with falls (and delirium), which should reinforce policies for daily spontaneous breathing trials, light sedation/sedations holidays, and benzodiazepines (as well as antipsychotic medications). In addition, clinicians should not hesitate to promote rehabilitation and early mobilization, even among those at risk for falls. The family's integration (and training) as essential team members of the rehabilitation process should be a priority. Taken together, it seems clear: the most compelling, modifiable strategy for fall prevention is to comply fully with the now well-known ICU Liberation Bundle (15)!

Both authors: Division Pulmonary and Critical Care Medicine, Department of Medicine, University of Michigan, Ann Arbor, MI

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Do Tracheostomy and Gastrostomy Confer Immortality in COVID-19?*

KEY WORDS: acute respiratory distress syndrome; COVID-19; gastrostomy; tracheostomy

Cathline Layba, MD, FACS[1]
David J. Wallace, MD, MPH[2]

The elective tracheostomy procedure is one of the oldest surgical interventions, with an early description attributed to the Greek physician Asclepiades (1). Although Asclepiades is principally known for his emphasis on the relationships between nutrition, exercise, light, and hydrotherapy with health, he also performed a version of today's elective tracheostomy

***See also p. 819.**

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procedure for the treatment of cynanche, a group of afflictions involving the floor of the mouth and the throat (1). Today the indications for tracheostomy have expanded beyond diseases of the upper airway, with over 100,000 percutaneous tracheostomy procedures performed annually in the setting of acute respiratory failure alone in the United States (2). Importantly, percutaneous tracheostomy performed for patients with acute respiratory distress syndrome is considered an elective procedure and should be reserved for patients who are expected to survive their acute illness (3).

Durable access to the stomach for the purpose of nutrition and medication administration using a percutaneous approach is a newer procedure, first described in a collaboration between a gastroenterologist and a pediatric surgeon in the late 1970s (4). Despite its more recent arrival to medical care, the number of percutaneous endoscopically placed gastrostomy tubes has grown to more frequently than 100,000 procedures per year in the United States—making it one of the most performed invasive surgeries in patients with critical illness. Like tracheostomy, percutaneous endoscopic gastrostomy is considered an elective procedure and is reserved for patients who are expected to survive their acute illness.

In this issue of *Critical Care Medicine*, Kiser et al (5) present an analysis of 30- and 90-day outcomes from a retrospective observational cohort study of patients with COVID-19 pneumonia who received both percutaneous tracheostomy and gastrostomy tube placement. The team collected data from four hospitals within a single healthcare system using a clinical medical record registry, including patients who received both procedures between February 2020 and August 2020. They reported short-term outcomes and sought inform clinical decision-making related to both procedures for patients with COVID-19.

The overall outcomes in this cohort are encouraging. The results tell us that among selected patients referred for both procedures in a four-hospital network in Boston, through 6 early months in the COVID-19 pandemic, 90-day mortality was very low and many patients even returned to home. The results are consistent with other recent studies of tracheostomy in patients with COVID-19, including a similarly sized and timed cohort from New York City, where mortality was 7.5% (6), and the interim results of the larger National Health Service COVIDTrach cohort, which reported a 12% mortality during the first follow-up period (7). Based on these findings, it would seem that combined tracheostomy and gastrostomy can be safe in patients with COVID-19.

Applying the results of the study by Kiser et al (5) to clinical decision-making, however, is challenging. While we know that a decision was made by the treating team to perform tracheostomy and gastrostomy, there is insufficient information reported on how that decision was made and what factors went into making it. Complicating matters further, there is evidence that tracheostomy timing varies substantially across hospitals in the United States, a finding that was present even before the COVID-19 pandemic (8). Additionally, while several publications have reported encouraging outcomes for COVID-19 patients following tracheostomy, others are less optimistic, including one study reporting 30-day mortality of nearly 30% in a combined cohort of patients who underwent either percutaneous or open surgical tracheostomy (9) and another reporting 31% mortality at 1 year (10). Without knowing more about how timing and severity of illness factored into the decision to proceed with tracheostomy and gastrostomy in the current study by Kiser et al (5), it is hard to say more than that the clinicians appeared to have made good choices in retrospect.

How are we to reconcile varying reported outcomes after tracheostomy and gastrostomy in COVID-19? Likely culprits are that, across studies, the patients are different, the treating teams are different, or some combination of these factors is true. Additionally, given that tracheostomy and gastrostomy are elective procedures performed at varying decision thresholds, intended for patients with anticipated survival, and performed at the very earliest several days after starting mechanical ventilation, observational studies of outcomes for patients who receive these procedures can be impacted by a form of selection bias known as survivorship or immortal time bias. Classically, immortal time bias occurs in an observational study when the exposure definition includes time when the outcome of interest is not possible. In the case of studies evaluating outcomes following of tracheostomy and gastrostomy, it would be an error to include time prior the procedure in a survival outcome, as patients in the exposure group survived this period by virtue of the fact that they had the procedures performed. On the other

hand, any patient who died prior to consideration of tracheostomy and gastrostomy tube would be automatically included in the nonexposed group, resulting in additional bias in favor of the procedures. To their credit, the authors of the current study by Kiser et al (5) did not make this analytic error, but immortality bias is evident in other recent studies evaluating the impact of these procedures on outcomes in the setting of COVID-19.

Interpretation of clinical outcomes following tracheostomy and gastrostomy is also complicated by the potential for reverse causality. Reverse causality refers to the situation when the directional association between an exposure and outcome is reversed—the outcome leads to the exposure. In the cases of tracheostomy and gastrostomy, the elective procedures should generally be performed in patients are considered to have promising survival chances (i.e., the anticipated outcome leads to the exposure). Although optimal timing has not been established, there is also the hope that these procedures improve the quality of care for patients with prolonged respiratory failure (i.e., the exposure leads to an improved outcome). On the other hand, poorly timed tracheostomy and gastrostomy could negatively impact quality of care, with examples including procedural complications resulting from very early tracheostomy in patients with little physiologic reserve, tracheostomy dislodgment in a patient who is receiving prone ventilation, or complications arising from prolonged endotracheal intubation (11). Untangling the magnitude and directionality of these relationships is a challenge, and yet it is essential when the outcomes experienced in one setting are hoped to be deployed in another.

A preventable tragedy of COVID-19 would be to "not" learn while doing. There has been incredible innovation in trial design, data sharing, and models of research collaboration since very early in the pandemic—and this must continue. We applaud the authors collecting, analyzing, and sharing their institutional results, as this is the only way that we will collectively address critical knowledge gaps and ultimately improve the care of our patients. It is fitting that over 2,000 years ago, the originator of the elective tracheostomy advocated for medical care that was "cito tuto jucunde"—quick, safe, and joyful. While the optimal timing of tracheostomy and gastrostomy placement in COVID-19 remains to be determined, it is encouraging that there is growing evidence that the procedures can be performed safely in some patients and that many patients even return to their lives.

1 *Division of Trauma and Acute Care Surgery, Department of Surgery, Wright State University, Fairborn, OH*

2 *Department of Critical Care Medicine, University of Pittsburgh School of Medicine, Pittsburgh, PA*

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