Noninvasive CPAP With Face Mask: Comparison Among New Air-Entrainment Masks and the Boussignac Valve

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BACKGROUND: The performances of 2 noninvasive CPAP systems (high flow and low flow air-entrainment masks) were compared to the Boussignac valve in 3 different scenarios. METHODS: Scenario 1: pneumatic lung simulator with a tachypnea pattern (tidal volume 800 mL at 40 breaths/min). Scenario 2: Ten healthy subjects studied during tidal breaths and tachypnea. Scenario 3: Twenty ICU subjects enrolled for a noninvasive CPAP session. Differences between set and effective CPAP level and F_{IO_2}, as well as the lowest airway pressure and the pressure swing around the imposed CPAP level, were analyzed. The lowest airway pressure and swing were correlated to the pressure-time product (area of the airway pressure curve below the CPAP level) measured with the simulator. P_{aO_2} was a subject's further performance index. RESULTS: Lung simulator: Boussignac F_{IO_2} was 0.54, even if supplied with pure oxygen. The air-entrainment masks had higher swing than the Boussignac ($P = .007$). Pressure-time product correlated better with pressure swing (Spearman correlation coefficient [ρ] = 0.97) than with lowest airway pressure ($\rho = 0.92$). In healthy subjects, the high-flow air-entrainment mask showed lower difference between set and effective F_{IO_2} ($P < .001$), and lowest airway pressure ($P < .001$), compared to the Boussignac valve. In all measurements the Boussignac valve showed higher than imposed CPAP level ($P < .001$). In ICU subjects the high-flow mask had lower swing than the Boussignac valve ($P = .03$) with similar P_{aO_2} increase. CONCLUSIONS: High-flow air-entrainment mask showed the best performance in human subjects. During high flow demand, the Boussignac valve delivered lower than expected F_{IO_2} and showed higher dynamic hyper-pressurization than the air-entrainment masks. *Key words: devices; equipment; development and evaluation/technology assessment; PEEP; CPAP; noninvasive ventilation.* [Respir Care 2013;58(2):305–312. © 2013 Daedalus Enterprises]

Introduction

CPAP is a useful technique in a wide range of respiratory failures, such as acute cardiogenic pulmonary edema,[1] immunodeficiency-related pneumonia,[2] or postoperative complications of abdominal surgery.[3–6] Noninvasive CPAP rapidly diminishes dyspnea and work of breathing, and it improves gas exchange and vital parameters,[7] often reducing the need for endotracheal intubation.[8]

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In the last few years CPAP face masks have been used in out-of-hospital emergency situations in patients with acute cardiogenic pulmonary edema.[9,10] Several countries have a technician-based emergency system with properly trained staff able to recognize and treat acute cardiogenic pulmonary edema with noninvasive CPAP devices.[11] CPAP face masks make the emergency transport of patients needing positive pressure easier than mechanical ventilators and other cumbersome devices, because they are small, light, and handy.[12] The early application of CPAP therapy in respiratory failure in these scenarios may prevent the deterioration of clinical conditions before the patient reaches the emergency department,[13] and several studies showed that CPAP is as effective as CPAP plus pressure support in the treatment of acute cardiogenic pulmonary edema.[14,15] A reliable and effective CPAP system is a key factor to its use in the emergency setting. Some important features of an ideal CPAP system include that set parameters, like CPAP level and F_{IO_2}, should coincide with the ones actually supplied to the patient; the system also has to maintain a stable F_{IO_2} even during maximum effort, and should reduce the patient's work of breathing, avoiding inspiratory depressurization and fluctuations around the preset CPAP level.[16,17]

This study was aimed to test 2 new noninvasive CPAP face masks (high-flow and low-flow air-entrainment mask) in comparison with a widely used device (ie, Boussignac valve) by evaluating reliability and efficacy in different stress conditions, with a lung simulator, in healthy subjects and in ICU patients during weaning from mechanical ventilation.

QUICK LOOK

Current knowledge

CPAP is a useful technique in a wide range of respiratory diseases, including acute cardiogenic pulmonary edema and immunodeficiency-related pneumonia. Noninvasive CPAP reduces dyspnea and work of breathing, improves gas exchange, and reduces the need for endotracheal intubation. Devices for noninvasive CPAP vary widely in characteristics and performance.

What this paper contributes to our knowledge

Three CPAP devices (Boussignac CPAP valve, and StarMed air-entrainment face masks with high and low flow CPAP valves) were evaluated in a lung model, in normal volunteers, and in patients with respiratory failure. The StarMed high and low flow CPAP valve systems demonstrated greater consistency in F_{IO_2} and maintained a more consistent airway pressure. The effects of device performance on patient outcomes remain to be determined.

Methods

Devices

Two types of air-entrainment mask with a preset mechanical CPAP valve (Ventumask, StarMed, Mirandola, Italy) and the Boussignac CPAP valve (Vygon, Écouen, France) with a standard face mask were studied (Fig. 1). The air-entrainment mask is a face mask geared with a non-traumatic, inflatable cushion and a precalibrated CPAP valve with an overpressure safety system. The circuit is equipped with an air-entrainment valve able to supply a predefined F_{IO_2} level using 2 different sources of oxygen. The first one passes through the air-entrainment valve, where it is mixed with environmental gases, while the second oxygen flow inlet is engaged downstream from the valve. The air-entrainment system, generating a pressure difference between the inner and outer compartments of the circuit, allows the system to increase the total flow supplied to the subject.

Two different types of air-entrainment mask were tested: the low-flow mask provides a total flow of 51–64 L/min, while the high-flow mask provides 58–75 L/min, both with a total amount of oxygen flow of 15–27 L/min. Tables provided by the manufacturer indicate, for each level of CPAP, the oxygen flows needed in order to obtain the desired F_{IO_2}.

The Boussignac CPAP valve is a light-weight, handy, and easy to use small plastic cylinder (5.5 cm long, 1.3 cm internal diameter) fittable in a standard face mask (Hudson

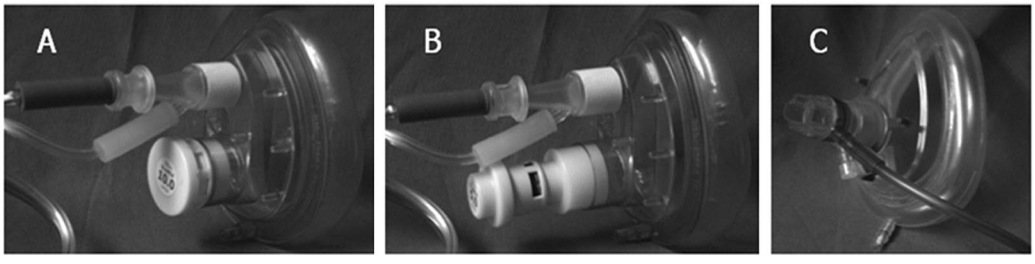

Fig. 1. A: High-flow air-entrainment mask. B: Low-flow air-entrainment mask. C: Boussignac CPAP valve.

RCI, Research Triangle Park, North Carolina). Four microchannels in the wall of the valve transform the gas flow in high-velocity micro-jets, which in turn generate a positive pressure resulting from the entrained air, like a "virtual valve." The Boussignac valve is a validated device in hypoxemic respiratory failure.[10,18,19] Within the Boussignac the CPAP level depends on the delivered oxygen flow[20]; moreover, the F_{IO_2} cannot be set a priori; according to experimental studies, it is generally > 0.9 in eupneic subjects (tidal volume 500 mL, breathing frequency $\leq$ 25 breaths/min).[21]

The different face masks were all tested for air leaks: the absence of a pressure drop was an essential feature to assess the devices without the confounding effect of preanalytical errors. Then adequate mask size was chosen before each human subject session.

Experimental Scenarios

Scenario 1. A pneumatic lung simulator with a preset frequency and excursion, generating a sinusoidal flow pattern, was used. A plastic hollow cube, expressly drilled (Teknik, Ossona, Italy), was interposed between the piston and the different masks. During lung simulator study the pattern was set to simulate tachypnea: 40 cycles/min with 800 mL. Both the air-entrainment mask systems were evaluated at 3 levels of CPAP (5, 7.5, and 10 cm H_2O) and at different values of F_{IO_2} (0.4 and 0.5 for low-flow mask, 0.4, 0.5, 0.6 for high-flow mask), adjusting the gas flow mixtures according to the instructions provided by the manufacturer. The Boussignac CPAP valve was set at CPAP of 5, 7.5, and 10 cm H_2O, using 22, 27, and 30 L/min of oxygen, respectively, according to the experimental findings by Templier et al.[21] Three measures were taken for each device; the average value was then used in the comparisons.

Scenario 2. Once we obtained the local ethics committee permission and informed consent, 10 healthy volunteers were recruited. All the subjects tested the 3 devices according to a computer-generated random order. Each volunteer, in sitting position, first performed 15 seconds of breaths at tidal volume, then 15 seconds of deep and fast breaths as hyperventilation (Fig. 2). Pressure curves were registered for each mask at every CPAP and F_{IO_2} level as used during the lung simulator study, for a total of 18 measurements (9 with high-flow mask, 6 with low-flow mask, 3 with Boussignac CPAP valve).

Scenario 3. ICU patients were recruited after meeting the criteria for weaning from mechanical ventilation (resolution of disease for which the patient was intubated, cardiovascular stability with no need or minimal vasopressors, no continuous sedation, adequate oxygenation [defined as $P_{aO_2}/F_{IO_2} \geq 150$ mm Hg with PEEP $\leq$ 8 cm H_2O], and $P_{aCO_2} < 50$ mm Hg).[22] Exclusion criteria were Glasgow coma scale < 14 and facial surgery. Once we obtained informed consent, soon after the extubation, they were submitted to 2 subsequent trials of 15 min noninvasive CPAP with high-flow mask and Boussignac, separated by a 30 min resting time. The first device to be used was randomly assigned for every subject before the protocol. Both the high-flow mask and the Boussignac were set at CPAP of 5 cm H_2O and F_{IO_2} of 0.5.

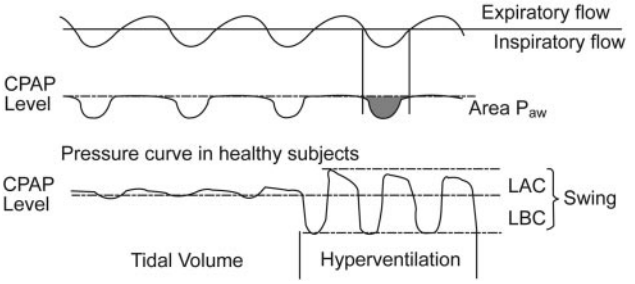

Fig. 2. Traces of respiratory curves. Area P_{aw} = area of the airway pressure curve below the CPAP level. LAC = level above CPAP due to dynamic hyper-pressurization. LBC = minimum airway pressure level below CPAP. Swing = airway pressure oscillation around the CPAP level.

Measurements

Data were collected through an analog to digital converter at a sample rate of 200 Hz and stored for subsequent analysis by means of dedicated software (Colligo, Elekton, Milan, Italy). Because the baseline conditions for each scenario were different, the experimental protocols and some of the measurements used for the comparisons were adapted.

Scenario 1. The gas flow was measured with a pneumotachograph (Fleisch 2, Fleisch, Lausanne, Switzerland) positioned between each face mask and the lung simulator. Before each session the pneumotachograph was calibrated as described by Tang et al.[23] Airway pressure was measured by a pressure transducer connected to a standard multiparametric monitor (M1046A, Hewlett-Packard, Palo Alto, California). F_{IO_2} was measured at the side port of each device[6] through a rapid oxygen analyzer (Handi, Maxtec, Salt Lake City, Utah). The measured variables were the difference between set and measured F_{IO_2}, the lowest pressure under the set level of CPAP (level below CPAP), the maximal airway pressure oscillation (pressure swing), and the area of the airway pressure curve below the CPAP level (area P_{aw}), considered as an indirect index of work of breathing (see Fig. 2).[24] Area P_{aw} was then used as the reference standard to test the discriminative capacity of both the level below CPAP and the pressure swing to

Table 1. F_{IO_2} at Airways on Pneumatic Lung Simulator* and Healthy Subjects During Tests

		ΔF_{IO_2}, median (IQR)		*P*	Absolute F_{IO_2} With Boussignac CPAP Valve
		High Flow Mask	Low Flow Mask		
Pneumatic lung simulator		−0.07 (−0.08 to −0.06)	−0.10 (−0.13 to −0.08)	.04†	0.54 (0.50 to 0.56)
Healthy subjects	Normal breaths	0.01 (−0.01 to 0.02)	0.07 (0.05 to 0.09)	< .001†	0.84 (0.78 to 0.92)
	Hyperventilation	−0.14 (−0.20 to −0.10)	−0.09 (−0.12 to −0.05)	< .001†	0.51 (0.44 to 0.60)
P for normal breaths versus hyperventilation		< .001†	< .001†		< .001†

* Pneumatic lung simulator at 40 cycles/min with tidal volume of 800 mL.
† Via Wilcoxon rank sum test.
ΔF_{IO_2} = difference between set and measured F_{IO_2}.

assess the work of breathing. A Spearman correlation between each indicator and the area P_{aw} was used to describe the ability of the prediction. During the whole respiratory sequence, the increase in airway pressure at the end of expiration was named the level above CPAP.

Scenario 2. In healthy subjects the indexes that we considered were the difference between set and measured F_{IO_2}, the airway pressure swing, the level below CPAP, and the level above CPAP.

Scenario 3. In ICU subjects, 3 parameters were taken into account: P_{aO_2}, breathing frequency, and pressure swing. For each human subject, airway pressure and F_{IO_2} were measured with the same methods used with the simulator, placing the transducers inside the face masks. A measure of total air leakage was performed by the operator with a verbal numerical rating scale based on tactile sensitivity, ranging from 0 (no air leakage) to 10 (highest air leakage).[25]

Sample Size and Statistical Analysis

Based on preliminary observations, 10 healthy subjects and 20 ICU subjects were necessary to detect, with a 0.8 power, a significant difference ($\alpha = .05$) on airway pressure swing at tidal volume ventilation. The distribution of each continuous variable was initially tested with the Shapiro-Wilk test for normality. Results are expressed as mean ± SD when normally distributed, or as median and interquartile range if not. Comparisons of data obtained from the 3 different systems were performed by analysis of variance with the Scheffé multiple-comparison test or by Kruskal-Wallis test, when appropriate. Comparisons between 2 variables were performed by the Student *t* test or Wilcoxon rank sum test, when appropriate. Spearman correlations were made to examine the relationship between the variables. A $P < .05$ was considered significant. The analysis was carried out using statistical software (Stata 9.2, StataCorp, College Station, Texas).

Results

Lung Model

With the lung simulator the difference between set and effective F_{IO_2} was lower with high-flow mask than with low-flow mask (Table 1). F_{IO_2} comparison was not performed for the Boussignac CPAP valve, since it is not possible to set any a priori value, but a relevant decrease from the supposed value[21] was observed (see Table 1).

The minimum airway pressure level below CPAP was lower in both the air-entrainment mask systems, compared to the Boussignac CPAP valve (Table 2). The airway pressure swing was greater with high-flow mask and low-flow mask than with Boussignac CPAP valve (see Table 2). A tidal volume ventilation pattern (16 cycles/min × 400 mL) was tested before each tachypnea session (data not shown), and the results were similar to that observed in healthy subjects. Statistically significant correlations were observed between both the area P_{aw} ($\rho = 0.97$) and the level below CPAP ($\rho = 0.92$) with the airway pressure swing (Fig. 3).

Human Studies

Healthy Subjects. Ten volunteers were tested (Table 3). Air leaks were absent in all the tested devices. Measurements and statistical comparisons were made for every level of CPAP (5, 7.5, and 10 cm H_2O) at every considered F_{IO_2}, finding no differences in pressures and measured F_{IO_2} among these sets. We then decided, for the sake of simplicity, to put together all the measurements, even if referred to different settings.

The median and IQR difference between measured F_{IO_2} at tidal volume and during hyperventilation was greater with the Boussignac CPAP valve (−0.34, IQR −0.45 to −0.14), compared to both low-flow mask (−0.17, IQR −0.20 to −0.12, $P < .001$) and high-flow mask (−0.15, IQR −0.22 to 0.10, $P < .001$.) No statistically significant differences were observed between the 2 mask systems ($P = .39$).

Table 2. Indexes of Efficacy Measured on Lung Model at 40 Cycles/Min With Tidal Volume of 800 mL

	Pressure, median (IQR), cm H_2O			*P*			
	High Flow Mask	Low Flow Mask	Boussignac CPAP Valve	All 3 Devices*	High Flow vs Low Flow Mask†	High Flow Mask vs Boussignac CPAP Valve†	Low Flow Mask vs Boussignac CPAP Valve†
LBC, cm H_2O	−0.10 (−0.12 to −0.07)	−0.10 (−0.13 to −0.09)	−0.02 (−0.03 to −0.01)	.06	.04	.01	.12
Swing, cm H_2O	0.11 (0.08 to 0.13)	0.14 (0.13 to 0.16)	0.07 (0.07 to 0.08)	.007	.03	.02	.02
LAC, cm H_2O	0.01 (0.01 to 0.01)	0.03 (0.03 to 0.04)	0.04 (0.04 to 0.05)	< .001	.001	.01	.02
Area P_{aw}, cm H_2O·s	−0.02 (−0.03 to −0.01)	−0.03 (−0.04 to −0.02)	−0.01 (−0.01 to 0.00)	.02	.09	.052	.02

* Via Kruskal-Wallis test
† Via Wilcoxon rank sum test
LBC = minimum airway pressure below CPAP
Swing = airways pressure oscillation around the CPAP level
LAC = pressure above CPAP due to dynamic hyper-pressurization
Area P_{aw} = negative pressure-time product measured as the area of pressure curve below the CPAP level from the beginning to the end of an inspiratory cycle.

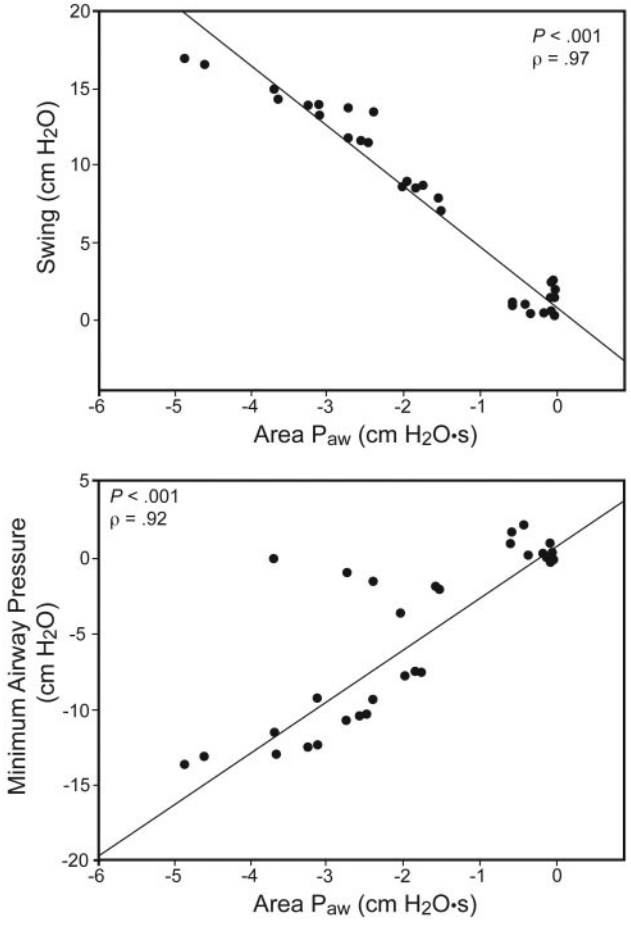

Fig. 3. Lung simulator correlations between the area of the airway pressure curve below the CPAP level (ie, the negative pressure-time product measured as the area of pressure curve below CPAP level from the beginning to the end of an inspiratory cycle, area P_{aw}) and the minimum airway pressure level below CPAP (LBC) and the airway pressure oscillation around the CPAP level (swing). LBC = minimum airway pressure level below CPAP. ρ = Spearman correlation coefficient.

Table 3. Case Mix of the Human Studies

		Healthy Subjects (*n* = 10)	ICU Subjects (*n* = 20)
Male, no. (%)		5 (50)	14 (70)
Age, y		28 ± 5	68 ± 12
Weight, kg		62 ± 11	79 ± 29
Height, cm		171 ± 11	165 ± 8
Normal breaths	f, breaths/min	21 ± 4	
	V_T, mL	509 ± 209	
Hyperventilation	f, breaths/min	47 ± 14	
	V_T, mL	847 ± 282	
Admission Type, no. (%)			
Medical			4 (20)
Scheduled surgical			14 (70)
Unscheduled surgical			2 (10)
Stay, median (IQR) d			2 (2–10)
SAPS II score			30 ± 16
COPD, no. (%)			11 (55)

Values are mean ± SD unless otherwise indicated.
f = breathing frequency
V_T = tidal volume
SAPS = Simplified Acute Physiology Score

Both high-flow mask (−11.2 cm H_2O, IQR –13.5 to −9.0 cm H_2O) and low-flow mask (−11.0 cm H_2O, IQR –13.4 to −9.0 cm H_2O) showed a lower level below CPAP, compared to the Boussignac CPAP valve (−5.5 cm H_2O, IQR −8.1 to −3.1 cm H_2O, $P < .001$, Fig. 4). The airway pressure swing during tidal-volume ventilation was higher with the low-flow mask (1.9 cm H_2O, IQR 1.1 to 2.7 cm H_2O) and the Boussignac CPAP valve (2.2 cm H_2O, IQR 1.6 to 2.6 cm H_2O), compared to the high-flow mask (0.5 cm H_2O, IQR 0.3 to 0.6 cm H_2O, $P < .001$). During hyperventilation the high-flow mask (10.1 cm H_2O, IQR

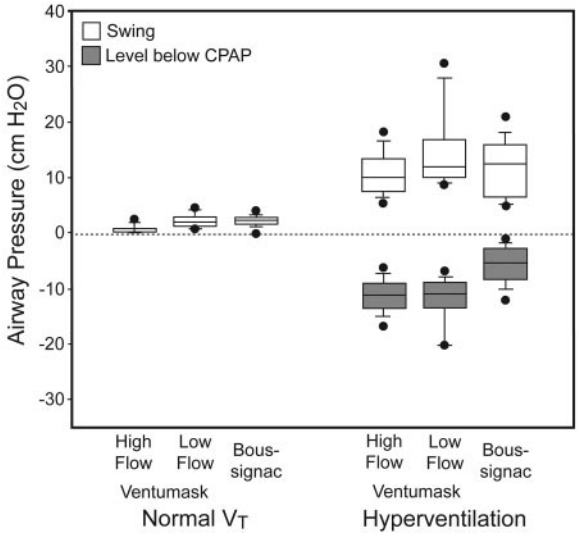

Fig. 4. Human study (healthy subjects): efficacy of the 3 devices; level below CPAP and airway pressure swing in tidal volume and hyperventilation. The white bars indicate the swing values. The shaded boxes indicate the level below CPAP values. The horizontal lines within the bars indicate the medians. The top and bottom borders of the boxes indicate, respectively, the 75th and the 25th percentiles. The top and bottom whiskers indicate, respectively, the 95th and the 5th percentiles of the distribution. Outliers are indicated by black dots. See Table 1 for *P* values.

7.4 to 13.2 cm H_2O) showed a lower airway pressure swing than the low-flow mask (11.9 cm H_2O, IQR 10.1 to 16.6, $P < .001$), with no differences with the Boussignac CPAP valve (12.2 cm H_2O, IQR 6.6 to 15.1 cm H_2O, $P = .40$, see Fig. 4).

The level above CPAP was significantly higher with the Boussignac CPAP valve than with either air-entrainment mask, both during tidal-volume ventilation and hyperventilation. At tidal-volume ventilation: Boussignac CPAP valve 2.5 cm H_2O, IQR 2.2 to 2.8 cm H_2O; high-flow mask 0.1 cm H_2O, IQR –3.1 to 0.5 cm H_2O; low-flow mask −0.5 cm H_2O, IQR –2.6 to 1.2 cm H_2O ($P < .001$). During hyperventilation: Boussignac CPAP valve 6.1 cm H_2O, IQR 4.4 to 9.0 cm H_2O; high-flow mask 1.0 cm H_2O, IQR –2.1 to 1.7 cm H_2O; low-flow mask 2.5 cm H_2O, IQR 0.5 to 6.4 cm H_2O ($P < .001$).

ICU Subjects. Twenty subjects were enrolled (see Table 3). Air leaks were absent in all the tested devices. Both the high-flow mask and the Boussignac CPAP valve increased blood oxygenation, compared to the basal values: P_{aO_2}/F_{IO_2} increased from 172.2 ± 45.8 mm Hg to 283.2 ± 105.6 mm Hg with the Boussignac CPAP valve ($P = .002$), and to 277.6 ± 99.2 mm Hg with the high-flow mask ($P = .001$), without differences between the 2 systems ($P = .97$). No significant differences were found between the breathing frequency values in basal conditions and at the end of each 15 min trial (basal 19 ± 6 cycles/min, high-flow mask 20 ± 6 cycles/min, Boussignac CPAP valve 19 ± 6 cycles/min, $P = .89$). Airway pressure swing was significantly lower with the high-flow mask (0.76 ± 0.09 cm H_2O) than with the Boussignac CPAP valve (1.02 ± 0.08 cm H_2O, $P = .03$).

Discussion

The aims of respiratory failure treatment are the correction of hypoxia and the reduction of work of breathing. We studied the ability to fulfill these aims with 3 different noninvasive CPAP systems, during normal breathing and during maximal respiratory stress obtained with high volumes and rates: this "in vitro and in vivo" approach allowed us to explore the technical performances of these devices, simulating a wide range of clinical situations. The in vitro hyperventilation pattern was similar to the breathing of healthy subjects who hyperventilated and maximized the stress of the systems we compared, although in the clinical setting the subjects more frequently present with a rapid shallow breathing.

The air-entrainment mask systems prevented a considerable F_{IO_2} fall as the breathing frequency increased, and allowed a flow-independent regulation of F_{IO_2} due to the air-entrainment system. Since the work of breathing during CPAP is mostly determined by the fluctuations of the airway pressure around the imposed CPAP level, any swing results in an increased respiratory effort.[26] As a proxy of the in vivo work of breathing, we used the airway pressure swing rather than the level below CPAP, because it considers the amount of isometric work required to return to the baseline level of CPAP at the beginning of each breath. This choice was supported by the better correlation with area P_{aw}, as we found in the lung simulator scenario.

Both of the masks (high flow more than low flow) maintained the CPAP level closer to the set one better than the Boussignac in all the human conditions we tested, under mild or severe stress.

A 10-fold difference in the magnitude of the pressure swing was noted between the healthy subjects and the ICU subjects. This gap is due on the one side to a likely reduced respiratory functional capacity of patients[27]: they were older, with high prevalence of COPD, and frequently recovering from general anesthesia. On the other hand, the healthy subjects were asked to breathe deep and fast, while the ICU subjects maintained their own spontaneous respiratory pattern.

F_{IO_2} Benchmark

In the healthy subjects the F_{IO_2} drop registered between tidal-volume respiration and simulated tachypnea was significantly higher with the Boussignac CPAP valve. This difference may be due mainly to the mismatch between the

delivered gas flow and the amount demanded by the subject during valve functioning. The virtual expiratory valve of the Boussignac opens immediately when inspiration begins and the system becomes open to the environment. Then, the higher the inspiratory peak flow, the greater the inlet of air, with a resulting decrease of F_{IO_2}. This phenomenon could have some relevance in staging the degree of hypoxia during tachypnea, leading to a wrong consideration of a patient's oxygenation (ie, S_{pO_2}) due to an F_{IO_2} that is lower than expected. A "super" Boussignac system has in fact recently been proposed to overcome this problem.[28]

Regarding the comparisons of relative F_{IO_2} differences, the high-flow mask performed slightly better than the low-flow one. This result, even if statistically significant only in the bench study, could be related to the relatively smaller diameter of the low-flow mask valve, which creates an excessive downstream resistance, preventing the in-flow of all the gas needed, as reported by the manufacturer instructions. Despite the differences observed in the bench results and in the healthy subjects in terms of F_{IO_2}, no differences of P_{aO_2} or breathing frequency were observed in subjects, yet depression was more important, suggesting a greater respiratory effort. This could have been because CPAP with face mask was performed as primary prophylaxis for post-extubation complications in subjects who had already met the criteria for weaning from mechanical ventilation and extubation. In this particular population, P_{aO_2} and breathing frequency, although useful clinical indexes, lack adequate sensitivity to detect a significant difference between the devices. Thus, the present data need to be confirmed by studies in acute respiratory failure settings.

Pressure Benchmark

Our observations suggest a clinical role for high-flow mask in reducing work of breathing, relevant both as a first line treatment in respiratory failure and at the weaning from mechanical ventilation; the difference in performance between the high-flow mask and the Boussignac CPAP valve decreased in the stress condition, though not reaching statistical significance, because of the high spread of swing values. The smaller depressurization associated with a similar airway pressure swing, shown by the Boussignac CPAP valve when compared to the masks, may be justified by a dynamic hyper-pressurization due to the resistance offered by the virtual expiratory valve to the expiratory flow. This flow-dependent behavior of the Boussignac CPAP valve suggests that during the expiratory phase additional work is required for expiratory muscles to overcome the increased system resistance. Between the mask systems, the high flow (whose expiratory valve has larger diameter) does not hyper-pressurize, maintaining a lower pressure swing, in comparison to the low-flow mask. This level above CPAP due to dynamic hyper-pressurization could worsen the load conditions of the respiratory muscles, producing a mechanical disadvantage and determining undesired hemodynamic effects like decreased venous return and increased right ventricular work load.

Both of the masks need a significantly lower supply of oxygen flow than the Boussignac CPAP valve to maintain the same pressure within the circuit. This advantage could be useful for managing patients in settings with limited oxygen availability, like out-of-hospital situations.

Limitations of the Study

The main limitations of the present study are the absence of esophageal pressure monitoring to describe the work of breathing in the human studies, and the lack of airway resistance measurement in both the human and bench studies. In preliminary test simulations the esophageal balloon caused an increase of air leaks in the face mask systems, so derivative and indirect indexes of work of breathing were adopted. Another limitation of this study is the duration of the period at high breathing frequency, which was shorter than a respiratory failure-driven tachypnea.

Conclusions

In conclusion, according to the tests performed on both the simulator and human subjects, the high-flow mask seemed to be the most effective device: it maintained a more stable F_{IO_2} and showed a smaller pressure swing, compared to the other 2 tested devices. Particularly during high flow demand, the Boussignac CPAP valve demonstrated an unexpected expiratory hyper-pressurization that could worsen the load conditions of respiratory muscles, determining an increase of the work of breathing. Because of these reasons, the Boussignac CPAP valve—even if handy and light-weight—proved to be less reliable in terms of F_{IO_2} supply and CPAP stability.

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