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SCIENTIFIC ARTICLE

In vitro evaluation of the method effectiveness to limit inflation pressure cuffs of endotracheal tubes[☆]



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Abstract

Background and objective: Cuffs of tracheal tubes protect the lower airway from aspiration of gastric contents and facilitate ventilation, but may cause many complications, especially when the cuff pressure exceeds 30 cm H₂O. This occurs in over 30% of conventional insufflations, so it is recommended to limit this pressure. In this study we evaluated the in vitro effectiveness of a method of limiting the cuff pressure to a range between 20 and 30 cm H₂O.

Method: Using an adapter to connect the tested tube to the anesthesia machine, the relief valve was regulated to 30 cm H₂O, inflating the cuff by operating the rapid flow of oxygen button. There were 33 trials for each tube of three manufacturers, of five sizes (6.5–8.5), using three times inflation (10, 15 and 20 s), totaling 1485 tests. After inflation, the pressure obtained was measured with a manometer. Pressure >30 cm H₂O or <20 cm H₂O were considered failures. **Results:** There were eight failures (0.5%, 95% CI: 0.1–0.9%), with all by pressures <20 cm H₂O and after 10 s inflation (1.6%, 95% CI: 0.5–2.7%). One failure occurred with a 6.5 tube (0.3%, 95% CI: –0.3 to 0.9%), six with 7.0 tubes (2%, 95% CI: 0.4–3.6%), and one with a 7.5 tube (0.3%, 95% CI: –0.3 to 0.9%).

Conclusion: This method was effective for inflating tracheal tube cuffs of different sizes and manufacturers, limiting its pressure to a range between 20 and 30 cm H₂O, with a success rate of 99.5% (95% CI: 99.1–99.9%).

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PALAVRAS-CHAVE

Método;
Insuflação;
Balonetes;
Cânulas;
Pressão

Avaliação *in vitro* da eficácia de método para limitar a pressão de insuflação dos balonetes das cânulas endotraqueais

Resumo

Justificativa e objetivo: Os balonetes das cânulas traqueais protegem as vias aéreas inferiores da aspiração de conteúdo gástrico e facilitam a ventilação pulmonar, mas podem provocar diversas complicações, principalmente quando a pressão do balonete supera 30 cm H₂O. Isto ocorre em mais de 30% das insuflações convencionais, sendo recomendada a limitação desta pressão. Neste estudo avaliou-se *in vitro* a eficácia de um método para limitar a pressão dos balonetes à faixa entre 20 e 30 cm H₂O.

Método: Utilizando um adaptador para conectar a cânula testada ao aparelho de anestesia, regulou-se a válvula limitadora deste a 30 cm H₂O, insuflando o balonete por meio do acionamento do botão de fluxo rápido de oxigênio. Realizaram-se 33 testes para cada cânula de três fabricantes, de cinco tamanhos (6.5 a 8.5), utilizando três tempos para insuflação (10, 15 e 20 segundos), totalizando 1485 testes. Terminada a insuflação, mediu-se a pressão obtida com um manômetro. Pressões >30 cm H₂O ou <20 cm H₂O foram consideradas falhas.

Resultados: Ocorreram oito falhas (0,5%; IC 95%: 0,1–0,9%), sendo todas por pressões <20 cm H₂O e após insuflações de 10 segundos (1,6%; IC 95%: 0,5–2,7%). Uma falha ocorreu com cânula 6.5 (0,3%; IC 95%: –0,3–0,9%), seis com cânulas 7.0 (2%; IC 95%: 0,4–3,6%), e uma com cânula 7.5 (0,3%; IC 95%: –0,3–0,9%).

Conclusão: Este método mostrou-se eficaz para insuflar os balonetes de cânulas traqueais de diferentes tamanhos e fabricantes limitando sua pressão à faixa entre 20 e 30 cm H₂O, com incidência de sucesso de 99,5% (IC 95%: 99,1–99,9%).

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Introduction

When high pressure and low volume (HPLV) or high volume and low pressure (HVLP) endotracheal tube cuffs are inflated, they exert pressure on the tracheal wall and may lead to mucosal ischemia. This is directly related to the occurrence of complications in up to 90% of patients, including discomfort, sore throat, granuloma formation in the vocal cords, hoarseness, and serious complications such as recurrent laryngeal nerve and vocal cords paralysis, bloody sputum, tracheal-esophageal fistula, and tracheal rupture.^{1–4}

There are several methods for injecting air into the tracheal tube cuff. The gold standard method is the direct measurement of cuff pressure (C_{pressure}) with calibrated manometer, analog⁵ or digital,⁶ and is recommended in adult and pediatric patients.^{5,7–9} However, its use is not routine in Brazil.

The injection of air into the cuff with a syringe is the most used method. This method is simple, fast, and low cost, but the relationship between the volume of injected air and the resulting cuff-to-tracheal wall pressure ($C-T_{\text{pressure}}$) is non-linear, causing cuff distention in 30–98% of cases,^{7,8,10,11–13} depending on the population studied, endotracheal tube used, and the clinical context.¹⁴

Other methods to limit the $C-T_{\text{pressure}}$ have been proposed, such as the techniques of minimal occlusive volume (MOV) and minimum leak technique (MLT), but without scientific confirmation of clinical benefit.⁶ Pressure adjustment alternative techniques have been suggested or are

under development, using modified endotracheal tubes,¹⁵ special syringes,¹⁶ and hospital equipment available in the units,^{17–21} however without eliminating the need for additional equipment.

When the circular system is used as the pressure source to inflate the tracheal tube cuffs, it is possible to limit the maximum pressure in the system through the adjustable pressure relief valve (APRV), also called pop-off valve, making it impossible for the CP and $C-T_{\text{pressure}}$ reach values higher than the maximum set by the APRV adjustment. In order to do this, simply adapt the output of the circular system to the Luer-type entry of the endotracheal tube pilot balloon—a method not found in the scientific literature.

The possibility of limiting the pressure within the cuff to safe levels using a simple, widely available, and low cost method can reduce the occurrence and magnitude of various complications, many of them serious. This issue motivated the present study designed to evaluate an *in vitro* efficacy of endotracheal tube cuff insufflation method, with the internal pressure set between 20 and 30 cm H₂O.

Method

An *in vitro* experimental study of the efficacy of a method for endotracheal tube cuff inflating was performed. Given the nature of this study, the assessment by the Institution Research Ethics Committee was waived.

Sample size calculation was based on previous studies, which demonstrated that the incidence of pressure in the range of 20–30 cm H₂O with conventional method of



Figure 1 Adapter used to connect the anesthesia machine circular system outlet to the tracheal tube pilot balloon.

insufflation is 27–35%.^{8,11} Confidence interval was calculated for the success rate of each endotracheal tube model of the same manufacturer, same size (internal diameter in mm), and time of insufflation—time—diameter—manufacturer combination (TDM). Considering a success rate of 95%, total error rate = 15%, and 95% confidence level, it was obtained an $n = 32$ per group (TDM combination).

Three different times (10, 15 and 20 s) for the insufflation of endotracheal tubes of five different diameters (6.5, 7.0, 7.5, 8.0 and 8.5 mm inner diameter) and three manufacturers (Dahlhausen, Portex and Rüschi) were tested, resulting in 45 groups (different TDM combinations). In order to identify possible biases caused by the different performance of each operator, or by the same operator change in performance due to multiple repetitions of tests, each repetition was numbered and performed following an established sequence. Also, in order to identify a possible change in performance due to a defective endotracheal tube, three endotracheal tubes of the same size and manufacturer were used, numbered 1–3, and 11 insufflations were made per tube, per test, resulting in 33 tests per group totaling 1485 tests. For insufflations lasting 10 s, the sequence of tubes was 1, 2 and 3; for insufflations lasting 15 s, the sequence of tubes was 3, 1 and 2; and for insufflations lasting 20 s, the sequence of tubes was 2, 3 and 1, so that all of the numbered tubes were used in all positions in the insufflation sequence. Moreover, the operators take turns, alternating the order of insufflation, so that each one performed 10, 15 or 20 s insufflations with tubes of each size and each manufacturer.

The practical part was performed by two operators, a doctor specialist in anesthesiology (Operator 1), and a 3rd year resident doctor in anesthesiology (Operator 2), both with previous experience of 100 repetitions each in the proposed insufflation method.

To perform the coupling between the 15 mm standard outlet of the anesthesia machine circular system and the standard Luer connection of the tracheal tube pilot balloon, an adapter is required. The adapter, made by the investigator himself used a standard 15 mm Adams connector of a 7.5 endotracheal tube (internal diameter in mm) to a 3 mL syringe without the plunger (Fig. 1). Thus, the anesthesia

machine circular system is adapted to the 15 mm connector, while the standard Luer-type connection of the syringe is adapted to the endotracheal tube pilot balloon, opening its valve to allow insufflation.

The anesthesia machine used for the tests was the Dräger Fabius GS[®], whose APL valve was set to the maximum pressure of 30 cm H₂O and oxygen flow set to 10 L min⁻¹. Then, the adapter is connected to the anesthesia machine 15 mm outlet, and the reservoir bag for ventilation is inflated by operating the high-flow oxygen button.

Before each insufflation, the maximum air volume of each tube cuff was aspirated with a syringe. Then, the portion corresponding to the endotracheal tube cuff was placed inside a 20 mL syringe without the plunger (of 20 mm internal diameter), fixed to the test table surface with tape, keeping the cannula passively resting on it and also fixed to the table with tape.

One of the two operators spontaneously started each insufflation connecting the tracheal tube pilot balloon with the anesthesia machine through the adapter. After the predetermined time for insufflation, the adapter was disconnected from the pilot balloon, interrupting the insufflation. Then, an aneroid manometer (Cuff Pressure Gauge, VBM Medizintechnik, Sula, Germany) was used to measure the pressure achieved with the insufflation.

Values between 20 and 30 cm H₂O were considered appropriate, and values less than 20 cm H₂O or exceeding 30 cm H₂O were considered failures. Statistical analysis was performed using SPSS 13.0 for Windows, with 95% confidence intervals, and obtained data on the proportion of general failure and failure for the following variables: manufacturer, size, insufflation time, and operator.

Results

All 1485 tests were performed with no test discarded. Of the 1485 tests, 1477 (99.5%) had pressures considered adequate and eight tests failed (0.5%) (95% CI: 0.1–0.9%). All cases of failure occurred due to inappropriately low pressures.

Comparison between manufacturers

Comparing the different manufacturers of the cannulas used, there was no failure in tests with the cannulas manufactured by Dahlhausen, 6 failures (1.2%) with the cannulas manufactured by Portex (95% CI: 0.2–2.2%), and 2 failures (0.4%) with the cannulas manufactured by Rüschi (95% CI: –0.2 to 1.0%).

Comparison between cannulas' sizes

There was one failure (0.3%) with the 6.5 mm cannula (95% CI: –0.3 to 0.9%), six failures (2.0%) with the 7.0 mm cannula (95% CI: 0.4–3.6%), one failure (0.3%) with the 7.5 mm cannula (95% CI: –0.3 to 0.9%), and no failure with the 8.0 and 8.5 mm cannulas.

Table 1 Incidence of general failure and for each observed variable (results expressed in % and 95% CI).

Variables	Failure	95% CI limits	
		Lower	Upper
<i>General</i>	0.5%	0.1%	0.9%
<i>Brand</i>			
Dahlhausen	0	0	0
Portex	1.2%	0.2%	2.2%
Rusch	0.4%	-0.2%	1.0%
<i>Size</i>			
6.5	0.3%	-0.3%	0.9%
7.0	2.0%	0.4%	3.6%
7.5	0.3%	-0.3%	0.9%
8.0	0.0%	0.0%	0.0%
8.5	0.0%	0.0%	0.0%
<i>Time</i>			
10	1.6%	0.5%	2.7%
15	0.0%	0.0%	0.0%
20	0.0%	0.0%	0.0%
<i>Operator</i>			
1	0	0	0
2	1.1%	0.3%	1.9%

Comparison between the insufflation times

All eight failures occurred in tubes insufflated for 10 s (1.6%; 95% CI: 0.5–2.7%); there was no failure with 15 and 20 s insufflations.

Comparison between operators

All eight failures occurred with the Operator 2 (1.1%; 95% CI: 0.3–1.9%).

The general and specific failure ratios for each observed variable are shown in [Table 1](#).

Discussion

The incorporation of inflatable cuffs to tracheal tubes represented a huge technological advancement, promoting greater safety for patients and allowing the advance of pulmonary ventilation techniques.^{22,23} However, its use is associated with several complications related mainly to the cuff high pressure (C_{pressure}).^{2,3,24} Limiting C_{pressure} to 30 cm H₂O significantly reduces the complications associated with the airway^{4,25}; thus, the use of a method to limit C_{pressure} is mandatory.^{7,26}

The gold standard method for C_{pressure} control, consisting of calibrated manometers,^{5–7} enables continuous or intermittent measurement of C_{pressure} in real time, enabling to adjust it without interrupting the measurement. Among its limitations are the equipment high cost and the need for regular calibration. However, this method did not spread among health professionals, particularly among physicians, and is not routinely used after or during tracheal intubation maintenance.

In this study, we performed an in vitro test of an alternative method of tracheal tube cuff insufflation, limiting C_{pressure} to pressures not greater than 30 cm H₂O, and it was not found in the literature any publication with the same or similar method. Also, for this reason this study was initially carried out in vitro to test the method's functionality before exposing patients to a technique without scientifically proven effects.

In this study there were eight failures in 1485 tests (0.5%; 95% CI: 0.1–0.9%), all due to inappropriately low pressures. This represents an extremely small proportion of failure when this result is compared with the most clinically used method—cuff insufflation by injecting air from a syringe, that has a proportion of hyperinsufflation between 23.5% and 64.5% of cases,^{8,9,11,12} and may reach up to 98%.¹³ Among these failures, six (75%) occurred in a single experiment (Portex tube, #7.0, 10 s of insufflation, Operator 2), and the other two failures in separate experiments (one with Rüs ch tube #6.5, 10 s of insufflation, Operator 2, and one with Rüs ch tube #7.5, 10 s of insufflation, Operator 2).

Despite the experimental design of this study, some variables are impossible to control and may have contributed to these failures. Among these variables are the nominal pressure of oxygen network, quality of tracheal tubes manufacture, operator performance, and the cuff's relationship with the buffer in the insufflation.

The input pressure of the medical gases used in anesthesia equipment is maintained in the range of 4.5–5.5 kgf cm⁻². However, this pressure eventually shows fluctuations, which can increase or reduce the flow of oxygen during the triggering of the high flux of O₂ button, directly interfering in the cuff insufflation process by the method in this study.

Regarding tracheal tubes construction pattern, small variations in the cuff composition or format change the elastance ($\Delta\text{pressure}:\Delta\text{volume}$ ratio), with a direct effect on the obtained results.

Another factor to consider is the performance of each operator. Even applying the method with attention and technical accuracy, intra- and interpersonal variations in the process execution may interfere with the final pressure measured by allowing the pilot balloon valve opening and/or closing for times or at different times, unintentionally adding or removing a cuff gas aliquot. Despite the difference of experience between the operators who performed the tests, both had the same degree of training in this method, having performed at least 100 insufflations each in a previous pilot study. Therefore, the different failure incidences between operators may not be attributed to the degree of experience with this method. However, small variations in performing the method cannot be ruled out as possible causes for the failures seen with Operator 2, albeit very infrequent (1.1%; 95% CI: 0.3–1.9%).

The type of buffer chosen can also influence the outcome, since the shape and physical properties (compliance and elastance) modify the cuff. Thus, without the buffer, the cuff would inflate freely, requiring more time to reach the maximum allowable pressure by the APRV. Therefore, the presence of a buffer served to reduce the insufflation time to values close to what is expected in humans, but with no claim to simulate the human trachea. This would be possible with the use of materials specifically made for this

purpose, using concentric tubes made of polyurethane and latex thin membranes,²⁷ but its manufacture would require complex laboratory resources, precluding its use in this work.

The choice of a 20 mL syringe as a buffer was due to the fact that it was a rigid tube, easily found, low cost, with an internal diameter of 20 mm—similar to the average internal diameter of the adult male trachea. Because the objective of this study was to evaluate the effectiveness of a method to limit the pressure within the cuff, the buffer's diameter and compliance did not need to have the same characteristics of the human trachea, since, regardless of these, the valve set to 30 cm H₂O would limit the pressure increase above this value. However, the use of a fixed diameter buffer associated with different size tubes may influence the method's performance as the cuffs of smaller tubes require more volume and for a given flow more time, in order to reach sufficient size, so its walls come in contact with the buffer and allow the balance of C_{pressure} . Larger tubes reach the balance of C_{pressure} in less time. This could explain why the failures occurred with the smaller tubes and in the shortest insufflation time, even though with very low incidence. This problem could be solved by keeping insufflation for a longer time or using a smaller inner diameter buffer. However, it does not represent a disadvantage of this method in clinical practice, as the patient's trachea inner diameter is not a modifiable factor, and most often unknown. The choice of tube size takes into account the patient's sex and anthropometric data (weight, height, larynx size) and naturally maintains the size ratio between the outer diameter of the chosen cuff tube and the inner diameter of the patient's trachea, minimizing or even eliminating this problem. However, clinical studies are needed to prove it.

In an attempt to correlate some of these factors with the occurred failure episodes, the tests were conducted following a fixed and pre-established order, according to the sequence number of the three tubes, of each size and manufacturer, numbered 1–3. However, the incidence of failure in this study was quite small, not allowing its association with any seen factors. All eight failures occurred with the shortest insufflation time (10 s) and a single operator (Operator 2), with six of them (75%) in a single experiment (Portex tube, #7.0, three failures with tube #1, two with #2, and one with tube #3. One cannot say that these failures found in this particular experiment are due to the short time to insufflation, or uncontrolled factors such as those mentioned above. Possibly, these failures do not result from human error, as the Operator 2 showed extremely low failure rate of only 1.1% (95% CI: 0.3–1.9%). Nor of short time to insufflation, since despite all the failures have occurred in tubes inflated for 10 s the proportion of failures in this group was 1.6% (95% CI: 0.5–2.7%), with mean pressure values similar to those of other insufflation times (10 s: 24.30 cm H₂O; 15 s: 25.77 cm H₂O; 20 s: 25.35 cm H₂O).

What is stated in the preceding paragraphs may explain the pressure differences seen after same size tubes insufflation, using the same method. The existence of such variables beyond the proposed method control does not diminish the data value, as the same variables will be found in other contexts and will similarly influence the result of applying this method in clinical studies or even in clinical practice.

Among the limitations of the proposed method may be mentioned that it does not completely prevent the under-pressurization of cuffs, although rarely, and does not allow pressure measurement and its setting, allowing only to limit it to the maximum value considered safe. Its use is also not possible in anesthesia machines without graded APRV and is inadvisable in cases where it is not possible to measure the circular system pressure due to the failure of APRV communication with the machine manometer, as in machines of lower standard quality.

The fact that there have been no failures related to inappropriately high pressures (greater than 30 cm H₂O) demonstrates that this method, while effectively limiting the cuff pressure, may be useful to reduce injuries related to mucosal and other airway structure compression by the cuffs. Other studies, in clinical settings and with other devices bearing inflatable cuffs, such as tracheotomy tubes, supraglottic airway devices, and double-lumen tubes, should be conducted in order to demonstrate the practical use and possible benefits of this method.

Conclusion

The proposed and applied method in this study was effective to insufflate in vitro the tracheal tube cuffs of different sizes and manufacturers, limiting its internal pressure to a range between 20 and 30 cm H₂O.

Conflicts of interest

The authors declare no conflicts of interest.

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