Reducing the Risk for Microaspiration and Postintubation Pulmonary Complications In the Surgical and Critical Care Settings: Innovations in Endotracheal Tube Cuff Design

Despite significant advances in endotracheal tube (ETT) design and management of intubated patients, infectious and noninfectious postintubation pulmonary complications—ranging from bronchospasm to respiratory failure—remain costly and significant causes of morbidity and mortality. In the surgical setting, postoperative pulmonary complications (PPCs) affect 1 in 8 patients, are a leading cause of hospital readmissions, and are associated with 70% of all postoperative hospital deaths among patients without known respiratory problems before surgery. Among noncardiac surgery patients, postoperative pneumonia has been shown to increase hospital costs by 55% and hospital length of stay (LOS) by 89%. It accounts for $8.98 billion in hospital costs, $3.42 billion of which is incremental resource use added by PPCs to elective surgery costs.

Among the most common PPCs, ventilator-associated pneumonia (VAP)—defined as pneumonia occurring in a mechanically ventilated patient after 48 hours of endotracheal intubation—affects up to 40% of patients in surgical intensive care units (ICUs), which have high rates of mechanical ventilation, and accounts for 25% of infections in medical ICUs. Aspiration is a leading cause of VAP, and both are targets for clinical intervention.

Artificial airway use is associated with 80% of cases of hospital-acquired pneumonia,
The Role of Microaspiration
In Pulmonary Infection

The pathogenesis of pulmonary infection is multifactorial and requires several key processes. Microaspiration of fluids from the subglottic space and bacterial colonization of the lower respiratory tract can lead to pulmonary infection including VAP.11,18 Colonization of the lower respiratory tract is associated with ventilator-associated tracheobronchitis—an intermediate condition in the continuum between colonization and pneumonia.19

Certain characteristics of intubation favor aspiration of bacteria from the oropharynx into the lower respiratory tract; thus, the ETT may function as a direct portal for the organisms entering the lungs.19,21,22 The tube breaches anatomic barriers formed by the glottis and larynx,12,19 thus impeding normal mechanical host defenses. Impairment of the cough reflex during intubation further impedes natural reflexes that normally would prevent aspiration. An ETT forms a favorable surface for biofilm formation and acts as a reservoir for infective microorganisms, which subsequently may be dislodged into the lung by ventilator gas flow.2,15,16 Infection results from the microbial invasion into the normally sterile lower respiratory tract and lungs, overwhelming host defenses and increasing the risk for infection.15,16,21 Dual mechanical and pathogenic factors contribute to risks for microaspiration, which is a formidable but modifiable complication (Table 1).15

The earliest ETT cuffs required high pressures (>60 cm H2O) to achieve a seal and were associated with frequent tracheal injury23; high-volume, low-pressure (HVLP) cuffs introduced in the 1970s have demonstrated inadequate sealing.21,24,25 The diameter of the inflated conventional cuff is up to twice as large as the diameter of the trachea;23,24 thus, even with properly sized tubes and appropriate inflation, leakage occurs down a gravitational gradient, often as a result of folding in the cuff wall.22,26

Differential sealing properties can have clinical consequences. A prospective study found gastric pathogens—evidence of microaspiration—in the sputum found in the lungs of 28% of postoperative patients; this group had a 40% incidence for pneumonia compared with 12% in patients without microaspiration.27 An earlier bench study confirmed evidence of frequent microaspiration with conventional low-pressure cuffs: Nearly 80% of tubes leaked all 20 mL of fluid placed above the cuff.28

Diagnosis of Microaspiration

Despite its prevalence in critical care and surgical settings, microaspiration remains challenging to diagnose. Few available markers—including methylene blue—can provide accurate quantitative diagnosis in intubated patients.15 Methylene blue is reliable but relatively complex to use in the clinical setting because it requires fiber-optic bronchoscopy for detecting its presence under the tracheal cuff.15 Limitations also are apparent with other available aspiration markers. Among these are nonabsorbable radioisotopes (eg, technetium 99m sulfur colloid)—the use of which is restricted to nuclear medicine departments—and pepsin, which occurs naturally in gastric contents but not in tracheal secretions; its use diagnostically can be problematic because it may be degraded in the alkaline environment of the lung.15

Strategies for Preventing Postintubation Complications

Various strategies may aid clinicians in reducing or preventing postintubation complications in surgical and critical care settings. These include reducing patient time on mechanical ventilation, limiting bacterial colonization, and reducing microaspiration.15,29

Figure 1. TaperGuard cuff.
Image used by permission from Nellcor Puritan Bennett, LLC, Boulder, Colorado, doing business as Covidien.
Specific measures are known to reduce VAP incidence in critical care settings and include elevating the head of the bed, prophylaxis of stress gastritis, and limiting sedation.30–32

Reducing Microaspiration

Cuff pressure is highly variable over time. A prospective observational cohort study of patients in the ICU intubated with high-volume, low-pressure cuffs found that only 18% of patients spent 100% of recorded time with normal cuff pressure (ie, 20–30 cm H2O), and cuff underinflation was a risk factor for microaspiration and VAP.33 Pneumonia prevention and management guidelines issued jointly by the American Thoracic Society/Infectious Diseases Society of America (ATS/IDSA) recommend maintaining a cuff pressure greater than 20 cm H2O16 for the prevention of VAP, and the Society for Healthcare Epidemiology of America34 (SHEA) recommends maintaining a cuff pressure of at least 20 cm H2O.35–37

Although evidence to support semi-recumbent positioning for the prevention of microaspiration is incomplete, a role for it has been established.29,38 Semi-recumbent positioning is recommended in a number of practice guidelines, including those issued jointly by the ATS/IDSA and a guideline issued by SHEA.29,35

Limiting Bacterial Colonization

Evidence suggests that subglottic secretion drainage can reduce the risk for early- and late-onset VAP.11,35,39,45 In a randomized prospective study, continuous aspiration of subglottic secretions (CASS) in ventilated patients after major heart surgery significantly reduced antibiotic use in the whole cohort, as well as VAP incidence in high-risk patients (ie, those who required mechanical ventilation for >48 hours) compared with intermittent aspiration.31 Recently, a study that assessed intermittent aspiration with routine care in patients requiring mechanical ventilation for at least 48 hours found significantly lower incidence of early- and late-onset VAP compared with the control group.40 A recent meta-analysis confirmed a highly significant reduction in VAP of approximately 50% in mechanically ventilated patients who, at the time of original intubation, received an ETT with subglottic secretion drainage capability.41 Continuous suctioning has been found to be cost-effective compared with intermittent ventilation, despite challenging scenarios of VAP incidence and associated costs; costs attributed to a single VAP episode range from $5,365 to $57,000.43,44

Varying levels of evidence also support general VAP prophylactic measures (eg, infection control, oral decontamination, stress ulcer prophylaxis, and avoidance of gastric distention).31,35,45

Reducing Time on Mechanical Ventilation

Mechanical ventilation is accompanied almost universally by administration of large doses of sedatives. However, this combination is associated with significant morbidity.32 Duration of mechanical ventilation can be associated with adverse patient outcomes, and evidence supports reducing duration of mechanical ventilation in intensive care populations.29 In a prospective study that used pepsin-positive tracheal secretions as a marker for gastric-content aspiration in critically ill tube-fed patients, 88.9% had evidence of at least 1 aspiration event; high sedation, aspiration, and use of paralytic agents were significant independent risk factors for pneumonia.46 Paired sedation-and-weaning protocols can result in shorter duration of ventilation and reductions in hospital and ICU LOS.34

Considerations in Selecting an ETT

The contribution of the ETT cuff to microaspiration and pulmonary complications is substantial. Two main functions of ETT cuffs are to produce a protective, airtight seal between the tube and the tracheal mucosa to facilitate positive pressure ventilation and to protect the lower airway.35 However, decades of clinical experience with conventional cuffs (cylindrical shape; HVLP; <30 cm H2O) have confirmed that pooling and leaking across the cuff leads to aspiration—the main route of bacteria to invade the lower airways.21,22 This is confirmed by the finding that persistent cuff underinflation (<20 cm H2O) is independently associated with pneumonia.33 Also, the presence of pepsin in tracheal aspirates is an independent predictor of pneumonia in intubated patients.46

Recently introduced cuff designs were developed to alleviate problems with conventional HVLP ETTs and to provide

| Table 1. Risk Factors for Microaspiration in Intubated Critically Ill Patients |
|-----------------------------|-----------------------------|
| **Tracheal tube**           |                             |
| Longitudinal folds in HVLP tracheal cuff |                  |
| Underinflation of tracheal cuff |                   |
| **Mechanical ventilation**  |                             |
| Zero PEEP                   | Low peak inspiratory pressure |
| Tracheal suctioning          |                             |
| **Nasogastric tube and enteral nutrition** |          |
| Gastric distension          | Gastroesophageal reflux     |
| **Patient-related factor**  |                             |
| Pressure above cuff         | Tracheal diameter           |
| Viscosity of secretions above the cuff |          |
| Supine position             | Sedation                   |

Adapted from reference 15.
improved sealing properties across a range of tracheal diameters. Available cuff materials include PVC, polyurethane (PU), and guayule latex, whereas the cuff shapes may be cylindrical or tapered. PU-cuffed tubes are characterized by a thinner wall (7 vs the more typical 50 microns) that creates a stronger seal at safe cuff-inflation pressures.47,48 Cuff material and positive pressure have been shown to be major determinants in reducing leakage past the cuff.9

Certain tapered cuff designs ensure a “sealing zone” that aligns the outer cuff diameter with the internal tracheal diameter15; a smaller force transmitted to the trachea may reduce the risk for tracheal injury. Both PVC- and PU-tapered shape tubes have demonstrated, in bench and clinical studies, high sealing properties that aid in preventing fluid leakage.25,47 Zanella et al demonstrated that both the PU and PVC cuffs required incremental levels of PEEP to prevent fluid leakage.9 The finding of PEEP as a protective factor is important because PEEP loss occurs frequently in clinical practice.

Another recent randomized study evaluated tracheal cuff leakage in morbidly obese gastric bypass patients (N=63), a population at high risk for microaspiration.50 Preliminary findings showed that the TaperGuard ETT provided 100% protection against microaspiration detected by bronchoscopy, compared with a microaspiration rate of 4% (13 of 32) among patients intubated with a cylindrical PVC tube (Hi-Lo) (Figure 2).50 The relationship between VAP and microaspiration from inadequately sealing cuffs is a topic of clinical and scientific interest.

### Table 2. Comparison of Different Cuff Materials in Reducing Fluid Leakage

<table>
<thead>
<tr>
<th>Endotracheal Tube</th>
<th>Material</th>
<th>Shape</th>
<th>Diameter, cm</th>
<th>Length, cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Double-layer prototype</td>
<td>Guayule latex</td>
<td>Cylindrical</td>
<td>3.6</td>
<td>3.4</td>
</tr>
<tr>
<td>Hi-Lo (Covidien)</td>
<td>PVC</td>
<td>Cylindrical</td>
<td>3.6</td>
<td>3.4</td>
</tr>
<tr>
<td>Hi-Contour (Covidien)</td>
<td>PVC</td>
<td>Cylindrical</td>
<td>3.2</td>
<td>3.2</td>
</tr>
<tr>
<td>Microcuff (Kimberly-Clark)</td>
<td>PU</td>
<td>Cylindrical</td>
<td>4.7</td>
<td>2.3</td>
</tr>
<tr>
<td>Ivory (Smiths Medical)</td>
<td>PVC</td>
<td>Cylindrical</td>
<td>3.3</td>
<td>3</td>
</tr>
<tr>
<td>SealGuard (Covidien)</td>
<td>PU</td>
<td>Tapered</td>
<td>4.7</td>
<td>1.6-2.4</td>
</tr>
<tr>
<td>TaperGuard (Covidien)</td>
<td>PVC</td>
<td>Tapered</td>
<td>3.8</td>
<td>1.4-2.5</td>
</tr>
</tbody>
</table>

PVC, polyvinylchloride; PU, polyurethane
Based on reference 9.
interest. A retrospective analysis of intubated patients following the introduction of ETTs with PU cuffs showed a significant reduction in VAP to 2.8 per 1,000 ventilator-days, compared with no less than 5.3 with the use of conventional ETTs.\textsuperscript{51} Under specific clinical circumstances (ie, patients expected to receive mechanical ventilation for >3 days), the TaperGuard Evac tube has been associated with significantly lower clinically diagnosed VAP incidence rates.\textsuperscript{49}

VAP incidence can remain high even with adherence to prevention protocols including oral care and patient positioning, and switching from a cylindrical to a tapered cuff may be a reasonable approach to mitigating this risk. In preliminary data reported in 2011, reduction in days to successful extubation and VAP rate was achieved after conversion from the Hi-Lo cylindrical tube to an ETT with a tapered cuff and subglottic secretion suction (SealGuard Evac).\textsuperscript{52}

Although there is insufficient evidence to support the selection of one ETT over another on the basis of VAP prevention, adequate sealing is a key element in reducing downstream complications. Modifications in design and material of ETTs represent an important advance in VAP prevention.\textsuperscript{9,15}

**Conclusion**

Unexpected intraoperative complications (eg, bleeding, hypotension, or long duration of surgery or mechanical ventilation) can increase the risk for VAP. Thus, determining effective interventions (eg, initial selection of an ETT in the operating room) that may reduce microaspiration risks and subsequent VAP require clinical judgment. Institutional cost–benefit analysis may be prudent for understanding incremental costs of preventive measures compared with costs of managing PPCs. Although the clinical importance of ETT selection may not be fully appreciated, initial placement of the most appropriate tube may have clinical consequences both intra- and postoperatively, in the ICU; failure to do so may represent a lost opportunity for prevention.

**Case Study 1**

A 67-year-old man undergoing an open right hemicolecotomy.

Sabrina Bent, MD

The patient had been diagnosed with adenocarcinoma of the right colon by colonoscopy 2 weeks earlier. The patient had a significant smoking history (ie, 1 pack/day for 33 years), obstructive sleep apnea, hypertension, type 2 diabetes mellitus, and gastroesophageal reflux disease. Four years earlier, he had undergone an open radical prostatectomy, and an open cholecystectomy 27 years earlier. A history of pneumonia was reported following his prostatectomy, which resulted in a readmission to the hospital less than 1 week after being discharged. His chest x-ray showed no acute disease, but was noted to have mild hyperinflation. His labs, including complete blood count and complete metabolic panel, were within normal limits with the exception of the glucose level, which was 206 mg/dL.

The anesthetic management consisted only of general anesthesia with ETT placement without regional anesthesia due to patient refusal of all neuraxial anesthetics. The patient was intubated with the TaperGuard Evac ETT to allow subglottic suctioning of his secretions during the operation and to decrease his risk for VAP if postoperative ventilation was necessary. A nasogastric (NG) tube was placed for gastric decompression during surgery and for the postoperative period.
Intraoperatively, the NG tube was placed on full suction to empty the stomach upon insertion, but was left open to gravity for the remainder of the surgical procedure. Approximately 100 mL of clear, yellow gastric secretions were initially aspirated from the NG tube. The suction port of the TaperGuard Evac ETT was set to low intermittent suction at 150 mm Hg. The suction regulator had a preset cycle of intermittent suctioning for 15 seconds followed by an 8-second pause. The operation lasted approximately 5 hours. During this time, approximately 18 mL of viscous straw-colored fluid was suctioned from the subglottic opening of the ETT. A portion of the secretions was steriley collected in a Lukens trap for culture.

The surgery was uneventful and the patient was extubated at the end of the procedure. He was subsequently taken to the postanesthesia care unit on 10 L per minute of oxygen via non-rebreather face mask. He was weaned to 2 L per minute of nasal cannula oxygen prior to transport to the telemetry floor of the hospital for continuous pulse oximetry monitoring. The patient was placed on a hydromorphone patient-controlled analgesia pump for postoperative pain management. The oxygen was discontinued on postoperative day (POD) 2.

The cultures from the subglottic secretions collected intraoperatively grew Escherichia coli (respiratory pathogen), Streptococcus pneumonia (respiratory pathogen), and Stomatococcus mucilaginosus. The remainder of the postoperative course was unremarkable and the patient was discharged home on POD 6. He was seen by his internist more than 4 weeks postoperatively and had no symptoms or signs of pneumonia. His pulmonary status was unchanged compared with his preoperative baseline. The patient was very pleased with his outcome and lack of postoperative pulmonary complications.

Note: The case study presented is a composite and not intended to identify a specific patient.

Case Study 2

A 24-year-old man undergoing emergency splenectomy following a motorcycle accident.

Eric Toschlog, MD

The patient had been involved in a motorcycle accident and was taken to the trauma resuscitation area. He was observed to be apneic and unresponsive in the field, and was intubated by the aeromedical crew. His intubation was challenging in the austere environment of the crash scene, and he was noted to aspirate.

On arrival to the resuscitation bay, his airway was intact; he had bilateral decreased breath sounds and faint femoral pulses. He had bilateral chest wall subcutaneous emphysema and paradoxical chest wall movement from a clinical left flail chest. Bilateral chest tubes were placed urgently with release of pleural air and hemothorax. His hemodynamics improved sufficiently for him to be taken to get a computed tomographic scan.

His injury constellation included subarachnoid and intraparenchymal shear hemorrhages; an unstable cervical spine fracture; numerous bilateral rib fractures, including a left hemopneumothorax; and a splenic laceration with contrast extravasation suggestive of active arterial hemorrhage. He became hypotensive during imaging, and was taken urgently to the operating room for splenectomy.

After a rapid splenectomy and large-volume blood product resuscitation, he stabilized. At this time, the anesthesiologist performed a video laryngoscopy to assess the safety of an ETT change. This decision was based on the knowledge that the patient would likely undergo a prolonged ICU stay with high risk for acute lung injury and VAP. Additionally, his spine and brain injuries would preclude a number of components of the VAP prevention bundle. It appeared that a subglottic secretion drainage ETT would be his best preventative strategy for VAP. General practice has been to avoid changing an ETT unless this is done in a controlled environment and under optimal conditions. But this was a special case. Using video laryngoscopy, the anesthesiologist had clear visualization of the initial ETT traversing the vocal cords, and felt that it would be safe to change to a subglottic secretion drainage ETT. The tube change to the TaperGuard Evac ETT proceeded uneventfully.

The patient progressed through a 6-week ICU stay, complicated by acute lung and kidney injury, abdominal compartment syndrome, and inanition. With regard to VAP prevention measures, he was not amenable to sedation hold, was too edematous to implement oral care, and chemical deep venous thrombosis prophylaxis was contraindicated for the early portion of his ICU stay. Secondary to severe acute respiratory distress syndrome, he underwent a prolonged period of pharmacologic paralysis and rotation therapy. This precluded elevation of the head of the bed for multiple weeks. But at the time of his tracheostomy 3 weeks after injury, minimal secretions had accumulated above the ETT balloon and, most importantly, he did not contract VAP. Although the decision to change the ETT during the initial laparotomy was difficult, the subglottic secretion drainage may have contributed to the lack of pneumonia in this high-risk patient.
References


52. Flores T, Borg U. Effect of endotracheal tube with taper shaped cuff and subglottic secretion (SGS) suction port intubation days in an urban ICU. Presented at the 2011 Critical Care Congress of the Society of Critical Care Medicine; January 16, 2011; San Diego, CA. Abstract 343.