5.8 A New, Airway Pressure Regulated, Atraumatic Endotracheal Cuff: Experimental and Clinical Evaluation

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Abstract

Excessive pressure exerted by inflatable cuffs against the tracheal wall is a major cause of tracheal damage. Despite the introduction in recent years of so-called “low pressure” cuffs, cases of acute and chronic tracheal damage still occur. Excessively high cuff to trachea pressures have been documented in some of these thin-walled, highly compliant cuffs, especially when the cuffs were overinflated.

A parachute like cuff has been developed which distends whenever distal airway pressure exceeds atmospheric pressure. The inflating gas enters the cuff directly from the trachea through large openings provided near the cuff’s distal edge. Experimental and clinical testing, during positive pressure ventilation, have shown that this new cuff seals the airway with a cuff to trachea pressure which is continuously identical to distal airway pressure. The mechanism of automatic inflation precludes the possibility of overinflation of the cuff, thus avoiding the most serious hazard of cuffs available at the present time.

Background

The inflatable endotracheal cuff was described over 100 years ago in 1871 by the German surgeon Trendelenburg. It was designed to prevent aspiration of blood and to maintain a clear airway during oropharyngeal operations (1). In the same article in which he described his cuffed tracheostomy tube, Trendelenburg also described a case of tracheal stenosis caused by it. Thus, the first report of this new and important therapeutic method included a description of what we now recognize as one of its most serious complications. Cuffed tubes are still used to prevent aspiration, but the most common indication for their application today is positive pressure ventilation, for administration of either general anesthesia or ventilatory support. As the frequency of the use of cuffed tubes and the duration of intubation have increased, so have the frequency and severity of related complications (2, 3).

Laryngotraheal damage in intubated patients can occur at the tracheostoma and at contact sites with the side of the tube, its tip, or the inflated cuff. Of these, cuff induced tracheal injury is the more common and more serious. Although multiple factors such as residual sterilizing agents on the cuff, infection, steroid therapy and arterial hypotension have been implicated as contributing to tracheal damage, it is now universally accepted that ischemic necrosis of the tracheal wall caused by elevated cuff to trachea pressure is the primary cause of the complications listed in Table 1 (3, 4).
Specific characteristics of endotracheal cuffs determine both their efficiency and the extent to which they produce tracheal injury (5). These can be defined as:

1. **Residual cuff volume** is that volume of air which can be withdrawn from a cuff after it has been inflated at a pressure of 15 cm H$_2$O (11.1 Torr) and allowed to deflate passively to a pressure of 1.0 cm of H$_2$O (0.73 Torr), outside the trachea.

2. **No-leak ventilation** is said to occur when the entire inspiratory volume is exhaled through the lumen of the tracheal tube, with no leakage around the cuff.

3. **Just seal cuff volume** is the minimal amount of air required to inflate a cuff in order to obtain no-leak ventilation. (Synonym: minimal occlusive volume).

4. **Intracuff pressure** is the pressure within the cuff, measured through the inflating tube (Fig. 1).

5. **Cuff to trachea pressure** is the pressure exerted by the cuff upon the internal tracheal wall. Cuff to trachea pressure should be measured at the anterior tracheal wall and can be further characterized as; end inspiratory, end expiratory, peak, and mean. (Synonym: lateral cuff pressure) (Fig. 1).

6. **Slope pressure** is that rise in cuff to trachea pressure which occurs when 1 ml of air is added to a cuff’s just seal volume.

7. **Aspiration protection** is prevention of contamination of the lower airway with liquid or solid particulate matter.

The minimal cuff to trachea pressure required to protect against aspiration is generally accepted as 10 to 15 Torr, equal to the hydrostatic pressure of a liquid column rising from the cuff to the oropharynx in an upright position (6). Several investigators report, however, that aspiration is not entirely prevented by inflatable cuffs even at higher cuff to trachea pressures (7, 8).

Intensive experimental and clinical investigations were performed by several research groups in the late 1960’s to identify the causes of cuff induced tracheal injury (3, 4, 5). These studies led to the conclusion that high cuff to trachea pressure results in ischemic damage to the tracheal wall, leading to the complications listed in Table 1. The cuffs available at that time had zero residual volumes and required extremely high (200-300 Torr), intracuff pressures to seal the trachea (9, 10). These cuffs exerted excessive cuff to trachea pressures because of