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Bronchial blockers under pressure: *in vitro* model and *ex vivo* model

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Abstract

Background: Pressures (P_e) exerted by bronchial blockers on the inner wall of the bronchi may cause mucosal ischaemia. Our aims were as follows: (i) to compare the intracuff pressure (P_i) and P_e exerted by commercially available bronchial blockers in an *in vitro* and an *ex vivo* model; (ii) to investigate the influence of both the inflated intracuff volume and cuff diameter on P_e; and (iii) to estimate the minimal sealing volume (V_{Smin}) and the corresponding P_e for each bronchial blocker studied.
Methods: The P_e exerted by seven commercial bronchial blockers was measured at different inflation volumes using a custom-designed system using *in vitro* and *ex vivo* animal models with two internal diameters (12 and 15 mm).
Results: In the same conditions, P_i was significantly lower than P_e ($P<0.05$), and P_e was higher in the *in vitro* model than in the *ex vivo* model. The P_e increased with the inflated volume, with use of the small-diameter model ($P<0.05$). *Ex vivo* models needed a higher minimal sealing volume than the *in vitro* models, and this volume increased with the diameter (e.g. the V_{Smin} at a positive pressure of 25 cm H_2O required a P_e ranging from 12 to 78 mm Hg on the 15 mm *ex vivo* model and from 66 to 110 mm Hg on the 12 mm *ex vivo* model).
Conclusions: The P_i cannot be used to approximate P_e. The diameter of the model, the inflated volume, and the bronchial blocker design all influence P_e. A pressure higher than the critical ischaemic threshold (i.e. 25 mm Hg) was needed to prevent air leak around the cuff in the *in vitro* and *ex vivo* models.

Key words: bronchial blockers; endobronchial devices; one-lung ventilation; pressure measurements; thoracic surgery

Editor's key points

- Pressures exerted by bronchial blockers on the inner wall of the bronchi may cause mucosal ischaemia, but there are insufficient data on this topic.
- Pressures exerted by seven commercial bronchial blockers were measured using *in vitro* and *ex vivo* animal models.
- Pressures exerted by the cuffs on the bronchus cannot be estimated by the intracuff pressures, and may frequently exceed the bronchial capillary pressures.

Lung separation is a technique that allows the isolation of one lung from the other and permits the isolated ventilation of one lung or the ventilation of each lung separately. Before this development, carried out for the first time in 1931 by Gale and Waters,[1] only brief intrathoracic surgical procedures were possible, because the movement of the lung and the development of sudden respiratory distress caused by the resulting pneumothorax made these procedures difficult and risky.[2] Since then, research has led to the introduction of new technologies and alternative methods to separate the lungs.[3]

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Lung separation can be carried out by two techniques: double-lumen tubes or bronchial blockers.[4] A double-lumen tube is basically made up of two small-lumen tracheal tubes of unequal length fixed side by side. The shorter tube ends in the trachea, whereas the longer one is placed in either the left or right bronchus, selectively ventilating the left or right lung, respectively. Bronchial blockers are devices inserted through a tracheal tube in one of two bronchi, with a single lumen and distally equipped with a single cuff that, inflated with an appropriate volume, allows the seal of the airways and the collapse of the lung.[2]

An inflated cuff exerts a pressure on the tracheal wall to create a seal (P_e), and this pressure should not exceed the capillary pressure in order to avoid an insufficient supply of oxygen to sustain the demand of tissues in the area, which leads to cellular damage and death.[5] Therefore, P_e plays an important role, because it may lead to the occurrence of complications.[2] Previous studies demonstrated that high contact pressures can cause a reduction in mucosal flow, with the risk of mucosal ischaemia.[5–8] Tracheal mucosal damage occurs as a direct consequence of tracheal hypoperfusion.

This pressure is not easy to estimate, both in models and in clinical practice.

Other research groups have focused on the measurement of the pressure exerted by bronchial blockers on *in vitro* models.[9–11] For the cuff of a tracheal tube, this pressure is approximated by the intracuff pressure (P_i).[10] However, recent studies have shown that these two pressures often differ substantially and display different trends with inflated volume; P_i shows a linear trend with volume, whereas the P_e trend is strongly non-linear.[11] Therefore, small differences in inflated volume may correspond to a high pressure increment.

Moreover, the P_e is known only for some commercially available bronchial blockers in an *in vitro* model. Therefore, it is necessary to investigate the P_e exerted by the most popular bronchial blockers and its relationship with the inflated intracuff volume. This analysis can lead to estimation of the P_e at the minimal sealing volume (V_{Smin}).

The aim of this study is threefold: (i) to perform a comparative analysis of the pressures exerted by six bronchial blockers and by the Fogarty embolectomy catheter on the inner wall of an *in vitro* and an *ex vivo* model, analysing the difference between P_i and P_e; (ii) to investigate the influence of both the inflated intracuff volume and the inner diameter of the models on P_e; and (iii) to estimate the V_{Smin}, and the corresponding P_e, of each bronchial blocker under test.

Methods

We compared six bronchial blockers: Arndt and Cohen (both sold by Cook Critical Care, Bloomington, Indiana, USA), Uniblocker and Fuggiano (both sold by Fuji Systems Corporation, Tokyo, Japan), EZ blocker (Teleflex, Wayne, Pennsylvania, USA), and Coopdech (Daiken Medical, Tokyo, Japan). We also included in our study the Fogarty embolectomy catheter, frequently used in the past as a bronchial blocker. Experiments were performed on both *in vitro* (i.e. two latex ducts with different diameters) and *ex vivo* models (i.e. excised pig bronchi). All the experiments were performed by inflating the cuffs to the volume recommended by the manufacturer.

Bronchial models: *in vitro* and *ex vivo* models

The *in vitro* models consist of two latex passages (ducts) with different inner diameters (i.e. 12 and 15 mm), simulating the sizes of the left and right human bronchi. These two tubes were custom fabricated through successive immersions of a mould in uncured latex.

The *ex vivo* animal models consist of two freshly excised swine mainstream bronchi. Their inner diameters were measured with callipers: 12 mm for the left bronchus, and 15 mm for the right one. The experiments on *ex vivo* models were carried out 2 h after the animal was butchered, in order to avoid post-mortem changes in the mechanical properties of the excised tissue.

Measurement systems

The P_e exerted by bronchial blockers was measured with a custom-designed system based on two piezoresistive force sensors (FSR 400; Interlink Electronics Inc., Los Angeles, California, USA) chosen for their geometrical features [i.e. circular active area with small diameter (5.08 mm) and small thickness 0.30 mm (SD = 0.03 mm)] and for their measurement range (i.e. from 0.2 to 20 N); see Fig. 1. The measurement process is described in detail in a previously published work.[12] Briefly, the cuff of each bronchial blocker was inserted within the duct and inflated with an air volume ranging from 1 to 8–12 ml, in steps of 1 ml. The maximal volume inflated (i.e. 8–12 ml) was chosen either by using the values recommended by manufacturers or, when it was not specified (i.e. EZ blocker), avoiding rupture of the cuff from excessive pressure. The sensor output for each inflated volume was recorded to estimate P_e. Simultaneously, we also measured P_i by connecting the cuff to a manometer.

Lastly, we investigated the V_{Smin} necessary to seal the latex duct by inserting the cuff of the bronchial blockers within the bronchus model and by applying a pressure difference of 25 cm H_2O at the two extremities of the cuff. This pressure was continuously monitored using a manometer, with the value of 25 cm H_2O being chosen because it is considered to be the highest value normally applied during mechanical ventilation (positive pressure ventilation) in clinical settings.[11]

The distal end of the bronchus model was submerged in a water-filled vessel, and the cuff was inflated with increasing volume in steps of 0.5 ml. This solution allows the identification of bronchial blocker leaks, by noting air bubbles arising under the water, and recording the V_{Smin}, as indicated by a lack of this bubbling.

Statistical analysis

Differences between experimental data were compared using Student's paired *t*-test and were considered significant for $P<0.05$. The statistical analyses were performed in the Matlab® (MathWorks, Natick, Massachusetts, USA) environment.

Results

We focused on the following factors: (i) a comparative analysis of P_e exerted by the most commonly used bronchial blockers in clinical practice; (ii) P_i, highlighting the difference from P_e; and (iii) the V_{Smin} of each device under test, analysing the P_e needed to ensure occlusion of the ducts.

In vitro experiments concerning P_e and P_i

The relationship between P_e and the inflated volume was non-linear for all the bronchial blockers; P_e increased with the volume at a growing rate. Moreover, the diameter of the duct strongly influenced P_e; for each bronchial blocker, P_e was significantly higher using the 12 mm model than the 15 mm one ($P<0.05$). The data also showed that P_e experienced wide variations in the range of inflated volume recommended by the manufacturers (e.g. the recommended range for the Cohen is from 6 to 9 ml, and in this

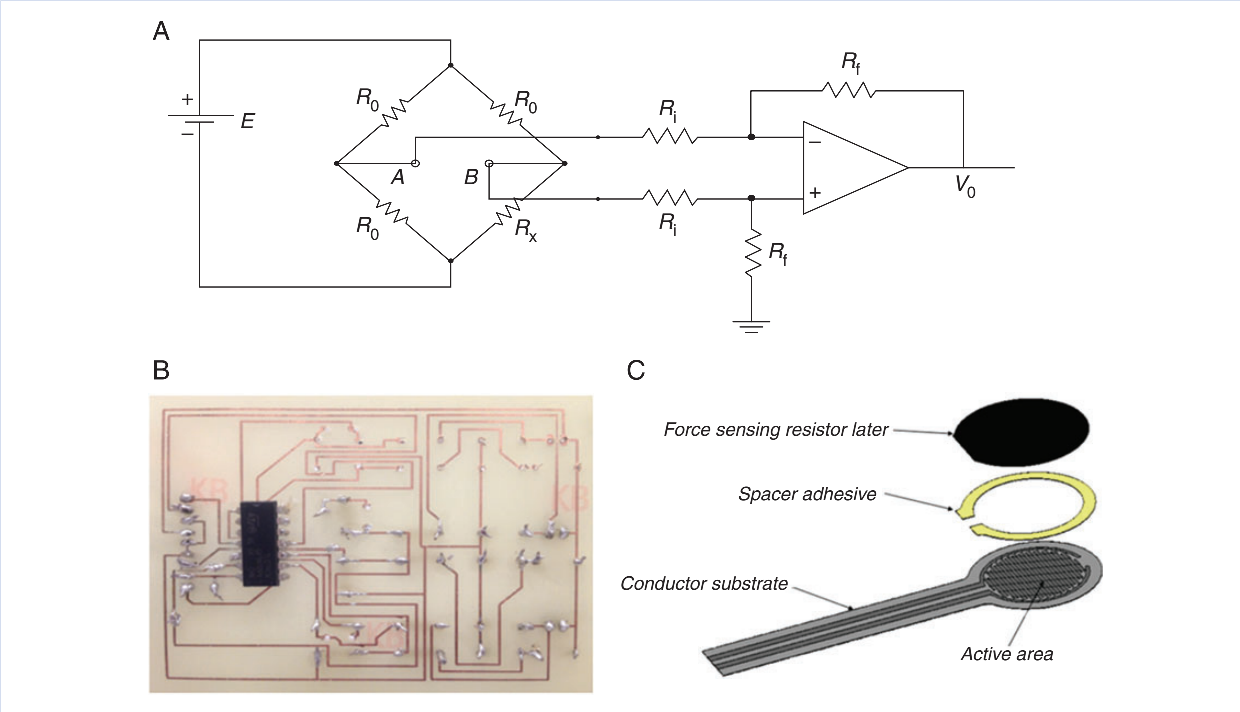

Fig 1 (A) Schematic diagram of analog preprocessing electronics. (B) Printed circuit board of the two preprocessing circuits. (C) Basic FSR construction. E, supply voltage of the Wheatstone bridge; R_o, resistance of the Wheatstone bridge; R_x, resistance of the force sensong resistor; V_u, voltage output of the Wheatston bridge; R_i and R_f, resistance of the amplification stage; V_o, voltage output of the measurement system; FSR, force sensing resistor.

range P_e changes from 144 to 217 mm Hg for the 15 mm model and from 167 to 397 mm Hg for the 12 mm model). The P_i values were significantly lower than P_e values for each bronchial blocker and for both diameters (P<0.01). Figure 2 clearly indicates that P_i and P_e show different values and different trends with volume. Therefore, it is a coarse approximation, often made in literature, using the value of P_i to estimate P_e.

Ex vivo experiments concerning P_e

Ex vivo experiments were carried out in order to simulate a more realistic scenario. The P_i was not measured because we demonstrated during *in vitro* tests that P_i is largely different from P_e. Data are shown in Fig. 3.

In this model, we also demonstrated the non-linear increasing trend of P_e with volume. For each bronchial blocker, P_e was significantly higher on the bronchus with smaller diameter (P<0.05) and experienced wide changes using the range of inflated volume recommended by the manufacturers (see the legend of Fig. 3). By comparison with *in vitro* tests, P_e measured on the excised pig bronchi showed lower values for the same bronchial blocker, at the same volume, for both the diameters.

Minimal sealing volume: *in vitro* models and *ex vivo* models

These experiments were performed to investigate the V_{Smin}.

Results for the *in vitro* model are reported in Table 1. Table 1 also reports the minimal pressure needed to seal the two latex models for each bronchial blocker. This pressure was estimated by considering the relationship of P_e *vs* volume reported in Fig. 2. The V_{Smin} decreases with the diameter, whereas the P_e increases with the diameter.

Results obtained on the porcine model are shown in Table 2, which shows the minimal pressures needed to seal the two *ex vivo* models for each bronchial blocker. This pressure was estimated by considering the relationship of P_e *vs* volume reported in Fig. 3. The main findings are as follows: (i) V_{Smin} measured during the *ex vivo* test was significantly higher than the value obtained *in vitro* for each bronchial blocker and for both the diameters (P<0.05); and (ii) P_e measured during the *ex vivo* test was significantly lower than the value obtained *in vitro* for each bronchial blocker and for both the diameters (P<0.05).

Discussion

One of the most important findings of this study is that P_e is significantly different from P_i, and it depends on the diameter of the ducts for both the models; the bigger the duct, the lower the pressure. These results highlight the difficulty that clinicians face in selecting the optimal inflated volume in order to avoid either the risks related to excessive pressure or the malpositioning of the bronchial blocker. Often, the anthropometric features are not sufficient to guide clinicians in this choice. It has also been shown that the minimal inflated volume to prevent air leakage around the cuff is usually lower than the value suggested by the manufacturer, and it entails a P_e higher than the value reported in other studies.[13 14]

In the present study, a comparative analysis of the pressures exerted by seven commercial bronchial blockers was carried out, depending on the volume of air introduced into the cuff. Owing to the large difference between the size of the right and left human bronchi, we developed two models with different diameters, allowing us to evaluate the influence of geometrical size on the pressure values. The *in vitro* models consisted of two latex

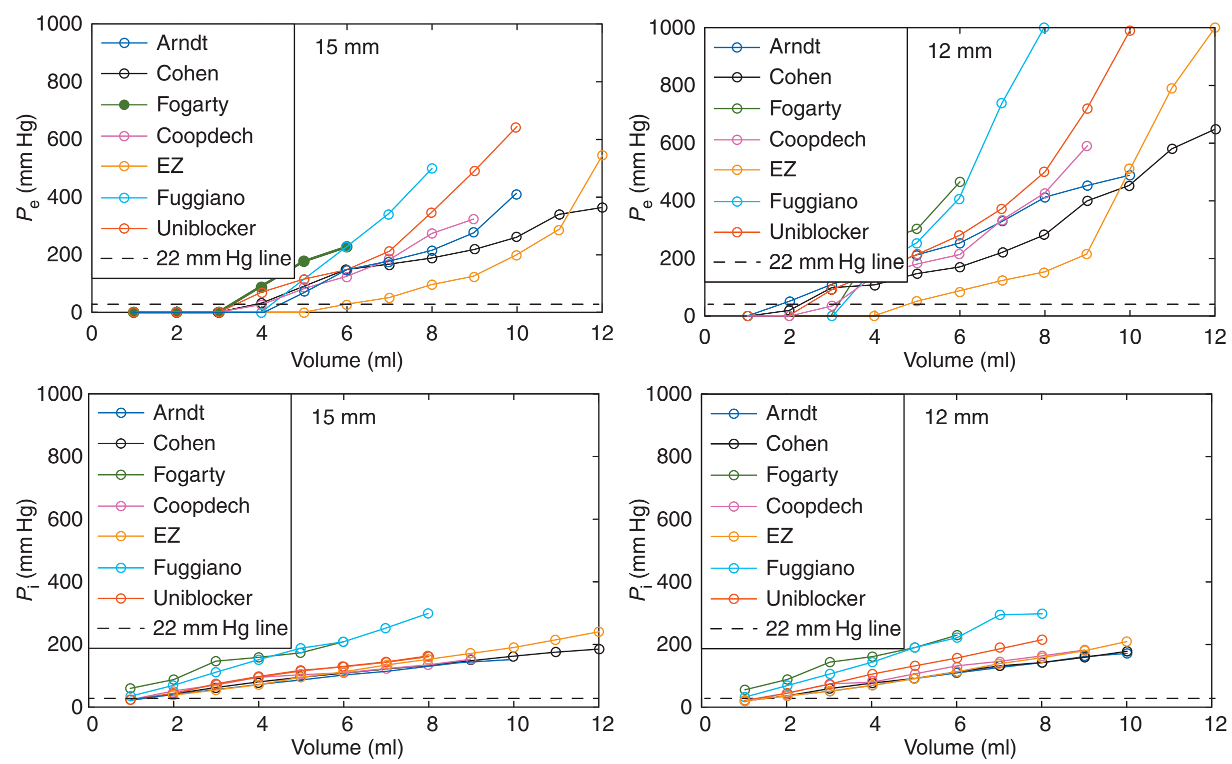

Fig 2 Pressure exerted by the bronchial blockers and intracuff pressure as a function of inflation volume. Data for the two diameters of the *in vitro* model are shown. A line parallel to the x-axis, at 25 mm Hg, indicates the critical ischaemic threshold.

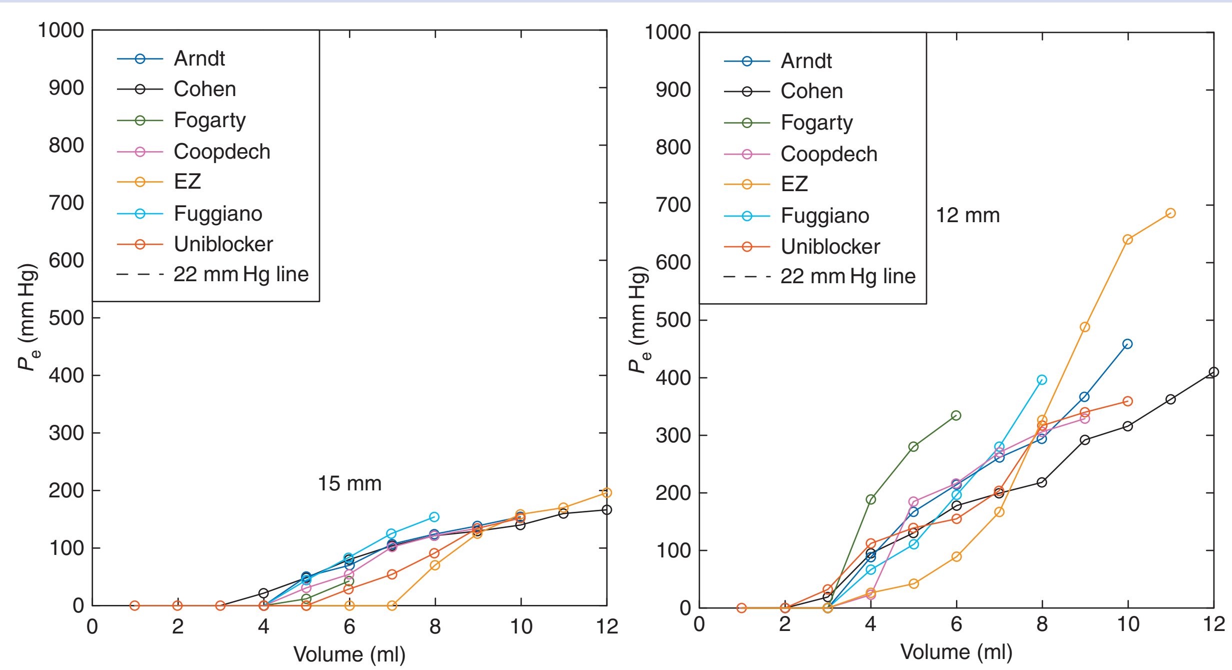

Fig 3 Pressure exerted by the bronchial blockers as a function of inflation volume. Data for the two diameters in the animal model are shown. A line parallel to the x-axis, at 25 mm Hg, indicates the critical ischaemic threshold.

Table 1 Minimal sealing volume and the corresponding P_e exerted by the bronchial blockers in an *in vitro* model. *d*, internal diameter; P_e, exerted pressure

Bronchial blocker	Volume (ml)		Pe (mm Hg)	
	d=15 mm	*d*=12 mm	*d*=15 mm	*d*=12 mm
Uniblocker	4.5	3.5	92	121
Fuggiano	4.5	3.5	56	82
Arndt	5.0	3.5	71	120
Coopdech	5.0	4.0	86	136
Cohen	5.5	4.5	105	126
Fogarty	4.0	3.5	86	118
EZ	6.5	5.5	38	66

Table 2 Minimal sealing volume and the corresponding P_e exerted by the bronchial blockers in a porcine model. *d*, internal diameter; P_e, exerted pressure

Bronchial blocker	Volume (ml)		P_e (mm Hg)	
	d=15 mm	*d*=12 mm	*d*=15 mm	*d*=12 mm
Uniblocker	6.5	4.0	41	109
Fuggiano	5.0	4.0	44	66
Arndt	5.5	4.0	60	87
Coopdech	6.5	4.5	77	102
Cohen	6.0	4.5	78	110
Fogarty	5.0	3.5	12	94
EZ	7.5	5.5	34	64

ducts of different internal diameters simulating the size of the left and right human bronchi. These were made in different thicknesses and of different material, compared with what was accomplished in previous studies,[11] in order to obtain distinct compliances and manufacture the ducts with mechanical characteristics more similar to the real bronchi. We also measured the intracuff pressure and the minimal sealing volume for each device assessed, highlighting the difference between the pressures necessary to ensure occlusion of the ducts.

Many patients who undergo one-lung ventilation are frail; therefore, monitoring of the pressure exerted by both tracheal and bronchial devices is a crucial issue. The real-time feedback of exerted pressure may be particularly beneficial to guide the clinician in order to minimize bronchial mucosal damage through optimal inflation of the cuff.

All the bronchial blockers tested in our study showed a higher pressure than the value sufficient to cause hypoperfusion and the resulting circulatory deficit.

The main limitationof the study is that the experiments were carried out on models, far from a clinical setting. In particular, the excised pig bronchi were analysed as a system in itself, without performing experiments on a complete intact animal, with the whole respiratory system and the organs and structures that surround it.

Our measurement system could be a first step to develop an instrumented cuff providing real-time feedback of the pressure exerted by bronchial blockers. Knowledge of the pressure could be particularly beneficial to identify the optimal volume of air to inflate each device, with the aim of minimizing tracheal damage.

Authors' contributions

Reviewing the relevant literature: C.M.P., N.V., A.M.
Study design: M.C., A.M., C.M.P., E.S., N.V.
Data collection and data analysis: E.S., P.S., N.V.
Manuscript preparation: A.M., E.S., C.M.P., N.V.
Manuscript revision: all authors.

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Declaration of interest

None declared.

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