

Continuous Positive Airway Pressure during Fiberoptic Bronchoscopy in Hypoxemic Patients

A Randomized Double-Blind Study Using A New Device

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Fiberoptic bronchoscopy (FOB) may worsen oxygenation and clinical status in severely hypoxemic patients. We conducted a prospective, randomized double-blind trial to compare the delivery of continuous positive airway pressure (CPAP) as a tool for maintaining oxygenation during FOB, to the delivery of oxygen only. Thirty consecutive patients who needed FOB for diagnostic purposes were enrolled. Their arterial oxygen pressure (P_{aO_2}) to inspired oxygen fraction (F_{IO_2}) ratio was below 300 mm Hg. CPAP was generated by a simple new device open to the atmosphere. During FOB and the 30 min thereafter, pulse oximetry values (Sp_{O_2}) were significantly higher in the CPAP than the Oxygen group ($95.7 \pm 1.9\%$ versus 92.6 ± 3.1 , $p = 0.02$). The lowest Sp_{O_2} values were observed in the Oxygen group ($93.5 \pm 2.4\%$ versus 88.6 ± 3.4 , $p = 0.002$). Arterial blood gases 15 min after FOB showed that P_{aO_2} had increased in the CPAP group and decreased in the Oxygen group ($\Delta P_{aO_2} = +10.5\% \pm 16.9$ versus $-15\% \pm 16.6$, $p = 0.01$). Five patients in the Oxygen group, but none in the CPAP group, developed respiratory failure in the 6 h after FOB and required ventilatory assistance ($p = 0.03$). We conclude that in hypoxemic patients, the use of a new CPAP device during FOB allowed minimal alterations in gas exchange and prevented subsequent respiratory failure.

Since its introduction in the late 1960s, fiberoptic bronchoscopy (FOB) has been increasingly used for diagnostic and therapeutic purposes. Because arterial oxygen tension (P_{aO_2}) usually decreases by 10 to 20 mm Hg after uncomplicated bronchoscopy, severe hypoxemia in nonintubated patients is an accepted contraindication to bronchoscopy. The American Thoracic Society recommends avoiding bronchoalveolar lavage (BAL) in spontaneously breathing patients with hypercapnia or hypoxemia that cannot be corrected to at least a P_{aO_2} of 75 mm Hg or to oxygen saturation greater than 90% with supplemental oxygen (1). In these situations, the option is either to attempt treatment on an empiric basis, or to perform endotracheal intubation and mechanical ventilation if this diagnostic procedure seems an absolute necessity.

This limitation has prompted the development of techniques of respiratory support to make the FOB procedure safer for hypoxemic or critically ill patients, without using invasive ventilation. In one open study, the investigators described the application of noninvasive positive-pressure ventilation to eight severely hypoxemic immunosuppressed patients during bronchoscopy (2). FOB was well tolerated by all these patients and no complications related to the procedure were noted, despite a very low baseline ratio of P_{aO_2} to fraction of inspired oxygen (P_{aO_2}/F_{IO_2}).

It has been shown that continuous positive airway pressure (CPAP) applied via a full-face mask can be effective in recruiting alveoli and increasing the efficiency of gas exchange in hypoxemic patients (3). We therefore designed a simple open system, based on the generation of positive airway pressure by a jet, for use on a face mask. As this CPAP device remains open to the atmosphere, it allows easy maintenance of a positive mask pressure and CPAP delivery while FOB is being performed. Using this device, we compared in severe hypoxemic patients tolerance of FOB without and with CPAP, which was delivered through a full-face mask.

METHODS

The study design was approved by the local Ethics Committee (Comité de Protection des Personnes dans la Recherche Biomédicale) and signed informed consent was obtained from all participating patients before the procedure.

Study Population

Adult patients were recruited in different departments and intensive care units (ICUs) of the Henri Mondor Hospital, a tertiary care university referral hospital with 1,028 beds and eight ICUs. Patients were considered eligible for the study if they met two criteria: (1) need for FOB for diagnosis purposes, and (2) hypoxemia, defined by $P_{aO_2} \leq 125$ mm Hg under a high F_{IO_2} mask driven by 10 L/min oxygen (Rush Medical, Bourg en Bresse, France). Patients were not included if any of the following criteria was present: (1) recent (less than 1 wk) acute myocardial infarction; (2) pH below 7.30; (3) $P_{aCO_2} > 60$ mm Hg; (4) $P_{aO_2} \leq 50$ mm Hg under an F_{IO_2} mask driven by 10 L/min oxygen; (5) platelet counts $< 30 \cdot 10^9/L$; (6) systolic blood pressure < 80 mm Hg; (7) encephalopathy or coma; and (8) indication for transbronchial biopsy.

Study Design and Measurements

The design of the study is shown in Figure 1. When the inclusion criteria were met and written informed consent had been obtained from the patient, F_{IO_2} was measured in a high F_{IO_2} mask, using a portable O_2 analyzer (Miniox I; MSA, Pittsburgh, PA).

The high F_{IO_2} mask was then removed and a full-face mask (Peters Laboratories, Bobigny, France) was installed over the patient's face and connected to a disposable standard-sized CPAP device (Vygon Laboratories, Ecoen, France), allowing the delivery of pressure by constant-flow oxygen insufflation (Figure 2). Four funnel-shaped microchannels are included in the wall of this device and connected to an external opening connected to the oxygen source. These microchannels generate high-velocity microjets, which in turn generate the pressure resulting from the air entrainment mechanism thus created. The device has a second opening allowing simple oxygen delivery without positive pressure. Experimental studies in a lung model and in humans have demonstrated the efficacy of a similar system for generating and maintaining positive pressure in endotracheal tubes (4, 5). Because our device remains open to the atmosphere, it allows bronchoscopy to be performed through the device and the mask, without modifying the jet flow or the resulting pressure (Figure 2).

The pressure in the mask was continuously monitored in the mask throughout the procedure, using a differential pressure transducer (± 140 cm H_2O ; MP45; Validyne, Northridge, CA). The two connectors of the system were connected with 3-meter-long tubings, but only one

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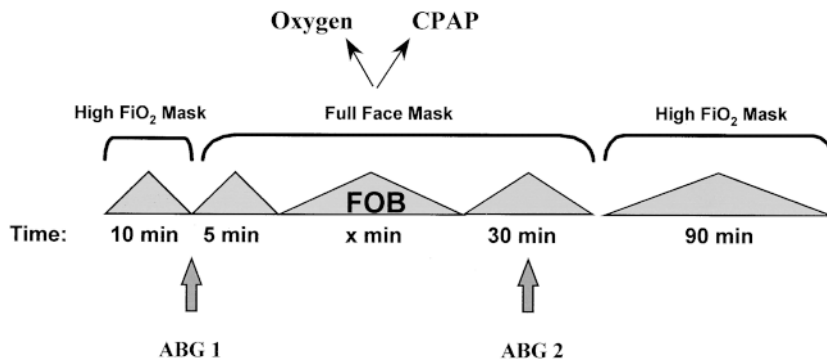


Figure 1. Design of the study. During the inclusion period (at least 20 min), the patient wore a high F_{iO_2} mask, driven by 10 L/min oxygen. Clinical parameters were recorded and arterial blood gases (ABG 1) measured. The high F_{iO_2} mask was then replaced by a full-face mask connected to the device and zero or positive pressure was generated. After 5 min with the full-face mask, fiberoptic bronchoscopy (FOB) was performed, and the full-face mask was left in place for 30 min after FOB. A second ABG measurement (ABG 2) was performed during this period (15 min after FOB). The full-face mask was then replaced by the high F_{iO_2} mask driven by 10 L/min oxygen.

of them was connected to the oxygen wall source. Randomization was performed and, depending on the random choice, either zero or positive pressure was generated with the CPAP device, depending on the site connected to the oxygen source. To keep the pressure groups comparable, randomization was stratified, depending on whether or not a BAL was needed. One of the investigators responsible for all the recordings and the setup (S.J., S.M., or J.C.R.), was aware of the mask pressure. The length of the tubings and the site of the oxygen source, located far from the patient's bed, allowed both the physician performing the FOB and the patient to be blinded to the site connected. The full-face mask was secured to the patient's face with an elastic strap. In the CPAP group, CPAP was titrated by the investigator in incremental steps of 2.5 cm H_2O up to 7.5 cm and oxygen flow was adjusted to ensure that the F_{iO_2} of the full-face mask was similar to that in the high F_{iO_2} mask of the other group.

After the patient had worn the full-face mask for 5 min, FOB was performed by an experienced respiratory physician (E.B., H.B., or B.M.), blinded to the mask pressure. No sedative or atropine was administered before the procedure. Topical anesthesia of the nose and larynx was performed with a 2% lidocaine hydrochloride spray and 10 ml of 1% lidocaine hydrochloride, respectively. The fiberoptic bronchoscope (Olympus IT 30, Rungis, France) was inserted through the mask and then through the nose, as shown in Figure 2. A plugged telescoping catheter procedure was performed for quantitative bacterial cultures as previously described (6), and BAL was performed by wedging the bronchoscope, either into a subsegment of the area with the most marked X-ray abnormality, or into the lingula or middle lobe. Warm sterile physiologic saline solution was infused (3×50 ml aliquots) and gently aspirated after each infusion. BAL fluid (BALF) aliquots were pooled and immediately processed for cytologic examination, and quantitative bacterial cultures were processed as previously described (7).

The full-face mask was maintained with the same pressure for 30 min after FOB, and was then replaced by the high F_{iO_2} mask driven by 10 L/min oxygen. Clinical parameters (respiratory rate, heart rate, and blood pressure) were recorded at the following times: (1) at inclusion, (2) just before FOB with the randomized pressure, (3) during FOB, (4) 5 and 15 min after the end of FOB, and (5) 35, 60, 90, and 120 min after FOB. Electrocardiographic and pulse oximetry (Sp_{O_2}) were continuously monitored throughout the procedure (Oxypleth 520A; Novamatrix, Wallingford, CT). Blood pressure was measured every 5 min using automated standard equipment (Hewlett-Packard monitor 78352A; Orsay, France). Airway pressure and Sp_{O_2} were monitored constantly throughout FOB. Arterial blood gases were sampled and analyzed using an ABL 520 analyzer (Radiometer, Copenhagen, Denmark) at inclusion before FOB, when patients were given oxygen via the high F_{iO_2} mask driven by 10 L/min of oxygen, and 15 min after the end of FOB, when patients received oxygen with or without CPAP.

If, at any time, the patient's Sp_{O_2} dropped below 80% for longer than 1 min, or even before these limits in case of poor clinical tolerance, the F_{iO_2} was raised until an Sp_{O_2} value of 90% was reached.

All patients were carefully monitored after FOB. The use of any form of ventilatory support thereafter was decided by the primary care physician, who was unaware of the mask pressure used during FOB. Respiratory failure was attributed to FOB when ventilatory as-

sistance was needed during the 6 h after it ended. The physicians involved in this study were not directly responsible for the care of the patients studied and did not take part in the discussions concerning their management. The clinical status of the patients was also evaluated 48 h after FOB.

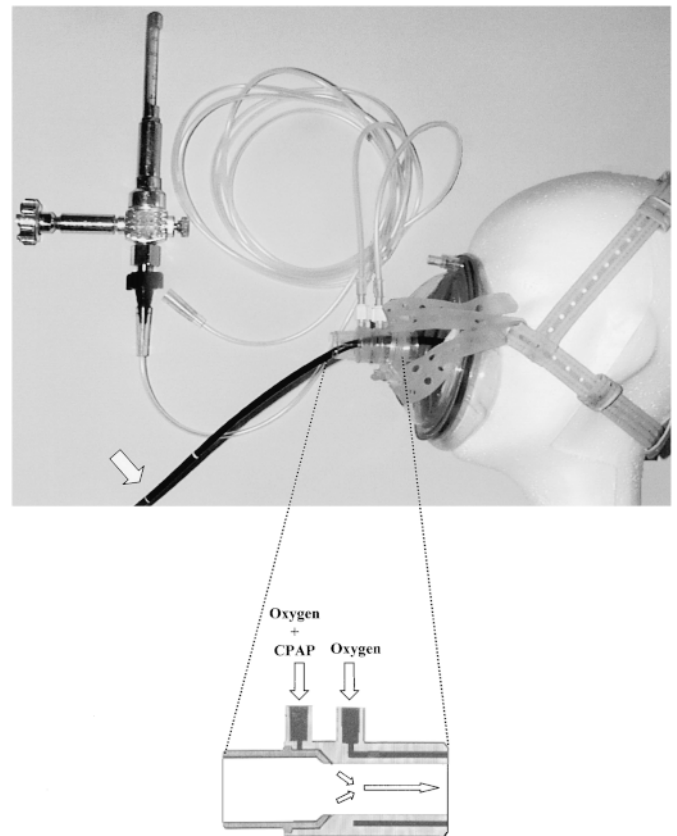


Figure 2. (Top panel) Representation of the full-face mask with the device, the two connection lines, the oxygen source, and the distal part of the bronchoscope. Only one of the two lines was connected to the oxygen source and, depending on the random choice, the investigator chose the line connected either to the pressure generation source or to the nonpressurized oxygen connection. FOB was performed by introducing the bronchoscope (arrow) into the nose through the device and the full-face mask as shown in the picture, after the mask had been secured with headstraps. (Bottom panel) Sketch of the standardized CPAP device. The microchannels included in its wall are connected to an external opening connected to the oxygen source, and generate high-velocity microjets responsible for the pressure generation (Oxygen + CPAP). A second opening allowed oxygen delivery without positive pressure (Oxygen).

End-points and Statistical Analysis

The primary end-point was the mean drop in Sp_{O_2} during FOB. The secondary end-points were arterial Pa_{O_2} after FOB, and the number of patients who developed respiratory distress after the procedure. The sample size was selected to allow the detection of a 3% difference in the mean Sp_{O_2} during bronchoscopy, assuming an α risk of 0.05 and β risk of 0.8. Results are expressed as means \pm SEM. When the patient had an Sp_{O_2} of less than 80% requiring increased delivery of Fi_{O_2} , the physiologic data obtained after this increase were not included in the analysis. Nonparametric analysis of variance (Friedman test) and the Mann-Whitney U test were used for sequential values. The need for ventilatory assistance was compared in the groups with and without CPAP using the Fisher exact test. *p* Values of 0.05 or less were considered significant.

RESULTS

Characteristics of the Population before FOB

Between May 1998 and February 1999, 31 consecutive patients fulfilled the study inclusion criteria but one patient refused to participate and 30 patients were enrolled. Fifteen patients each were assigned to the groups with and without CPAP. The baseline characteristics of the two groups were similar (Table 1). Chronic heart or respiratory diseases or immunosuppression were noted in 10 patients in the Oxygen group and nine in the CPAP group. In the Oxygen group, immunosuppression was due to acquired immunodeficiency syndrome (AIDS) (1), renal transplantation (1), bone marrow transplantation (1), neutropenia (1), and long-term corticosteroid treatment (1). In the CPAP group, it was the result of AIDS (1), heart (1) and liver (1) transplantations, aplastic anemia (1), and long-term corticosteroid treatment (2).

Pulse Oximetry and Arterial Blood Gas Monitoring

Changes in mean Sp_{O_2} during the entire procedure are shown in Figure 3. Fi_{O_2} was kept constant and similar in the Oxygen

and CPAP groups. When the high Fi_{O_2} mask was replaced by the full-face mask, Sp_{O_2} increased slightly but not significantly in both groups. During bronchoscopy, mean Sp_{O_2} was significantly higher in the CPAP group (95.7 ± 1.9 versus 92.6 ± 3.1 , $p = 0.02$) and this difference persisted 5 and 15 min after FOB (96.3 ± 1.7 versus 94.5 ± 1.2 , $p = 0.02$). During FOB, the difference between the two groups was even more pronounced for minimal Sp_{O_2} values (93.5 ± 2.4 versus 88.6 ± 3.4 , $p = 0.002$, Figure 4). Three patients in the Oxygen group had a Sp_{O_2} lower than 80% during FOB (Table 2) and required an increase of the Fi_{O_2} in the full-face mask.

Thirty minutes after the end of FOB, when patients were again breathing oxygen through the high Fi_{O_2} mask driven by 10 L/min, Sp_{O_2} was no longer significantly different in the two groups. Changes in Pa_{O_2} values are shown in Figure 5. Fifteen minutes after the end of FOB, mean Pa_{O_2} had risen significantly in the CPAP group ($p < 0.05$) but had dropped in the Oxygen group ($\Delta Pa_{O_2} = +10.5$ versus -15% from the baseline value, $p = 0.01$). In patients who had BAL (nine in each group), the difference between mean Pa_{O_2} in the CPAP and

TABLE 1
CHARACTERISTICS OF STUDY PATIENTS
BEFORE FIBEROPTIC BRONCHOSCOPY

	Oxygen		CPAP	
	Mean	Range	Mean	Range
Patient characteristics				
No. of patients	15		15	
Sex ratio, F/M	4/15		5/15	
Age, yr	58	35–78	57	26–83
Immunocompromised	5		6	
COPD	2		1	
CHF	3		2	
Chest X-ray				
Bilateral abnormalities	11		12	
Atelectasis	1		2	
Alveolar opacities	10		9	
Interstitial opacities	4		4	
Clinical parameters				
Respiratory rate, /min	30	18–44	32	20–60
Heart rate, /min	104	83–134	94	77–125
Mean arterial blood pressure, mm Hg	93	64–133	92	64–120
Blood gases				
Pa_{O_2} , mm Hg	92.7	57–120	87.5	51–124
Pa_{CO_2} , mm Hg	37.3	25–50	37.8	30–49.5
Sp_{O_2} , %	95.3	92–98	94.8	87–99
Fi_{O_2} , %	57	45–80	54	45–67
Pa_{O_2}/Fi_{O_2} , mm Hg	169	71–240	167	76–270
$P(A-a)_{O_2}$, mm Hg	253	136–384	269	184–472

Definition of abbreviations: CHF = chronic heart failure; COPD = chronic obstructive pulmonary disease; $P(A-a)_{O_2}$ = alveolo-arterial oxygen pressure difference.

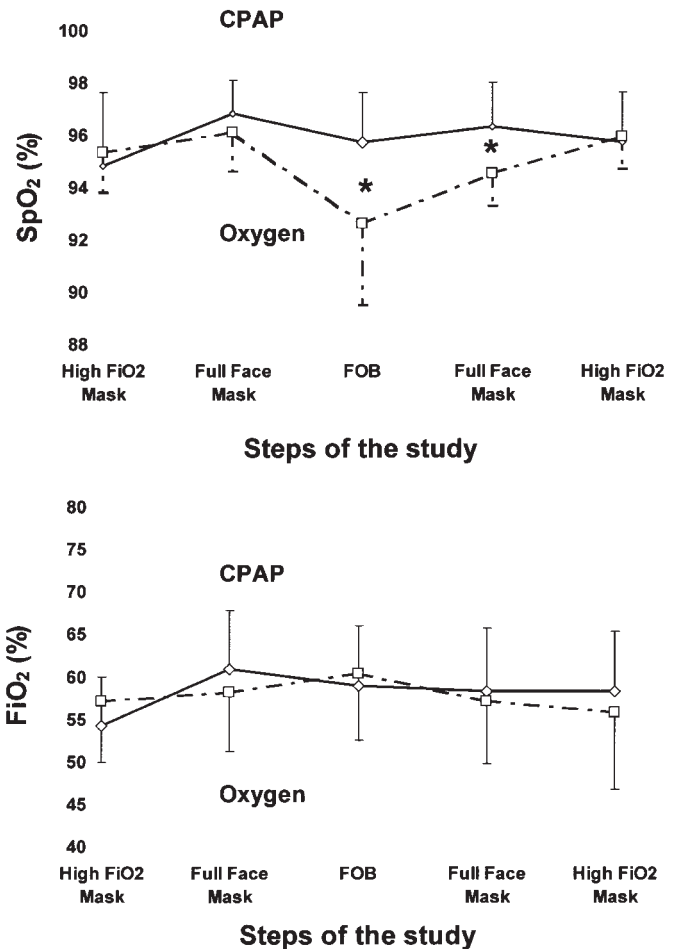


Figure 3. Variation in mean pulse oximetry (Sp_{O_2} , top panel) and Fi_{O_2} (bottom panel) during FOB. Mean \pm SEM of Sp_{O_2} or Fi_{O_2} values are shown for the five steps of the study: (1) at inclusion, when the patient is breathing with the high Fi_{O_2} mask; (2) when the patient is breathing at the randomized airway pressure with the full-face mask during the 5 min before FOB; (3) during FOB; (4) during the 30 min after FOB; and (5) during the next 2 h, when the patient is again breathing with the high Fi_{O_2} mask. Solid line: CPAP group; dotted line: Oxygen group; * $p < 0.01$, comparison between the two groups at the same point.

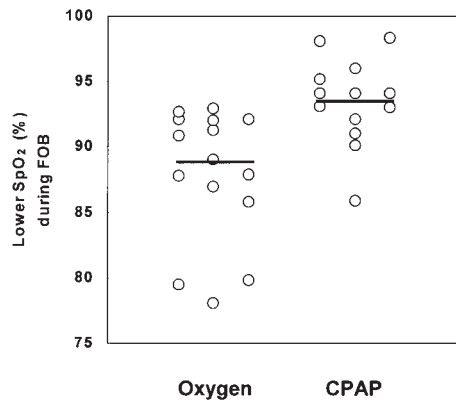


Figure 4. Minimal SpO₂ values recorded during FOB. Thick line represents the mean lowest SpO₂ values recorded in each group of patients.

Oxygen groups was even more pronounced (+11.8 versus -29.8% from the baseline value, *p* = 0.02).

Characteristics and Results of FOB

The duration of the FOB procedure did not differ in the two groups, as shown in Table 2. Five patients (three in the Oxygen and two in the CPAP group) underwent bronchial biopsies during FOB for suspected carcinomatous lymphangitis. The total duration of FOB was longer for these five patients (727 ± 109 s). In the results, we did not include the time taken for their biopsies, but only the duration of FOB until the biopsies were performed, so that these patients would be comparable to the others. BAL was performed in 18 patients. Slightly but significantly less BALF was recovered in the CPAP group, although the total number of cells in this group tended to be larger. The procedure yielded diagnostic information for 11 patients in the CPAP group and seven in the Oxygen group (*p* = 0.26). A causative infectious agent was identified by FOB in 14 cases. Two diagnoses of carcinomatous lymphangitis were obtained (one by BAL and one by bronchial biopsy). Fat embolism and drug-induced hypersensitivity pneumonia were diagnosed in two other patients.

Outcome

The clinical outcome after the FOB is shown in Table 3. During the 6 h after FOB, eight patients required ventilatory support: seven in the Oxygen group and one patient in the CPAP group (*p* < 0.03). In three cases, however, the need for ventilatory support was not triggered by FOB; thus, mechanical ventilation was needed in two such cases in the Oxygen group: one for hemothorax and the other for laparotomy, and CPAP was applied for persistent atelectasis which was already present before FOB in one patient in the CPAP group. In five cases,

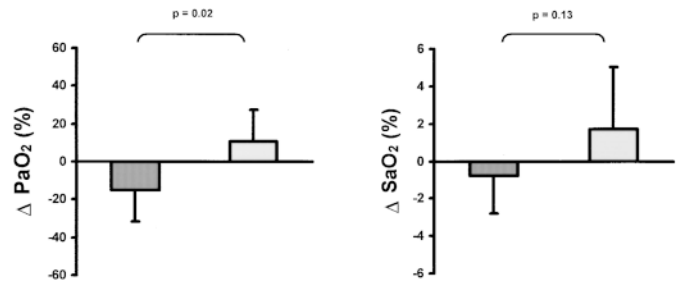


Figure 5. Changes in PaO₂ and SaO₂ before and after FOB. Means ± SEM of the difference between PaO₂ or SaO₂ 5 min before and 15 min after FOB, expressed as the percentage of change relative to the corresponding value 5 min before FOB.

the need for new ventilatory support was directly due to the FOB procedure. All these cases were in the Oxygen group (*p* < 0.04). During the 48 h after FOB, two additional patients in the Oxygen group were intubated at 24 h, and two in the CPAP group at 48 h.

DISCUSSION

The present results demonstrate that in hypoxemic patients, CPAP delivered through a full-face mask allows better tolerance of FOB than oxygen supplementation, both in terms of oxygenation and clinical outcome. We found that despite similar FiO₂ in the groups with CPAP and without, CPAP was effective in reducing the decrease in SpO₂ during FOB and for 15 min thereafter. Furthermore, the rate of subsequent respiratory failure caused by FOB was lower in patients receiving CPAP.

The positive airway pressure generated by the jet effect was the main factor responsible for maintaining adequate arterial oxygenation. When gas is injected into the small capillaries, the high-velocity jets in the mask create a constant positive pressure that greatly depends on the velocity of the gas injected and therefore on the oxygen flow rate and diameter of the capillaries. This pressure is, however, grossly independent of the patient's ventilation through the mask orifice. A major advantage of the CPAP device used, apart from its simplicity, is that it remains open to the atmosphere. This precludes any unforeseen risk of excessive airway pressure and allows FOB to be performed without disconnection or leaks. During FOB, recordings of airway pressure showed that it remained fairly constant despite the introduction of FOB into the external orifice of the system.

Several investigators have shown that bronchoscopy is associated with temporary alterations in gas exchange, hemodynamics, and lung mechanics (8–11). In nonintubated patients, FOB induces decreases in PaO₂ ranging from 10 to 30% of its baseline value. The normalization of gas exchange may take 2 h after FOB has ended (9). Among the suspected mechanisms of hypoxemia resulting from FOB, the role of the reduction in

TABLE 2
CHARACTERISTICS AND RESULTS
OF FIBEROPTIC BRONCHOSCOPY

	Oxygen (mean ± SEM)	CPAP (mean ± SEM)	p Values
Duration of FOB, s	305 ± 54	311 ± 44	0.8
Number of FOBs + bronchial biopsies	3	2	
Diagnostic yield of FOB	7	11	0.28
BAL	n = 9	n = 9	
Total cell number, · 10 ³ /ml	216 ± 133	872 ± 166	0.08
Volume recovery, ml	66 ± 15	43 ± 19	0.03

TABLE 3
CLINICAL OUTCOME OF PATIENTS IN THE
6 h AFTER FIBEROPTIC BRONCHOSCOPY

	Oxygen (n = 15)	CPAP (n = 15)	p Values
Need for Ventilatory Support in the 6 h after FOB			
Total	7	1	0.03
Attributed to FOB	5	0	0.04
NIV or CPAP	1	0	
Mechanical ventilation	4	0	

Definition of abbreviation: NIV = noninvasive ventilation.

alveolar ventilation, the increased ventilation-perfusion mismatch, and the increases in cardiac output and oxygen consumption have all been considered. In our study, we observed that 15 min after FOB, the patients who underwent this procedure with standard oxygenation experienced an 11% decrease in Pa_O₂ compared with the baseline value. This is in agreement with most results reported in the literature. By contrast, in the CPAP group Pa_O₂ rose significantly by 11% after FOB. We did not measure Pa_O₂ under CPAP just before FOB, but it is likely that CPAP induced a fast increase in Pa_O₂, and that this improvement was maintained throughout the procedure, as suggested by the Sp_O₂ measurements. Different studies, mainly in ventilated or hypoxemic patients, have shown that BAL itself may worsen the decrease in Pa_O₂ during FOB (8, 12, 13). Thus, 18 patients in our study underwent FOB with BAL, and the decrease in their Pa_O₂ during FOB was more pronounced than in the others patients, especially those in the Oxygen group, which confirmed the harmful effect of BAL on gas exchange in hypoxemic patients. This argues in support of the potentially beneficial role of CPAP when BAL has to be performed during FOB, because no decrease in Pa_O₂ was observed in the CPAP group.

It has been shown in different studies that in acute respiratory failure, the main effects of CPAP are to improve oxygenation by reducing intrapulmonary shunt and ventilation-perfusion mismatch, and to reduce the work of breathing. Katz and Marks studied the effect of CPAP in 16 patients with acute respiratory failure and showed a decrease in the total pulmonary power of breathing during inspiration, combined with increases in effective compliance and dynamic lung compliance (14). For patients with heart failure, different mechanisms have been described, such as the redistribution of edema fluid, an improvement in left heart function, and a decrease in the work of breathing (14–16). Because most of our patients had acute respiratory failure attributable to infectious pneumonia and not related to left heart failure or chronic obstructive pulmonary disease, we postulate that the improvement in gas exchange was mainly due to the recruitment of collapsed alveoli by end-expiratory positive pressure.

In our study, Sp_O₂ rose significantly after CPAP was started, and this improvement was sustained throughout FOB and 30 min thereafter. Although Sp_O₂ may not be a sufficiently sensitive parameter to allow a distinction to be made between the two groups at 30 min, the difference between the incidence of subsequent respiratory failure in each group might not result solely from the gas exchange improvement. Other effects, such as a decrease in the work of breathing, may have played a role. This might explain why some patients did not exhibit major alterations in gas exchange just after FOB, but nevertheless developed acute respiratory failure in the next few hours.

The risk factors for respiratory failure after FOB are not well defined in the literature, and most studies focused mainly on the immediate safety of BAL. On the basis of large retrospective analyses, several risk factors for developing adverse side effects have been described, including the presence of extensive pulmonary infiltrates, Pa_O₂ < 75 mm Hg, Sp_O₂ < 90%, and forced expiratory volume in one second < 1 L/min (1, 17). Trouillet and coworkers, in a study of 108 ventilated patients, showed that the presence of acute respiratory distress syndrome (ARDS) and frequent cycles with premature stop during FOB were associated with hypoxemia (10). However, in a recent large-scale study of the effects of BAL on patients with ARDS, only 5% of the series exhibited arterial oxygen desaturation below 90%, despite severe hypoxemia before BAL (18). In alert patients, Verra and coworkers found that both the results of pulmonary function tests before BAL, and chest X-ray findings correlated with the

lowest Sa_O₂ during FOB (11). In our search for risk factors associated with acute respiratory failure after FOB, we were unable to find independent variables associated with respiratory failure in a univariate analysis of our subjects (data not shown). The fact that baseline Pa_O₂ and Sp_O₂ did not differ significantly in the groups with and without CPAP confirmed that they are not accurate predictors of FOB tolerance in alert patients.

To sum up, we found that in patients with severe hypoxemia, CPAP during FOB allows minimal alteration of gas exchange. This effect was present whether or not BAL was performed. Most important, the use of CPAP prevented subsequent respiratory failure. The new CPAP device tested here seems to be a simple and useful way of performing FOB more safely in hypoxemic patients.

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