Atraumatic Endotracheal Tube for Mechanical Ventilation

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Background and objectives: Patients who need to stay under endotracheal intubation for long periods or when undergoing general anesthesia may develop tracheal lumen injuries due to pressure from distal cuff. In some cases, these injuries may evolve to stenosis or, occasionally, necrosis. The objective of this study was to present a modified endotracheal tube (METT) in which the cuff pressure is variable according to the cycle of mechanical ventilation (MV), which was tested on a lung simulator and animal model.

Methods: Two models of endotracheal tubes, a modified (METT) and a conventional (CETT), number 7.5 mm and 8.0 mm, were connected to a lung simulator in a mechanical ventilator adjusted with two tidal volumes (TV) of 10 and 15 mL.kg⁻¹ and a compliance of 60 mL.cmH₂O to evaluate the ventilatory efficiency of METT. Both models were also compared in Large-White pigs under general anesthesia and MV for 48 consecutive hours. Subsequently, animals were sacrificed for histopathological analysis of their tracheas.

Results: Both METTs (#7.5 and 8.0) presented air leaks in lung simulator. The smallest air leak (13%) was observed in METT #7.5 with TV = 15 mL.kg⁻¹, while the largest air leak (32%) was observed in METT #8.0 with TV = 10 mL.kg⁻¹. Nevertheless, both METTs showed good efficiency on the lung simulator. In animals, on histopathological analysis of their tracheas, it was found that METT caused less trauma to the epithelium when compared to CETT.

Conclusion: The use of a new model of ETT may decrease the risks of tracheal injury without hindering respiratory mechanics.

Keywords: Intubation, Intratracheal; Disposable equipment; Technology Assessment, Biomedical; Respiration, Artificial; Swine.

INTRODUCTION

Endotracheal tube (ETT) is used quite often in the medical field in patients requiring mechanical ventilation (MV). This might be for a short period for example in general anesthesia, or more prolonged periods such as in patients who need MV in intensive care units (ICU).

The endotracheal tube has a distal cuff, whose function is to seal and protect the airways, therefore preventing aspiration of secretions and allowing positive pressure ventilation. The distal cuff exerts a certain amount of pressure on the tracheal wall, which should not be elevated. If this happens, it could prevent blood flow to the tracheal mucosa. High-compliance and low-pressure cuffs may minimize the risk of mucosal ischemia, preventing injury. Therefore, the cuff inflation pressures should be adjusted between 20 and 30 cmH₂O 1.

The most common endotracheal complications caused by the ETT cuff include laryngitis, glottic edema, mucosal ulceration, laryngeal stenosis, tracheal stenosis or dilation, inadvertent esophageal intubation, and innominate artery fistula 2,3.

Tracheal ischemia may occur when the tracheal cuff is inflated with high pressures or when large ETTs are used for long periods. This may cause an inflammatory reaction and, often, tracheal stenosis. The studies of Cooper & Grillo 4 indicated that the pressure applied by the cuff on tracheal wall represents the main factor of tracheal stenosis. This complication varies between 1.5% and 19.5%. Other studies demonstrated that patients may develop laryngeal stenosis when intubated for short periods between 24 and 48 hours 3,5,6, more often affecting the glottis at the level of cricoid cartilage 5,7.

The pressure inside the cuff is the most important factor in the genesis of post-intubation tracheal injury 4,8. In an attempt to decrease the effects of cuff’s pressure on the tracheal epithelium, Kamen & Wilkinson 9 recommended auffed tube filled with foam. More than three decades ago, Arola & Antinen 9 in an experimental study with tubes with double cuffs inflated alternately reported pressures ranging from 63.8 to 74.3 mmHg. They stopped using this type of tube when they observed injuries in both contact points.
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REFERÊNCIAS / REFERENCES


Justificativa y objetivos: Pacientes que necesitan permanecer bajo intubación endotraqueal (IOT), durante largos períodos o que tienen que ser sometidos a la anestesia general, podrán tener lesiones en la luz de la tráquea debido a presiones ejercidas por el balón terminal. En algunos casos, esas lesiones podrán evolucionar para una estenosis o a veces necrosis. El presente trabajo quiso presentar un tubo endotraqueal modificado (TETM), en que la presión del balón varía de acuerdo con el ciclo de la ventilación mecánica (VM), siendo el mismo testado en un simulador pulmonar y modelo animal.

Método: En un simulador pulmonar acoplado a un ventilador mecánico y ajustado con dos volúmenes corrientes (VC) de 10 y 15 mLkg⁻¹ y complacencia de 60 mLCmH₂O⁻¹, fueron utilizados dos modelos de tubos endotraqueales: uno modificado (TETM), y el otro convencional (TETc), números (º7,5 y 8,0) mm, para evaluar la eficiencia del TETM #7,5 mm, con Vc = 10 ml.kg⁻¹, fue visto en el TETM #8,0 mm, con Vc = 15 ml.kg⁻¹. El menor de los escapes de aire (13%), fue visto en el TETM #7,5 mm, con Vc = 10 ml.kg⁻¹. En algunos casos, esas lesiones podrán evolucionar para una estenosis o a veces necrosis. El presente trabajo quiso presentar un tubo endotraqueal modificado (TETM), en que la presión del balón varía de acuerdo con el ciclo de la ventilación mecánica (VM), siendo el mismo testado en un simulador pulmonar y modelo animal.

Resultados: Los dos TETMs (#7,5 y 8,0) presentaron un escape de aire en el simulador pulmonar. El menor de los escapes de aire (13%), fue visto en el TETM #7,5 mm, con VC = 15 mLKg⁻¹ y complacencia de 60 mLcmH₂O⁻¹, fueron utilizados dos modelos de tubos endotraqueales: uno modificado (TETM), y el otro convencional (TETC), números (#) 7,5 mm y 8,0 mm, para evaluar la eficiencia de la ventilación con el TETM. También se hizo la comparación entre los dos modelos, en cerdos de la raza Large-White, bajo anestesia general y VM por 48 horas consecutivas. Posteriormente, los animales se sacrificaron para el análisis histopatológico de las tráqueas.

Conclusiones: El uso de un nuevo modelo de TET podrá disminuir los riesgos de lesión traqueal sin prejudicar la mecánica respiratoria.

Descripciones: ANIMAL: cerdo; AVALIACIÓN: COMPLICACIONES: intubación traqueal; EQUIPOS: tubo traqueal; REANIMACIÓN.
In an experimental study with rabbits, the authors evaluated tracheal blood flow. They demonstrated that tracheal mucosal ischemia is seen when the cuff pressure exceeds 30 mmHg. In another study also with rabbits, Nordin et al. demonstrated that a cuff pressure above 40 cmH2O causes mucosal ischemia and recommended that this pressure should be below 26 cmH2O.

To attenuate adverse effects caused by cuff pressure on tracheal mucosa during tracheal intubation a modified ETT (METT) was developed and patented, both nationally and internationally (Patent deposit # INPI: 11/08/2007. Patent number MU8702392-0U2, Classification A61M39/10). The main goal of the METT is to allow variation in the cuff internal pressure during respiratory cycles, according to MV.

Respiratory mechanics and occasional deleterious effects on the trachea were evaluated in a lung simulator (test lung). To demonstrate possible tracheal mucosal injuries, an animal model was ventilated mechanically with the conventional ETT (CETT) and compared to the METT.

METHODS

The new ETT model shows variation in the distal cuff pressure according to cycle of MV. The ETT model has three identical perforations within its distal cuff, of 3 mm each, to allow the cuff inflation during the inspiratory cycle and deflation in the expiratory phase. The tube also allows the use of an external tube to aspirate secretions that accumulates around the cuff.

An experimental study and a pilot study were performed to determine air leaks and tracheal injuries that the METT and CETT could cause, respectively.

A DX 3010® Dixtal mechanical ventilator was used cycled by volume with a tidal volume of 10 and 15 mL.kg-1 and positive end-expiratory pressure (PEEP) of zero and 5 cmH2O, respectively, with a respiratory rate of 12 cycles per minute, and an inspiratory/expiratory ratio of 1:2.

The lung simulation equipment used was the Vent Aid® Training/Test Lung (Michigan Instruments Incorporation, Michigan, MC). The adjusted compliance used in this simulator was 60 mL.cmH2O-1.

Endotracheal tubes #7.5 and 8.0 mm were used. The pressure on the CETT cuff was adjusted for 25 cmH2O, which differed from the METT, in which it varied during the respiratory cycle. A flow sensor of the respiratory profile monitor CO2MO PLUS DX-8100 (Dixtal/Novametrix, São Paulo, Brazil) was connected to both ETTS (placed between the mechanical ventilator and the pulmonary simulator). Air leakage was calculated by the difference between the inspiratory (Vi) and expiratory (Ve) volumes. Data regarding respiratory mechanics were stored continuously on a computer, for three minutes, by the software Analysis Plus®. At the end of this period, data were processed and analyzed.

An experimental pilot study was performed to compare both ETTS and the occasional occurrence of lesions. The same endotracheal tubes (METT and CETT, #7.5 mm) were used in two Large-White pigs with similar weights of 35 kg. The same mechanical ventilator of the first study was used cycled by volume (15 mL.kg-1), respiratory rate of 12 cycles per minute, PEEP = 0 cmH2O, FiO2 = 0.21%. CETT cuff pressure was set to 25 cmH2O. Both animals remained anesthetized and on mechanical ventilation for 48 hours. Afterwards, the animals were sacrificed and both tracheas were analyzed for possible macroscopic and histological injuries.

RESULTS

Table I shows the mean values obtained in the first experiment with the # 7.5 mm CETT and METT. Greater air leaking (23%) was observed in METT with TV of 10 mL.kg-1 and PEEP of 0 cmH2O, and lower air leaking (13%) with TV of 15 mL.kg-1 and PEEP of 5 cmH2O.

There was less air leakage in CETT (3% and 6%). The greater inspiratory pressure of METT cuff was 10.5 cmH2O, while the CETT cuff pressure was constant at 25 cmH2O.

Table II shows the mean values obtained with the #8 mm CETT and METT in which the greater air leaking (32%) was observed with TV of 10 mL.kg-1 and PEEP of 5 cmH2O. The lower air leaking (20%) was observed with TV of 15 mL.kg-1 and PEEP of 0 cmH2O.

The air leakage observed with the CETT was 8% and 13%. The greater inspiratory pressure in METT cuff was 10 cmH2O, while the pressure in CETT cuff was constant, at 25 cmH2O.

<table>
<thead>
<tr>
<th>Tidal volume</th>
<th>PEEP</th>
<th>METT Vi / Ve % leak</th>
<th>Cuff pressure (insp/exp)</th>
<th>CETT Vi / Ve % leak</th>
<th>Cuff pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 mL.kg-1</td>
<td>0</td>
<td>658 / 505 23%</td>
<td>4 / 0</td>
<td>695 / 667 4%</td>
<td>25</td>
</tr>
<tr>
<td>15 mL.kg-1</td>
<td>0</td>
<td>960 / 814 15%</td>
<td>7.5 / 0</td>
<td>1014 / 984 3%</td>
<td>25</td>
</tr>
<tr>
<td>10 mL.kg-1</td>
<td>5</td>
<td>659 / 514 22%</td>
<td>8 / 3</td>
<td>692 / 651 6%</td>
<td>25</td>
</tr>
<tr>
<td>15 mL.kg-1</td>
<td>5</td>
<td>962 / 835</td>
<td>10.5 / 3.5</td>
<td>1015 / 975 4%</td>
<td>25</td>
</tr>
</tbody>
</table>

CETT: conventional endotracheal tube; METT: modified endotracheal tube; PEEP: positive end-expiratory pressure (cmH2O); Vi/Ve: inspiratory and expiratory volumes (mL); % leak: difference between inspiratory and expiratory volumes (mL); cuff pressure (cmH2O) during the inspiratory and expiratory phases.
In the pilot study, the animal using METT showed macroscopically less severe tracheal lesions without visible lesions (Figure 1, arrow), while the animal using CETT showed areas of necrosis and ulcerations (Figure 2, arrow).

Microscopically, the animal using METT showed areas with preserved respiratory epithelium (Figure 3, arrow). On Table II – Mean Values of Both #8 mm Endotracheal Tubes (CETT and METT)

<table>
<thead>
<tr>
<th>Tidal volume</th>
<th>PEEP</th>
<th>METT Vi / Ve % modified leak</th>
<th>Cuff pressure (insp/exp)</th>
<th>CETT Vi / Ve % leak</th>
<th>Cuff pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 mLkg⁻¹</td>
<td>0</td>
<td>663 / 479 28%</td>
<td>3/0</td>
<td>697 / 630 10%</td>
<td>25</td>
</tr>
<tr>
<td>15 mLkg⁻¹</td>
<td>0</td>
<td>966 / 769 20%</td>
<td>6/0</td>
<td>1020 / 941 8%</td>
<td>25</td>
</tr>
<tr>
<td>10 mLkg⁻¹</td>
<td>5</td>
<td>660 / 451 32%</td>
<td>7/2</td>
<td>698 / 609 13%</td>
<td>25</td>
</tr>
<tr>
<td>15 mLkg⁻¹</td>
<td>5</td>
<td>964 / 749 22%</td>
<td>10/3</td>
<td>1024 / 923 10%</td>
<td>25</td>
</tr>
</tbody>
</table>

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histological evaluation the animal using CETT had an intense inflammatory process with ulcerated areas and erosions on tracheal epithelium (Figure 4, arrow). Extensive areas of de-epithelialization and foci of associated hemorrhage were also observed. In ulcerated areas neutrophilic perichondritis and acute inflammation extending up to the adventitia was observed, contrary to what happened to the animal using METT.

DISCUSSION

When compared with CETT, the METT showed in the first experiment lower cuff pressure. This did not depend on the phase of the respiratory cycle or larger tidal volumes and PEEP used. On the other hand, # 8 mm METT showed greater air leaking (32% higher than the CETT). In the pilot study, we observed that METT was associated with less tracheal injury, both macro- and microscopically.

Compared with CETT, the METT is composed of an identical endotracheal tube used for intubation. In order to have cycles during MV, the tube inside the cuff has millimetric holes. These holes cause the passage and exit of air during MV (both on inspiration and expiration). Since it is not constantly insufflated the contact with tracheal mucosa is smaller and, consequently, possible mucosal injuries are practically negligible. This comparative demonstration was possible in the pilot study with animals.

In general, the objective of ETTs is to allow the passage of air. The inflated cuff protects the airways from aspirating secretions, closing the trachea and allowing effective alveolar ventilation. Aspiration of gastric contents is not common during anesthesia, but it requires preventive measures such as the use of drugs that reduce its volume and acidity. However, tracheal intubation is the best method to prevent gastric aspiration in these situations. In the literature. Among the most common, we could mention subglottic laryngeal and tracheal stenosis.

Lindholm 17 investigated 35 cases of prolonged intubation with rubber, latex, and PVC tubes. In all cases, he observed damage in the area of contact with the cuff, with different degrees of inflammation and/or necrosis. Klainer et al. 18 demonstrated the presence of tracheal damage in the area of the low-pressure cuff after two hours of intubation, which was demonstrated through electron microscopy. Ciliary disorganization with loss of the histological pattern was observed in some areas.

Magovern et al. 8 developed a cuff with an external pressure regulator system. When excessive volumes of air are injected inside the cuff, another external cuff of an extremely elastic material distends. This will avoid an increase in pressure above 30 cmH2O in the internal cuff. This system has some drawbacks, such as the price (approximately 10 times more than the conventional tube) and it can frequently show rupture of the system.

In another extreme, Peagle et al. 19 investigated 54 patients in whom two models of PVC tube with latex cuff (red tube) were used and who died and underwent autopsy. Pressures were not systematically controlled, but they were between 150 and 300 mmHg. The histological study of the tracheas showed loss of ciliary epithelium with less than 12 hours of intubation. The inflammatory reaction extended to the margins of cartilage with signs of early necrosis.

Therefore, the METT represents an alternative to the situation presented and indicated by the pilot study presented here, since it causes little damage to the tracheal mucosa, as observed in the studied animal.

In the first phase of the study, the METT showed greater air leaking than the CETT. In an attempt to minimize this situation, a PEEP of 5 cmH2O was used. This measure was not effective in reducing the percentage of air leaking (Tables I and II).

Note that with the smaller diameter METT (# 7.5 mm) the percentage of air leaking was also smaller. The smaller diameter cuff of METT has a greater volume capacity when compared to the METT of greater diameter during the inspiratory phase, which could explain this reduction in air leaking. This will result in delayed emptying during the expiratory phase, therefore allowing better seal and less air leaking.

Bryant et al. 20 concluded, in their findings on ETT-related damage, that temporarily emptying the cuff or changing its position was not enough to prevent tracheal mucosa necrosis and/or cartilage damage.

An ETT with a pressure regulating valve of distal cuff is available on the market. This decreases tracheal trauma; however, the damages remain and its cost is very high.

With METT, less tracheal damage was observed without significant impairment of air leaking. The price, when produced in large scale, will not differ from the current price of CET-Ts. Further experimental and clinical studies are necessary to determine possible limitations of this method, which demonstrated to reduce the risk of tracheal damage without causing relevant harm to respiratory mechanics.
REFERÊNCIAS / REFERENCES


Justificativa y objetivos: Pacientes que necesitan permanecer bajo intubación endotraqueal (IOT), durante largos periodos o que tienen que ser sometidos a la anestesia general, podrán tener lesiones en la luz de la tráquea debido a presiones ejercidas por el balón terminal. En algunos casos, esas lesiones podrán evolucionar para una estenosis o a veces necrosis. El presente trabajo quiso presentar un tubo endotraqueal modificado (TETM), en que la presión del balón varía de acuerdo con el ciclo de la ventilación mecánica (VM), siendo el mismo testado en un simulador pulmonar y modelo animal.

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Resultados: Los dos TETMs (#7,5 y 8,0) presentaron un escape de aire en el simulador pulmonar. El menor de los escapes de aire (13%), fue visto en el TETM #7,5 mm, con VC = 15 ml.kg⁻¹ y el mayor (32%) en el TETM #8,0 mm, con VC = 10 ml.kg⁻¹. A pesar de eso, los dos TETMs presentaron una buena eficacia en el simulador pulmonar. En la evaluación del uso de los TETs en animales, analizando la histopatología de sus tráqueas, verificamos que el TETM causó menos áreas traumáticas en su epitelio en comparación con el TETc.

Conclusiones: El uso de un nuevo modelo de TET podrá disminuir los riesgos de lesión traqueal sin prejudicar la mecánica respiratoria.

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