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Abstract Many of the complications related to prolonged ventilation are related to inappropriate handling of endotracheal tube (ETT) cuff. This article reviews the possible complications associated with the ETT cuff, and the landmark development made in that field. The article challenges the present paradigm of cuff use and reviews the current clinical practice in that area.

Keywords Endotracheal tube · Cuff · Pressure · Ventilation · Suction

The primary goals of an endotracheal tube (ETT) management are assurance of an efficient gas exchange and prevention of complications due to mechanical ventilation. However, adverse events occasionally occur despite proper management. Many of the complications related to prolonged ventilation are related to the ETT cuff. This article reviews the possible complications related to the ETT cuff, and the landmark development made in that field. The article challenges the present paradigm of cuff use and reviews the current development in that area.

The principal function of the cuff is to seal the trachea from leakage of gas or secretions around it. Isolation of the lower airways enables efficient lung ventilation and reduces the risk of aspiration around the cuff and the consequential Ventilator Associated Pneumonia (VAP) [1]. However, an over-inflated cuff may cause local mechanical complications such as mucosal ulcerations, granulomas, tracheal stenosis, and tracheoesophageal fistulae [2–5]. Optimal ETT cuff pressure can be defined as the minimal pressure required for airway isolation. This intra cuff pressure is influenced by airway anatomy, cuff location, cuff material and structure, size and volume, and by peak inspiratory pressure. This value of minimal pressure should be dynamically adapted to changing conditions such as patient/head position, mucosal edema, perfusion pressure in the tracheal mucosa, tracheal elasticity and ventilation pressures.

1 The history of ETT cuff

Until the mid of the twentieth century there was no inflatable cuff and the ETTs were packed on both sides of the subglottis by anesthetic swabs to prevent gas escape. The swabs were connected with ribbon gauze strips sewn on by hand to aid the extraction of the ETT at extubation. Anesthetic gel or ointment was used to lubricate the tube and provide some relief for the patient's sore throat post-procedure.

Sir Frederic Hewitt who developed the first airway and Arthur Guedel MD, are the two pioneers of modern airway development. Until the introduction of the cuffed airway the technique used was "intratracheal" anesthesia, also called the "insufflation technique." A small rubber catheter

Shai Efrati and Israel Deutsch are shareholders in Hospitech Respiration, Ltd. The AnapnoGuard system developed by Hospitech Respiration is being presented in the article.

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was placed in the trachea after anesthesia was established by mask; the catheter was then attached to a gas delivery system. The waste gas exited out the open trachea [6].

Guedel collaborating with his close friend, Ralph Waters, M.D. had the idea of sealing off the trachea with a cuffed tube, eliminating the need to hold the mask. By using cuffed tube the trachea could be protected from aspiration, positive pressure could be used, and be less expensive due to small volumes of gas needed compared to quantities of gas required with open trachea exercising the "intratracheal technique" [6]. Guedel made the first cuff from fingers of rubber gloves and later on rubber condoms, with the ends cemented around the tube. The first cuff was between three and four inches long and was designed to lay half above and half below the glottis. The Guedel-Waters letters (held at the WLM-Wood Library-Museum of Anesthesiology, and the Arthur E. Guedel Memorial Anesthesia Center) document the many discussions the two had on what should be used for the cuff, where it should be positioned and how to introduce it. Guedel went on to cuffs made from dental rubber dams. These were 1.5 inches long and designed so that the upper edge was just below the vocal cords. This was known as the "flat" type cuff and is the one pictured in Guedel and Waters' paper on the cuffed tube, published in July–August 1928 (Fig. 1).

By April 1928, Guedel was often giving anesthesia with a cuffed tube. In fact, he did patients first and dogs afterward! After filling patients' mouths and noses with water and documenting that there were no gas leaks from the trachea, Guedel had the idea of anesthetizing and intubating a dog and dunking it in an aquarium for some time to demonstrate the set-up to others. The first "dunked dog" experiment (there were only two) was on May 8, 1928, at the Indiana University School of Medicine. The subject was convenient, one of the Guedel family's three dogs, a dog named "Airway." Airway was anesthetized with ethylene and intubated, and a Waters' canister set-up was attached. The dog was placed in an aquarium for an hour. He was then awakened and retrieved from the tank. After being extubated and placed on the floor, he shook himself off and laid down for a nap. The "dunked dog" experiment introduced the CO2 absorption technique and cuffed ETTs to a large audience, even though only a few attended the actual demonstration [7].

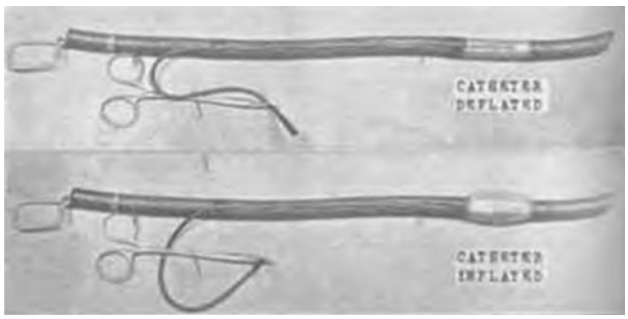

Fig. 1 First picture of a modern cuffed endotracheal tube, designed by Guedel and Waters. The tube was 14 inches long and had an internal diameter of only three-eights of an inch. The cuff was made by Guedel from either a dental dam or a Penrose drain. *Source*: Guedel and Waters [51]

From the time of Guedel's first demonstration of the effectiveness of rubber cuff, positioned under the vocal cords, the design of the cuffed tube had progressed, developing new generations of better sealing cuffs. However there is a huge gap between the sophisticated machines that were developed for ventilation and the cuffed ETT. On one side there is the ventilator embedding the state of art electronics and software and on the other side is the cuffed ETT, although made of advanced materials, it is still a simple pipe. Although the ETT and the cuff are in chain with the ventilator to provide adequate ventilation, and their functionality affects upstream and downstream functionality, they are not counted.

2 Cuff related complications

2.1 ETT mal position

ETT mal position may be manifested as a sizable airway leak around the cuff. In such occurrences the cuffs fails sealing the airway whether placed on the verge of the vocal cords or within a main bronchi.

Orotracheal intubation is the most common method of inserting an ETT [8]. Nasotracheal intubation is also possible, but much less common. Regardless of whether orotracheal or nasotracheal intubation is performed, the preferred position of the tip of the ETT is 2–4 cm above the carina. Nevertheless although physical examination is inaccurate at determining whether an ETT is in the correct position it is a must [9–11]. When leak is detected (usually a substantial one alarmed by ventilator algorithms) it is frequently misinterpreted as balloon rupture or accidental deflation, leading to unnecessary ETT replacement or to over inflation of the cuff [12]. The fixation of the cuff by bonding the ETT with tape or bandage ribbons around patient head cannot prevent cuff mal positioning. Fixation of the proximal of the ETT to patient's head does not fix cuff position neither its location. An attempt to fix cuff and ETT position with commercial tube holders failed to demonstrate superiority over standard tape in preventing ETT migration or dislodgement resulting in unplanned extubation.

Once the position of the ETT has been optimized, it should be reassessed periodically because the ETT can migrate over time. ETT migration is an inevitable

consequence of coughing, suctioning, and head movement. When comparing the position of the distal tip of the ETT on different chest radiographs, the clinician should ensure that the position of the patient's head is similar on each radiograph because the position of the ETT will change with the head position. Specifically, neck flexion advances the ETT toward the carina, while neck extension moves the tube away from the carina [13–15].

2.2 Cuff pressure

The common clinical practice of optimizing cuff filling is done by auscultation or by assessing inhaled/exhaled volume difference [16–18]. These methods are imprecise, so general guidelines are usually used. The general guidelines state that the cuff pressure should be maintained between 18 and 25 mmHg (possible maximal range of 15–30 mmHg). A cuff pressure above 18 mmHg will usually prevent an air leak (air escaping around the ETT cuff), will reduce aspiration around the cuff, and may decrease the rate of ventilator-associated pneumonia [19]. However, a cuff pressure above 25 mmHg may increase the risk of pressure necrosis at the site where the cuff contacts the tracheal mucosa. Needless to say that these guidelines are based on general statistics, and are not referred to specific patient anatomy, tube position, cuff characteristics and ventilation pressures as follows:

- A higher minimum cuff pressure is required to prevent an air leak at higher peak airway pressures. One observational study found that a peak airway pressure greater than 48 cmH_2O (36 mmHg) required a cuff pressure greater than 25 mmHg to prevent an air leak [20]. A cuff pressure at this high level increases the risk of pressure necrosis.
- When the patient is hemodynamic unstable and he is being treated with vasoconstrictors the perfusion pressure in the tissue (ex. tracheal mucosa) is significantly reduced. In this cases tissue hypoperfusion and hypoxia can happen even at lower cuff pressures (<25 mmHg).

In order to achieve good sealing at as low as possible cuff pressures, most ETTs commonly used today have high volume low pressure (HVLP) cuffs. Low volume, low pressure (LVLP) cuffs also exist, but their use is not widespread. The simple rational behind the HVLP cuffs is that when the cuff volume is higher the contact surface between the cuff and the tracheal mucosa is bigger, the pressure is spread over larger contact area and less pressure per contact point is needed in order to achieve sealing. Furthermore it assures no voids due to non circular (or near circular) tracheal shapes. Today the HVLP cuffs are the standard of care in most ICU's. However, HVLP cuffs did not reliably prevent leakage in vitro [20–24] or in vivo [18, 25, 26] studies. When fully inflated, HVLP cuffs reach a diameter 1.5–2 times larger than an average trachea of an adult. Leakage in HVLP cuffs occurs principally down longitudinal folds which form in the cuff membrane when inflated in the trachea [22, 23]. In order to achieve better sealing two types of solutions were proposed: the ultra-thin cuff and the LVLP cuffs:

- *Ultrathin cuffs* The recently introduced Microcuff HVLP ETT (Microcuff, Weinheim, Germany) features an ultrathin polyurethane cuff membrane. The cuff design consisting of an ultrathin (7 μm) polyurethane membrane, in contrast to conventional cuff membranes thickness that is 50 μm or above [27]. Within the acceptable upper limit for tracheal cuff pressure (25–30 cmH_2O) the Microcuff can prevent fluid leakage better than the standard HVLP cuffs. The use of a polyurethane-cuffed ETT is associated with a significant decrease in the rate of VAP [19, 27–29].
- The major limitation of the ultrathin cuff are related to its permeability, requiring intermediate/continuous monitoring and control in order to provide a permanent seal proof trachea during the entire intubation period. Due to temperature difference between the humid air in the lungs and the tube body temperature humidity infiltrates cuff and may end in occlusion of the inflation line. The permeability problem also exists in both directions in and out of the cuff. This is exhibited in "standard" HVLP cuffs that can be easily overinflated, generating excessive cuff pressure, which can result in mucosal injury. The "self inflation" effect is well recognized during nitrous (N_2O) administration. N_2O diffuses more rapidly into the cuff than nitrogen diffuses out of the cuff, thus creating excessive pressure even when the initial sealing pressure is satisfactory [30–32]. Cuffs made of Silicone or rubber attenuates the rapid increase in cuff pressure due to their higher compliance (V/P). In other words their increase in volume per increment pressure is higher than PVC or PU (polyurethane) cuffs. In the new Portex Soft Seal cuff, the plasticizer added to soften the PVC makes the cuff less permeable to nitrous oxide.
- *Low volume low pressure (LVLP) cuff* The cuff is designed to be fully inflated when used. This has two important consequences. First, the cuff does not develop longitudinal folds alongside the wall since the cuff is under tension. Secondly, the pressure exerted on the tracheal wall by the cuff is less than the intracuff pressure due to partial dissipation of intra cuff pressure into elastic forces within the cuff. The LVLP was evaluated in a randomized trial and a prospective cohort study, both of which were reported together [19]. The

amount of leakage from the subglottic space into the tracheobronchial tree was less frequent in the LVLP group. The major disadvantages of this technology are: inability to cover tracheal non circular shape, and high permeability that requires continuous pressure control.

Beside these main routes of progress other technologies are under development as the Laser Flex Cuffs, Foam cuffs and special geometry contour shaped cuffs. An example of special geometry is the tapered-shaped tracheal tube cuff made from polyurethane (PU) (Tapered Seal Guard Tracheal Tube, Covidien, Athlone, Ireland) represents a new strategy to reduce fluid leakage across the cuff [33]. The tapered cuff design ensures that there is always a 'sealing zone' where the outer cuff diameter corresponds to the internal tracheal diameter. Another example of special design cuff that ameliorate the formation of folds upon inflation within the trachea is the Double layer tube cuff: a standard high-volume low-pressure cuff wrapped with a second, highly elastic cuff made of a low-protein guayule natural latex rubber with 0.5 ml gel between the cuffs [34, 35]. All designs are aimed to provide better sealing at relative low intra cuff pressures.

3 Ventilation associated pneumonia (VAP) and the ETT cuff

VAP remains a frequent and costly complication of critical illness with a pooled relative risk of 9–27 percent and mortality of 25–50 percent [1, 36–39]. Strikingly, VAP adds an estimated cost of more than $40,000 to a typical hospital admission [38].

The most important mechanism of VAP is gross or micro-aspiration of oropharyngeal organisms into the distal bronchi, followed by bacterial proliferation and parenchymal invasion [40–42]. In the mechanically ventilated patient, a number of factors combine to compromise host defenses: critical illness, co morbidities, H2-blockers and antacid therapy, malnutrition impair the immune system, and most importantly, endotracheal intubation thwarts the cough reflex, compromises mucociliary clearance, injures the tracheal epithelial surface, and provides a direct conduit for rapid access of bacteria from the gastro-intestinal (GI) track and the nasopharynx into the lower respiratory tract [3, 41, 43–45]. Tracheal intubation increases the risk of pneumonia 6- to 20-fold [1, 36], and it would probably be more accurate to rename VAP as "endotracheal-intubation-related pneumonia".

The best way to handle VAP is by prevention. The prevention measures can be divided into two main groups: clinical practices guidelines and device-based technologies. All measures are aiming at altering at least one of the parameters playing a role in the pathogenesis of VAP: bacterial proliferation and shift of oropharyngeal/GI flora, aspiration of secretions around the ETT cuff, and injury to tracheal epithelium. The permanent conflict is between the need of approved sealing to prevent leakage and the possible consequents of ischemic damage or a tracheal injury due to high cuff pressure.

Except the traditional way of listening with a stethoscope to the leakage whistle noise flow created at PIP (Peak Inspiration Pressure) or ear barely to air leak rhonchus, there is no effective objective accurate measure of leakage. The existing leak detection by the ventilator volumetric calculation is inaccurate (low sensitivity) and when alarming it may be too late to prevent the secretions leak.

Cuff pressure itself is measured and supposed to be maintained by use of manometers or pressure support devices that use reservoirs to keep the pressure within set limits. So as a matter of fact the use of cuff pressure control devices is aimed to keep a constant arbitrary set pressure without any objective knowledge of whether this pressure is optimal for the specific patient, and furthermore without continuous correlation to leakage.

The failure of initial proper inflation combined with neglecting a routine cuff pressure adjustment is further accentuated when taking in account the objective parameters that influence cuff functionality. The intra cuff pressure is pendent to patient anatomy, location changes of the cuff and changes in ventilation/intra-lung pressures occurring during the period of intubation (due to periodic treatments, patient's weaning status, coughing, and deep suctioning). Besides, there are the clinic situations that make the cuff pressure even more unpredictable like in a case of a developing and then regressing tracheal mucosal edema, accompanied by elevation or drop in cuff intra pressure accordingly. Adding these factors to said above factors and the inherent features of the cuff (elasticity, thickness, permeability and other that are varying with pressure and temperature changes) and the result is a multi-factorial physical parameters where none of the influencing factors is controllable.

Moreover, the so call just seal inflation technique is not beneficial, because self-inflation leads to microtrauma and milking of subglottic secretions into the trachea. The HVLP cuffs are inflated to a baseline pressure that usually is lower than ventilator's peak pressure. During inspirium the pressure rises at the distal end of cuff and force is excreted on the distal walls of the cuff toward the tube proximity [23]. The tube holder on the proximal side and the circumferential friction forces acting on the cuff prevents its movement and as result this pressure rise is absorbed by the cuff. The absorbed forces are divided between the cuff itself (expressed by strain forces in cuff) and the Internal Cuff Pressure (ICP). On the other side, the proximal walls of the cuff are facing a stable external ambient pressure. Once there is an ICP rise due to external inhale forces the pressure

gap between the ICP and ambient pressure develops strain forces of elongation on the proximal walls of the cuff. The spatial distribution of strain forces on the proximal walls is expressed by spatial elongation of the proximal and circumferential walls of the cuff, minimizing elongated folds and decreasing their effective radii. During expirium the process is traversed. This cyclic process has two possible opposing effects with relation to cuff sealing:

1. *Pumping effect* Above cuff secretions may absorbed into the widening folds (during expirium) and pumped distally once the cuff folds radii is narrowed during inspirium. The pumping effect may exacerbate during closed tracheal suction (deep suction) that leads to profound negative tracheal pressure [46, 47].
2. *Sealing effect* Once absorbed within folds viscous secretions are stack within the folds and a sealing is achieved. High peek end expiratory pressure (PEEP) reduce the pumping effect and attenuate the progression of the viscose secretions along the folds [23, 48].

The final result of whether better sealing or increased leak depends on the basic cuff pressure, PEEP, negative pressure during deep suction and cuff walls thickness [23, 46–48]. At relative low cuff pressure and w/o, no PEEP, use of closed tracheal suction and thick cuff walls, the leakage effect will be dominant over sealing effect and vice versa.

How the leakage can be prevented?

In order to prevent aspiration during the intubation period two mission should be attain: good sealing with a well tolerated intra cuff pressure in combination with continuous effective evacuation of secretions from the subglottic space. As discussed above, an allegedly perfect sealing is not enough, since it will create an accumulated pool of secretions in an ideal bacterial colonized habitat (humid at body temperature) that will leak into the lungs at the first unavoidable sealing failure. A logical thinking would imply that the effect of highly concentrated bacterial leak on lungs might be worse than a continuous leak of diluted bacterial secretions. Therefore a continuous aspiration of the secretions will reduce the inoculums of bacteria infiltrating the lung once there would be a leakage.

Once said, the question now is how it can be done? The classical way is by using a continuous closed loop control system that orchestrates leakage detection, cuff pressure control, and evacuation of secretions throughout the entire intubation period.

Two types of methods for aspiration of subglottic secretions have been suggested:

- *Continuous aspiration of sublottic secretions* (*CASS*) The CASS was first introduced by Mallinckrodt Inc. Even thought the CASS system can lower bacterial colonization of the respiratory tract, its use can be hazardous. The use of the CASS method may lead to severe tracheal mucosal damage at the level of the suction port [49]. The etiology of mucosal damage is due to suction performed in a relatively small space (between the boundaries of the vocal cords, tracheal mucosa, ETT and ETT cuff) creating a vacuum that adheres the tracheal mucosa to the suction port. The anatomy of the subglottic area is presented in Fig. 2. The vacuum created in the subglottic area is responsible for the severe macroscopic and microscopic damage of the tracheal mucosa and is also responsible for the inability to perform effective suction in many patients intubated with tubes having one extra embedded evacuation lumen.
- *Intermittent ASS* (*IASS*) CASS is the ultimate ideal goal, however using frequent instead of continuous procedure of evacuation of secretions may be as effective as the continuous one, provided an adequate sealing exists between sequential evacuation procedures. The

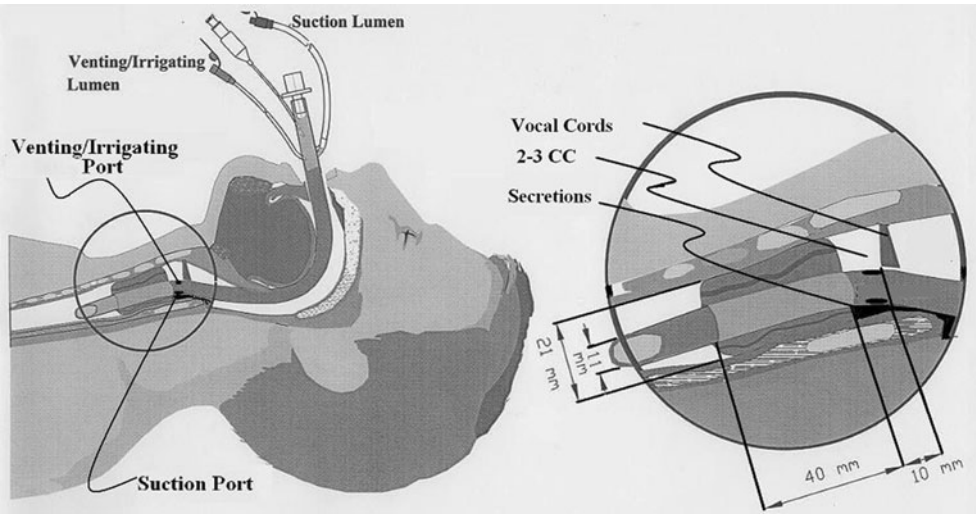

Fig. 2 The anatomy of the subglottic space with expected measurements in average male. The special ETT use in order to prevent the resultant vacuum in the subglottic space and the related mucosal damage. The AnapnoGuard system uses a specially designed ETT that has an extra lumen, in addition to the suction lumen. When the subglottic suction is activated the extra lumen is opened and the hazardous vacuum is prevented

intermittent suction relieves the subglottic space and the surrounding mucosa from the unwanted vacuum that might be created. The clinical data about the effectiveness of IASS is still scarce and this is the reason why no conclusion can be made with regard to its effectiveness and optimal mode of usage. Use of IASS whether automatically or manually will provide the required reduction in the inoculums of bacteria but it will be effective in VAP prevention once tracheal sealing is controlled continuously and the frequency of the suction will be matched with the rate of secretions creation.

4 Possible new direction for the near future

As stated above, subglottic aspiration of secretions combined with objective cuff pressure control represent the optimal solution.

In order to confirm complete sealing of the ETT cuff, maintain an optimal cuff pressure, and monitor the cyclic changes in the intra-cuff pressures during the respiration cycle, the AnapnoGuard system was developed (Hospitech Respiration Ltd., Petach Tikva, Israel). In brief, The AnapnoGuard System has been developed to detect any leak around the ETT cuff during the ventilatory cycle. As detailed elsewhere [50], the optimal tracheal sealing by ETT cuff is based on closed loop control of the CO_2 levels above the cuff and of intra cuff-pressure. Any leakage sensed above the cuff expressed by an increase of CO_2 level marks a non-optimal sealing of the trachea and the system sets the optimal pressure accordingly [42]. Moreover, the system automatically performs cyclic subglottic suction of secretions. However, unlike the CASS system, in order to prevent the resultant vacuum in the subglottic space and the related mucosal damage, the AnapnoGuard system uses a specially designed ETT that has an extra lumen, in addition to the suction lumen (Fig. 2). When the subglottic suction is activated the extra lumen is opened to ambient or to forced air input preventing the hazardous vacuum. Furthermore by periodical orchestrated operation the Anapnoguuard system irrigates the subglottic space via this extra lumen synchronized with the evacuation process, leaving a diluted reminiscent of secretions above the cuff. The substance of irrigated fluid can be saline and/or antiseptic solution. The AnapnoGuard system has recently gained CE approval and it is currently in use in clinical trials.

5 Thinking outside the box: cuff future roles

The mechanical ventilation of the respiratory tract can be divided into two parts. The first originates in the ventilator and ends at the connector of the ETT. The second part starts at same ETT connector and ends at distal end of the ETT. While the first part is quite a piece of modern art including state of art in electronics, mechanics and software, equipped with various sensors and manipulated with endless ventilation procedures, the second part is just a piece of narrow pipe made of plastic.

Respiratory monitoring is usually based on pressure, volume, and flow rate measured at the proximal tip of the ETT. While there is no significant difference in measured volume and flow rates at the proximal and distal ends of the ETT, the pressure is highly affected, mainly by the degree of obstruction of the ETT. In a pilot study it was found that once there is a complete sealing of the trachea at low intra cuff pressures, the ETT cuff can serve as a sensor for changes in tracheal/lung pressures (a kind of wedge pressure of the lungs). This sensor may be of significant importance for the new generation of ventilators. One of the major limitations for optimal performance of the new generation of the ventilators can be the pressure gradient fall between the ventilator and the lungs due to ETT obstruction [25, 26]. This pressure gradient leads to a false evaluation by the ventilator of the lung/tracheal pressure and because of that: (1) the ventilator's ability to detect the negative pressure induced by the patients for initiation of inspiration is reduced, leading to less effective assist ventilation; (2) the ventilator may inflate the lung with higher or lower pressure than truly needed. It seems plausible to speculate that once the method is directly synchronized with the new generation of ventilators, it might be possible to significantly improve individual ventilation performance. However, further clinical studies are needed in order to confirm this hypothesis.

6 Conclusion

The importance of appropriate ETT cuff pressure handling is finally getting its needed recognition. The ETT cuff, even though considered small in size, is responsible for many of the complications related to prolonged ventilation. In the near future an intense investigational and development work is necessary in order to reduce its related complications and assure its proper functionality.

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