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Effectiveness of the endotracheal tube cuff on the trachea: physical and mechanical aspects

Eficácia do balonete do tubo endotraqueal sobre a traqueia: aspectos físicos e mecânicos

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Abstract

Introduction: The inflation pressure of the endotracheal tube cuff can cause ischemia of the tracheal mucosa at high pressures; thus, it can cause important tracheal morbidity and tracheal microaspiration of the oropharyngeal secretion, or it can even cause pneumonia associated with mechanical ventilation if the pressure of the cuff is insufficient.

Objective: In order to investigate the effectiveness of the RUSCH® 7.5 mm endotracheal tube cuff, this study was designed to investigate the physical and mechanical aspects of the cuff in contact with the trachea.

Methods: For this end, we developed an *in vitro* experimental model to assess the flow of dye (methylene blue) by the inflated cuff on the wall of the artificial material. We also designed an *in vivo* study with 12 Large White pigs under endotracheal intubation. We instilled the same dye in the oral cavity of the animals, and we analyzed the presence or not of leakage in the trachea after the region of the cuff after their deaths (animal sacrifice). All cuffs were inflated at the pressure of 30 cmH₂O.

Results: We observed the passage of fluids through the cuff in all *in vitro* and *in vivo* experimental models.

Conclusion: We conclude that, as well as several other cuff

models in the literature, the RUSCH® 7.5 mm tube cuffs are also not able to completely seal the trachea and thus prevent aspiration of oropharyngeal secretions. Other prevention measures should be taken.

Descriptors: Thoracic Duct. Thoracic Wall. Tracheal Stenosis. Respiratory Aspiration of Gastric Contents. Suction.

Resumo

Introdução: A pressão de insuflação do balonete (*cuff*) do tubo endotraqueal tanto pode causar isquemia de mucosa traqueal em pressões elevadas, e assim ocasionar morbidade traqueal importante, quanto pode causar microaspiração traqueal de secreção de orofaringe ou, ainda, ocasionar pneumonia associada à ventilação mecânica, caso a pressão do balonete seja insuficiente.

Objetivo: A fim de investigar a eficácia do balonete do tubo endotraqueal RUSCH® 7,5mm, este estudo foi desenhado para investigar aspectos físicos e mecânicos do balonete em contato com a traqueia.

Métodos: Para isto, foi desenvolvido modelo experimental *in vitro* para avaliar o escoamento de corante (azul de metileno)

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Abbreviations, acronyms & symbols	
ICU	Intensive care unit
IMV	Invasive mechanical ventilation
OTI	Orotracheal intubation
PAMV	Pneumonia associated with mechanical ventilation

pelo balonete insuflado na parede de material artificial. Também foi desenhado estudo *in vivo* com 12 porcos da raça Large-White sob intubação endotraqueal. Foi instilado o mesmo corante na cavidade oral do animal e após óbito (sacrifício do animal) foi analisada a presença ou não de vazamento deste na traqueia

INTRODUCTION

The oro-tracheal intubation (OTI) procedure is used in cases in which invasive mechanical ventilation (IMV) is required, such as in intensive care units (ICU) and some general anesthesia. The first reported use of OTI was described by Dobel^[1].

Although it is a routine medical procedure, the OTI can bring numerous complications, including dental fractures, esophageal intubation, selective lung intubation, broncho-aspiration, tracheal injury, mucosal lesions and tracheal stenosis^[2-4]. The morbidity associated with OTI is attributed to factors such as size of the tube, pressure of the cuff, movement of the tube or accidental extubation^[5,6].

The main goals of the OTI are to ensure the pulmonary gas exchange through IMV and protect the airway from the bronchoaspiration of oral and gastric contents. For this purpose, the endotracheal tube has a cuff that is permanently inflated after intubation on its distal end, isolating and protecting the airway from the digestive pathway^[1,3,5].

Tubes and cuffs of various materials and models are in constant improvement in search for a "perfect" model, as the pressure of the endotracheal tube cuff must be able to ensure the passage of adequate pressure volume, through mechanical ventilation, and it must also be sufficient to prevent aspiration of secretions that accumulate on the cuff and, at the same time, cannot compromise the tracheal perfusion. A minimum pressure of 20 cmH₂O is recommended so that the aspiration of secretions above the cuff and pneumonia associated to mechanical ventilation can be prevented^[7].

The upper limit of the pressure of the cuff associated with the impairment of the tracheal capillary perfusion varies in the literature between 30 and 50 mmHg^[8]. This limit is important because excess pressure in the cuff, although apparently increasing the seal with the trachea wall to prevent aspiration, can compromise not only the tracheal perfusion, but can increase the chance of complications in the long term,

pós-região do balonete. Todos os balonetes foram insuflados na pressão de 30 cmH₂O.

Resultados: Houve passagem de fluidos pelo balonete em todos os modelos experimentais *in vitro* e *in vivo*.

Conclusão: Podemos concluir que, assim como diversos outros modelos de balonetes na literatura, balonetes do tubo RUSCH® 7,5mm também não são capazes de vedar completamente a traqueia e com isso prevenir aspiração de secreções orofaríngeas. Outras medidas para a prevenção devem ser tomadas.

Descritores: Tubos Torácicos. Parede Torácica. Estenose Traqueal. Aspiração Respiratória de Conteúdos Gástricos. Sucção.

such as tracheitis, tracheomalacia, tracheal stenosis, among others^[2,5,9-11].

This concern with the quality of the seal of the cuff is justified because of the risk of microaspiration occurring in critical patients under prolonged OTI, which, associated with a weakened immune system, lead to a high incidence of pneumonia associated with mechanical ventilation (PAMV), responsible for high morbidity and mortality and high hospital costs^[12].

Objectives

The primary objective of this study was to analyze the effectiveness of the endotracheal tube seal of the RUSCH® cuff on the trachea (at the upper limit of pressure in the cuff: 30 cmH₂O) and obtain the physical and mechanical aspects related to the prevention of the flow of secretions.

The secondary objective of the study was to measure the actual area that the cylindrical cuff has contact with the tracheal mucosa.

METHODS

Study Design

The design of the experimental study has two aspects: *in vitro* and *in vivo*. We used 7.5 mm endotracheal tubes (RUSCH®) in both studies, as they are the most widely used tubes in adults. The measures described have been carried out with the use of a caliper with precision to one-hundredth of a millimeter (Mitutoyo® 530 series), and the data were rounded to the decimal for purposes of calculations. The pressure of the cuff was measured with a precision manometer, VBM® model.

Description of the *in vitro* experiment:

WE used the body of a 10 mL plastic syringe as a trachea model, since it has a diameter that approaches the trachea of an adult. The 7.5 mm oro-tracheal tube was introduced in the trachea model and its cuff was then inflated to the pressure

of 30 cmH₂O confirmed by the manometer. Direct measures were carried out for diameter, perimeter and area of contact of the cuff with the wall of the syringe. The sealing capacity of the cuff to prevent the flow of secretion was tested by applying 3ml of methylene blue diluted in 10 ml of water through the upper portion of the body of the syringe and observing if there was passage of the liquid through the outside of the cuff. The experiment was repeated twenty times and the values recorded. The dye was chosen as a qualitative marker of leakage (microaspiration); thus, there was no concern in measuring the amount of secretion leaked in this study.

Description of the *in vivo* experiment:

The experiment was approved by the Committee of Ethics in Animal Experimentation of the Institute of Biology of the University of Campinas (Unicamp), protocol number 2612-1. We used 12 Large White pigs (weighting approximately 30 kg). The animals were already being used for other experimental studies (which did not involve the cardiopulmonary system, aiming at the non-interference on the results, and were used because of ethical issues). The pressure in the cuff was measured with the manometer shortly after intubation and throughout the experiment; when necessary, we adjusted it to 30 cmH₂O. For each animal, we injected 3 ml of methylene blue diluted in 10 ml of water into the oral right rima. After remaining in IMV for 3 to 6 hours, the animals were sacrificed with intravenous potassium chloride, and, without being extubated, the trachea was carefully open so that we could visualize the presence or absence of methylene blue below the region where the cuff was inflated (aspiration of contents).

RESULTS

The *in vitro* study

Test of *in vitro* Instillation of Methylene Blue

By externally instilling methylene blue in the upper portion of the inflated balloon, we observed the immediate leakage of the liquid around it (Figure 1). At the end of four minutes of experiment, there was the passage of all the fluid injected in all artificial models.

Direct measurements

In the analysis of 20 endotracheal tubes, we reached a cuff diameter of 30.90 mm (29.82 to 31.15). The length of the cuff surface parallel to the tube was 2.20 mm (2.00-2.30).

Indirect Measurements

Pressure Effect

Diameter: for the 7.5 mm endotracheal tube, with the pressure in the cuff equivalent to 30cmH₂O (or 0.03 atmospheric pressure unit), we found the average measure of its diameter as 30.90 mm.

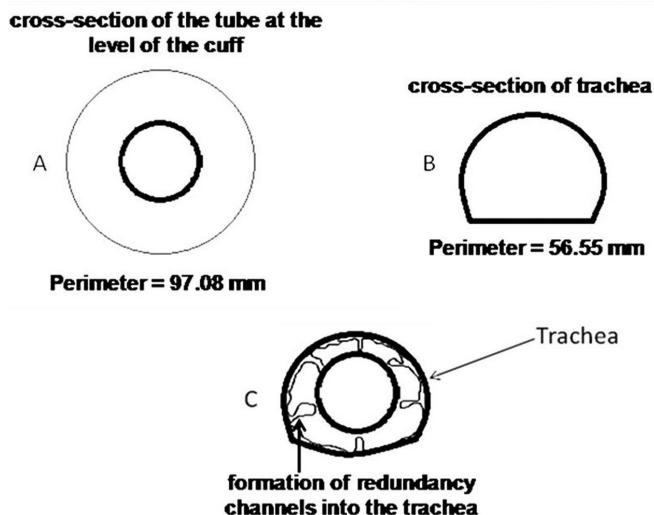


Fig.1 - Cross-sectional area of the tube (A) demonstrates its outer ring and inner cuff. Item B corresponds to the format of the trachea and its perimeter. (C) Cross-sectional area of the endotracheal tube adapted to the tracheal lumen with redundancy channels formed, which can allow the passage of fluids.

Perimeter: considering a circular cross-section in the cuff, the perimeter would be given by the following formula: perimeter = $2 \times \pi \times \text{radius}$, with a radius of 15.45 mm, obtained by dividing the diameter (30.90mm). Therefore, the perimeter found for the cuff was 97.08 mm ($2 \times 3.1416 \times 15.45$).

Area of contact of the cuff with the trachea: we measured it through its central portion, parallel to the tracheal wall with the inflated cuff. The contact area of 2.20 mm can be obtained by multiplying the perimeter by the longitudinal extension. Therefore, the area of contact of the cuff was obtained by the formula: area = width x length. That is, area = 20.00 mm x 97.08mm = 213.58mm² or 21.36cm².

Mass of weight over the area: an atmospheric pressure (atm) is defined as equivalent to the application of 10 tons in an area of 1m² or 10,000 Kg per 10,000 cm², or even 1 atm corresponds to 1kg per cm² of force.

Extrapolating these data for the pressure of the cuff on the wall of the trachea, we must consider a cuff inflated to the pressure of 30 cmH₂O or 0.03 atmospheric pressure units with contact area of the cuff of 21.36 cm in a 7.5 mm tube. The mass of the section of the trachea in contact with the cuff is given by: 1000 gr/cm² = 1 atm x 0.03 atm = X gr (X gr = 1000 X 0.03 = 30 gr per cm²), with a contact area of 21.36 cm² between the cuff and the wall of the trachea; in the area of contact with the cuff, we have a mass equivalent to 30 gr x 21.36 cm² = 640.8 gr of weight on the trachea.

Contact surface effect

Perimeter of the cuff: The average measure of the diameter of a trachea varies with age, gender and race. Himalstein

& Gallager^[13] measured, in autopsies, the tracheal diameter of 100 men without any known tracheobronchial abnormalities. Based on these data, we used the mean sagittal diameter of trachea of 16.9 mm^[14]. The human trachea measures approximately 12 cm in length, ranging from 9 to 16 cm. Its external diameter measures 23 mm laterally and 18 mm in the anterior-posterior diameter^[15], based on the mean internal measurement of 17 mm for an adult, which is obtained applying the formula to calculate the perimeter ($2 \times \pi \times \text{radius}$), with radius equal to 8.5 mm, obtained by dividing the tracheal diameter of 53.41 mm.

In comparison with the 7.5 mm endotracheal tube, we have that the perimeter of the inflated cuff at a pressure of 30 cmH₂O is 97.08 mm.

Difference between the measures of the perimeters of the cuff (7.5 mm tube) and the trachea

It is given through the subtraction of the perimeter of the cuff from the tracheal perimeter. Therefore, Δ of area = $97.08 - 53.41 = 43.67$ mm or 4.37 cm.

This means that the inflated cuff measuring 97.08 mm needs to be accommodated within another tube (trachea) that measures only 53.41 mm.

After the inflation of the cuff with 0.03 atm pressure, there is a redundancy of 4.37 cm of the plastic that makes up the cuff inside the trachea. Therefore, we conclude that the cuff does not behave the same way inside and outside the trachea.

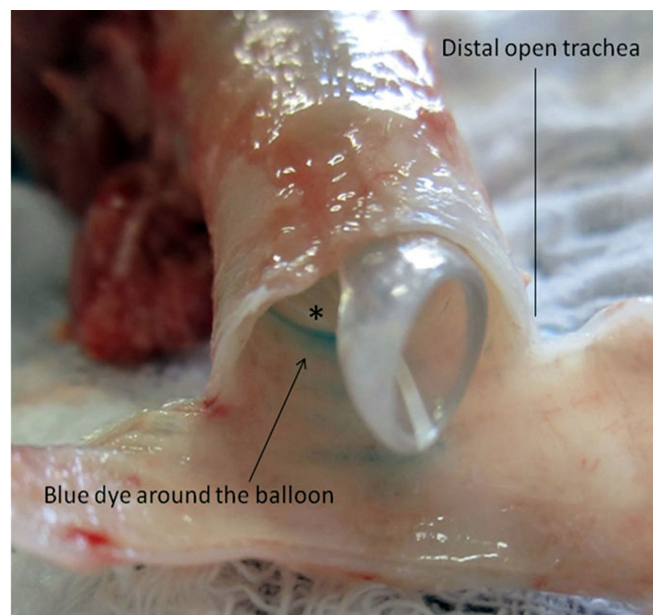


Fig. 2 - Porcine trachea isolated with a tracheal tube with cuff (*) inflated at 30cmH₂O pressure. The blue dye was introduced in the (proximal) upper region of the inflated cuff. After four minutes, the dye had leaked around the cuff (arrow).

There is a uniform distension of the cuff when it is inflated, which does not occur inside the trachea. During the *in vitro* performance of the experiment, we observed the formation of recesses on the surface of the cuff studied, named "longitudinal channels".

Results of the *in vivo* study

After the sacrifice of the animals with IV KCl, the tracheae were carefully extracted with a margin of 4 cm above and 4 cm below the location of the cuff.

Of the 12 pigs studied, there was a bluish dyeing of the mucosa after the cuff (just below it) in 100% of the observed tracheas. As this was a qualitative analysis, the amount of secretion leaked was not measured (Figure 2).

DISCUSSION

The main result of the *in vitro* study was the maximum leakage of the injected solution in less than 7 minutes. Similar results were found in the study of Dave et al.^[13] with similar study design, in which there was the passage of all the liquid injected at the superior part of the artificial trachea above the cuff on all PVC pipes without prior lubrication.

The passage (leakage) of secretions after the cuff is a phenomenon that is known and already described in patients under OTI with tubes with high-volume and low pressures. This finding can be explained by the formation of longitudinal channels on the surface of the cuff, which were recognized as responsible for the passage of this secretion, even with the inflated cuff at appropriate pressures^[14]. These longitudinal channels are formed from the redundancies of the inflated cuff plastic, which form "tunnels," with virtual light, which communicate the region just above the cuff with the region just below it, thus allowing the passage of secretions through the cuff^[11,14-18].

Longitudinal channels in the wall of the cuff were observed in this *in vitro* study. And, according to similar studies^[16], the result found can also be explained by the formation of these channels.

In the *in vitro* study, we also found secretion in the trachea below the cuff in all animals studied, which corroborates the hypothesis of occurrence of longitudinal channels present in the *in vivo* study, even with pressures in the upper limit of the safe range against ischemia of the tracheal mucosa (30 cmH₂O).

A possible solution to ease the passage of secretions by longitudinal channels would be the elevation of the pressure of the cuff. However, concerns in relation to the possible damage caused by this situation are widely discussed, as well as the prolonged permanence of the orotracheal tube. Extrapolating to the clinical setting, the complications to the patients requiring prolonged IMV can be worrisome^[19-22].

Some authors consider the maximum pressure of the inflation of the cuff as 25 cmH₂O (18.40 mmHg) so that the

capillary perfusion can be adequate^[5,23]. If pressures greater than 25-30 mmHg are maintained for a certain time, damage can be caused. If a continuous pressure equal to or higher than 67.5 cmH₂O (50 mmHg) is applied against the trachea during 15 minutes, the epithelium, tracheal membrane and cartilage can be destroyed. Thus, there must be a strict and frequent control of this pressure by the constant and continued measurement through a manometer.

According to Marjot^[24], a 38mmHg pressure in the cuff causes the obstruction of blood flow in the mucosa, and the pressure of the cuff must remain lower than 30mmHg to avoid this risk. Other authors^[2,5,6,9,19,20] claim that damage caused to the trachea is inevitable when the pressure in the cuff is higher than the perfusion pressure of the tracheal mucosa (20-35 mmHg); however, there is also the concern about insufficient inflation, which is also harmful, since the aspiration of oropharyngeal or gastric contents may occur. Traumas to the trachea, such as destruction of the epithelium, ulceration, stenosis, dilation and rupture, are associated to the sum of the pressure exerted by the cuff on the tracheal mucous membrane, intubation time and contact area of the cuff with the trachea^[21]. For some authors^[2,3], the pressure from the side walls is limited at 30 cmH₂O or 22 mmHg.

Luna et al.^[4] reported cases of patients who suffered swelling and rupture of the trachea despite the careful monitoring of the pressure of the cuff. According to the authors, the pressure in the cuff should not exceed 25 mmHg in patients with IMV that use a cannula with high-volume and low pressure. They also claim that the exact capillary pressure is not known, since it is impossible to measure it in normal conditions. On the other hand, the authors mention two known methods to calculate the capillary pressure of the trachea with approximate pressure of 25 mmHg and indirect functional measurement of the capillary pressure of approximately 17 mmHg^[25,26].

An injury caused by the pressure of the inflated cuff under the lining of the tracheal mucosa leads (in less than 48 hours) to varying degrees of inflammation and edema of the epiglottis and vocal cords^[23,24]. Experimental studies demonstrate ulceration, even necrosis, of the larynx in the cases of use greater than 48 hours^[21].

Similarly, lower pressures were tested, such as 10cmH₂O, resulting in important leakages of oropharyngeal secretions^[27]. An appropriate limit for the minimum acceptable pressure so there is no microaspiration is still discussed, and the pressure of 25 cmH₂O was suggested by Lomholt et al.^[28] as the minimum to prevent it.

This study has some limitations. In the *in vitro* model, although the diameter is similar to that of an adult trachea, the wall of the trachea is not rigid as the body of the syringe. The viscosity of the methylene blue is also not exactly the same as the oropharyngeal secretion. However, the characteristic of viscosity and composition of the secretions vary greatly

between patients (e.g. different comorbidities, medications with anti-drooling effect, presence of vomiting, infection of the oral cavity and even enteral diet). For this reason, we chose to use only methylene blue.

We also did not compare the use of positive expiratory pressure or lubricants around the cuff in this study. According to Lucangelo et al.^[14], positive expiratory pressure may slow secretion leakage in *in vitro* models, and Young et al.^[29] also showed that the rate of secretion leakage by the cuff is inversely proportional to the pressure of the cuff, varying with different positive expiratory pressures.

Authors such as Blunt et al.^[30] and Sanjay et al.^[31] developed *in vitro* models to evaluate the effectiveness of using gel lubricants to fill the longitudinal channels and thus prevent or slow the leakage of secretion by the cuff. However, Dave et al.^[13] say that this effect is transient and is lost in 24-120 hours. The authors also suggest that, to assess the quality of the seal of the cuff, the static *in vitro* models may be more suitable without using artifacts such as positive expiratory pressure or lubricants, because the difference between the effectiveness of the seals is more evident without this interference.

A limitation of the *in vivo* model consists in the fact that we could have checked the pressure of the cuff at shorter time intervals in order to evaluate pressure change over time, since a pressure less than 25 cmH₂O would be responsible for the leakage of fluids. On the other hand, intermittent measurements of the pressure of the cuff, with greater intervals, are closer to the routines in Intensive Care Units.

CONCLUSION

Similar to other works regarding the quality of the seal of the cuff, there was the passage of fluid in this study both in the *in vitro* and *in vivo* models for the cuff inflated with pressures considered as ideal.

Given this result, we can conclude that inflated cuffs with pressure regarded as ideal to prevent the ischemia of the tracheal mucosa are not able to completely seal the trachea against aspiration of oropharyngeal secretions, which may pose risks to patients intubated or under general anesthesia in lengthy surgeries.

Different models of endotracheal tubes and cuff measures and formats, such as continuous supraglottic aspiration, have been used; however, an ideal model is yet to emerge. While the ideal cuff is not developed, it is of great importance to take all precautions for the prevention of microaspiration, as well as the optimization of the time of intubation.

Conflict of Interest

The authors have no conflicts of interest. The choice for RUSCH® tubes occurred because of its use in the Service where the study was conducted. No materials were donated for the completion of the study.

Authors' roles & responsibilities

MSDN	Execution, analysis, writing and editing
GB	Preparation, supervision, execution, analysis, writing and editing
RQA	Preparation, execution, analysis and writing
TAB	Preparation, execution, analysis and writing
LRM	Analysis and/or interpretation of data, conception and study design, conduct of procedures and/or experiments
MMM	Preparation, supervision, execution, analysis, writing and editing
AJT	Preparation, supervision, execution, analysis, writing and editing

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