these premises, the majority of devices included in this study may not adequately assist patients because these devices showed a huge fluctuation of the airway pressures around the imposed PEEP level. During the eupneic and tachypneic breathing pattern simulations, the Dimar Easyvent, Deas Flowone, and Superflow showed the lowest pressure swing around the imposed PEEP level, which suggested a better ability to reduce the work of breathing. However, these results should be confirmed in clinical studies.

CPAP devices are mainly used in patients with acute respiratory failure and respiratory distress. The inspiratory pressure of the CPAP devices, according to our results in physiologic breathing simulation, was always above zero. Even during the stressful breathing test, 3 devices (Harol Compact Model II, Starmed Ventumask, and Boussignac) showed an inspiratory pressure of less than zero. A positive pressure maintained during the inspiratory phase may decrease the inspiratory effort and, thus, the work of breathing in patients with acute respiratory failure.[13]

Limitations

Our findings should be interpreted in the context of several limitations. First, this was an in vitro study, thus clinical studies are needed to confirm our results. Second, during breath simulation, we chose only 2 breathing patterns, which did not reproduce the broad spectrum of clinical conditions that can affect patients. Third, Starmed and Harol masks are now available in North America, Australia, and New Zealand, whereas Dimar and Deas masks were only recently introduced in the market. Fourth, the Deas Superflow, with the same characteristics of Deas Flowone but with the addition of a PEEP valve, was evaluated only in the breathing simulation tests.

Conclusions

As a result of the static and dynamic tests performed, we found a relevant variation in the effectiveness and efficacy of the 8 CPAP devices included in this study. The Dimar and Deas devices showed the best performance in terms of output flow generation and pressure swing around the imposed PEEP level compared with Starmed, Harol, and Bous-

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signac CPAP devices. The characteristics and limitations of different CPAP devices should be considered when used in patients with acute respiratory failure.

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