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Maria Katrina Abril, M.D.

Approval Sheet

Epidemiology of Tracheostomy Among Adults with Acute Respiratory Failure and Mechanical Ventilation in the US – a Serial Cross-sectional Study of the National Inpatient Sample 2002-2014

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Abstract Cover Page

Epidemiology of Tracheostomy Among Adults with Acute Respiratory Failure and Mechanical Ventilation in the US – a Serial Cross-sectional Study of the National Inpatient Sample 2002-2014

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M.D., University of Miami, 2014

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An abstract of

a thesis submitted to the Faculty of the James T. Laney School of Graduate Studies of Emory University in partial fulfillment of the requirements for the degree of Master of Science in Clinical Research

2020

Abstract

Epidemiology of Tracheostomy Among Adults with Acute Respiratory Failure and Mechanical Ventilation in the US – a Serial Cross-sectional Study of the National Inpatient Sample 2002-2014

By

Maria Katrina Abril

Background

Acute respiratory failure (ARF) with mechanical ventilation (MV) and tracheostomy is associated with significant morbidity and mortality. Better understanding of this population is essential for improved patient selection and resource allocation. We describe epidemiology of patients with ARF and MV who received tracheostomy.

Methods

We used the Healthcare Cost and Utilization Project's National Inpatient Sample (NIS) databases 2002-2014. We included patients ≥ 18 years old with International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnoses of ARF (518.5, 518.51, 518.52, 518.53, 518.81, 518.82, 518.84), MV (96.70, 96.71, 96.72), and tracheostomy (31.1). We used the SAS 9.4 *survey* procedures to account for the complex multi-stage NIS sampling design to produce national estimates of tracheostomy procedure occurrence rates.

Results

During the study period, there were an estimated 860,699 ARF-MV discharges which also had procedure coding for tracheostomy. The annual incidence of tracheostomy increased from 21.2 to 29.9 cases per 100,000 adults from 2002 to 2010, followed by a plateau until 2014. There was no change in the annual incidence of tracheostomy per 1,000 ARF-MV cases. The annual proportion of patients 51-60 and 61-70 years old increased from 16.0% to 21.8%, and

20.8% to 25.1%, respectively, while the annual proportion of patients from 71-80 and ≥81 years old decreased from 26.2% to 18.9%, and 14.3% to 9.0%, respectively. The median index hospital length of stay decreased from 31.9 to 25.9 days, and in-hospital mortality decreased from 25.2% to 14.7%.

Conclusions

From 2002 to 2014, 9.2% of patients hospitalized with ARF-MV underwent tracheostomy. The incidence of tracheostomy increased and was likely driven by the rise in the underlying ARF-MV population. Decreasing trend was noted in median hospital LOS, in-hospital mortality, and in the proportion of patients with advanced age. These results suggest that outcomes are improving but further research is warranted to evaluate if these promising outcomes translate to tracheostomy patients in outside facilities.

Cover Page

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Introduction

Acute respiratory failure (ARF) with mechanical ventilation (MV) is one of the most common diagnoses in adults admitted to the intensive care units (ICU). Over 90% of patients with ARF require ICU services resulting in high resource utilization [1]. ARF is the patients' inability to support their own oxygenation and/or ventilation—the process of expelling carbon dioxide—not solely the result of a chronic process. It is conventionally defined by an arterial blood oxygen tension of <60 mmHg or carbon dioxide tension of >45 mmHg, or both [2-4]. Patients with severe ARF can require mechanical ventilation (MV), where a machine is used to aide or replace patients' spontaneous breathing. This can be achieved with non-invasive means via a pressurized face mask, or by invasive means with the use of endotracheal tube (ETT).

Endotracheal intubation is a medical procedure where a tube is inserted through the nose or mouth into the trachea and connected to a mechanical ventilator to assist or completely support a patient's breathing. While invasive MV with an ETT can be lifesaving, the process of discontinuing or weaning an individual from MV back to spontaneous breathing once ARF has improved is difficult and associated with prolonged hospital and intensive care unit (ICU) stays. Some patients with severe ARF can require a prolonged period of MV support, ranging from several weeks to months. This intervention is also associated with a multitude of complications. The ETT bypasses protective laryngeal mechanisms which can result in bacterial contamination of the tracheobronchial tree and can lead to ventilator-associated pneumonia [5]. Other complications associated with the severe illness, immobility, and contemporaneously administered sedative infusions that occur in the setting of MV with ETT include pressure ulcers, delirium, and significant muscle weakness [6]. Moreover, ETT itself can cause direct local anatomical damage to oral, pharyngeal, and laryngeal structures.

One intervention to help reduce the likelihood of complications resulting from the use of an ETT for prolonged MV is a tracheostomy. Tracheostomy is a surgical procedure where a prosthetic tube is inserted directly into the trachea via an incision created in the anterior neck below the vocal cords to allow respiration. Tracheostomies, in place of ETT, can be offered for patients who require prolonged MV, traditionally defined as greater than 7-14 days. In the setting of ARF, tracheostomies are meant to be temporary and patients are assessed regularly for their ability to be sequentially weaned from MV followed by graduated downsizing and removal of the tracheostomy. Temporary tracheostomy, in lieu of an ETT, allows increased patient comfort, de-escalation of sedation requirement, increased mobility, and easier airway care [7]. More importantly, it also allows patients to transition out of the hospital to long-term acute care (LTAC) facilities that focus on liberation from MV while patients continue to recover.

Background

Tracheostomy, a surgical opening in the anterior neck that serves as an artificial airway, is one of the most common procedures performed in ICU patients with prolonged ARF and need for MV [7]. There is practice pattern variations among physicians but prolonged MV is typically defined as inability to wean after 10 to even 21 days with ETT [8-10]. The decision of when to proceed with tracheostomy is usually made based on patients' clinical status and how close they are to achieving independent and safe spontaneous breathing. This decision is made in close collaboration with the patients and their families. The optimal timing of performing tracheostomy is still debated. Although there have been studies that suggested that performing tracheostomy early (<10 days) offers some advantages over late tracheostomy (≥10 days) such as earlier weaning from MV, earlier ICU discharge, and lower rates of pneumonia, a separate study failed to demonstrate these benefits [11, 12].

Tracheostomy can be performed by different specialties such as general, trauma, and thoracic surgeons, otolaryngologists, ICU physicians, and interventional pulmonologists [13-16]. There are two general techniques: 1) open surgical technique typically done in the operating room, and 2) percutaneous dilatational tracheostomy (PDT) that can be performed at the bedside. PDT involves a small incision followed by several dilations through the anterior neck over a guidewire before inserting the tracheostomy tube under bronchoscopic guidance [17]. PDT, in contrast with surgical open tracheostomy, can forgo the wait for operating room availability or the need to transport critically ill patients outside of the ICU. The clinical indications, scarring rates, and mortality rates for both tracheostomy techniques are similar, but the percutaneous technique has been shown to be associated with lower bleeding and stomal infection rates compared to open surgical tracheostomy [18, 19]. Both surgical and percutaneous tracheostomies offer the same advantages mentioned above such as increased patient comfort, improved mobility, decreased sedation requirement, and facilitation of weaning from MV [7].

Tracheostomy is generally a safe and well-tolerated procedure but there are several contraindications such as uncorrectable fatal bleeding disorders, high oxygen requirement on the mechanical ventilator, hemodynamic instability, gross anatomical abnormalities of the neck due to tumor, thyroid disease, or significant scarring, cervical spine instability due to trauma or arthritis, suspected disease of the trachea and neck infection, and morbid obesity that obscures anatomical landmarks in the neck [20]. There are several procedure-related complications commonly discussed with patients and families. The most common intraoperative complication is pneumothorax or collapsed lung and incidence has been reported to be from 1.6% to as high as 17% [21]. Other complications include bleeding, tube misplacement, tracheal perforation, thyroid injury, recurrently laryngeal nerve injury, airway fire, and even cardiopulmonary arrest [21].

Once the underlying cause of ARF is resolving and the need for MV is obviated, patients can be considered for tracheostomy decannulation or removal. Several factors considered whether patients are safe candidates of removal of tracheostomy are absence of thick and tenacious respiratory secretions, ability to generate a strong cough and safely swallow, intact mental status, clinical stability without need for pharmacologic heart and blood pressure support, and no other critical organ failure. The safe removal of tracheostomy is facilitated by a multidisciplinary team composed of respiratory therapists, speech therapists, nurses, and physicians.

Data on the overall incidence of tracheostomy vary widely depending on patient subgroup. Tracheostomy incidence rates were found to be 1.7% in stroke (ischemic stroke, intracerebral hemorrhage, and subarachnoid hemorrhage), 24% in trauma, 36% in oral cancer with reconstructive surgery, and 9%-11% in all patients with invasive mechanical ventilation [4, 22-24]. Though they represent a relatively small proportion of MV patients, tracheostomy patients are resource-intensive and were reported to have total hospital charges of 1.74 billion dollars from 1993-2002 [3]. Given the significant morbidity and mortality of tracheostomy patients with ARF-MV [25, 26], as well as the significant healthcare costs they accrue, understanding of epidemiologic data is essential for careful patient selection and better resource allocation. Expanding our epidemiologic knowledge to include tracheostomy patients with both ARF-MV will provide an additional layer of understanding of the complexity of the tracheostomy population as we are focusing on a potentially more critically ill subgroup. In addition, better insight of this complex population is paramount as it can help better understand what the outcomes are and how these differ among clinically defined subgroups, help us anticipate what the procedural and post-procedural workforce and resource needs are, and prompt the development of alternative interventions targeted for patients at high risk of death. Therefore, in this project we will describe incidence, patient characteristics, hospital variables, and outcomes such as median length of stay (LOS) and in-hospital mortality.

Aims

Our aims are: **1: Estimate the national annual incidence of new tracheostomy cases in adults from 2002-2014 using the Healthcare Cost and Utilization Project's (HCUP) National Inpatient Sample (NIS).** 1a: Estimate incidence per 1,000 adult cases of ARF-MV, 1b: Estimate incidence per 1,000 adult hospital discharges, and 1c: Estimate incidence per 100,000 U.S. adults, **2: Describe the patient and hospital-level characteristics of adult tracheostomy patients with ARF-MV over 2002-2014 using HCUP NIS.** 2a: Describe clinical variables such as demographics, medical co-morbidities, severity of illness subclasses, and mortality risk subclasses, 2b:Describe hospital variables such as hospital region, bed size, and location/teaching status, and 2c: Describe clinical outcomes such as length of stay (LOS), mortality rate, and disposition at discharge.

Methods

Study design and Database

This is a serial cross-sectional study using the Healthcare Cost and Utilization Project's (HCUP) National Inpatient Sample (NIS) databases 2002-2014 [27]. The HCUP NIS is a nationally representative, administrative database of hospital discharges submitted by hospitals to statewide data organizations across the United States, and consists of approximately 7 million unweighted and 35 million weighted hospital discharge records annually [28]. It includes hospital stays from all non-federal (federal hospitals include Veterans Affairs and military hospitals), short-term, general, and other specialty hospitals and contains information on all patients, regardless of payer. [28, 29] It is derived from State Inpatient Database (SID) which, as of 2014, is comprised of 44 States and the District of Columbia, covering more than 96 percent of the U.S. population [28, 30]. Diagnoses and procedures in NIS are based on ICD-9-CM codes and there are up to 25 diagnoses and 15 procedures entered for each index hospitalization [28].

Over the 2002-2014 study period there were changes in the annual NIS sample design pertinent to this analysis: 1) Starting 2012, HCUP changed their sample design to a 20% stratified sample of discharges from all U.S. hospitals participating in HCUP while in the prior years, the NIS represents all the discharges from 20% stratified sample of U.S. hospitals participating in HCUP and 2) Long-Term Acute Care (LTAC) facilities were excluded because information on their LOS was not always uniformly available from all states participating in HCUP [29]. The 2012 and later revised sampling design produced a more precise national-level estimates than the prior sampling design. To allow trend analysis across these years despite the change in sampling design, new weights were developed to make estimates comparable in all the years [31]. Of note, the changes in 2012 have been reported to result in a one-time impact on overall hospital discharge counts (declined by 4.3%), LOS (declined by 1.5%), and in-hospital mortality (declined by 2%) [29, 31].

Hospital discharges are stratified and weighted based on census region (Northeast, Midwest, South, West) for years before 2012 and division (New England, Middle Atlantic, East North Central, West North Central, South Atlantic, South Central, Mountain, and Pacific) for years 2012 and later, ownership (public, private non-for-profit, and private investor-owned hospitals), location (urban vs rural), teaching status (teaching vs non-teaching), and bed size (small, medium, and large) [29]. The unit of observation is hospital discharge so it is possible that a patient with more than one admission may be randomly resampled and counted more than once.

Participants

We included all discharges with diagnoses of ARF, MV, and tracheostomy. To define ARF, a discharge must have one of the following ICD-9-CM codes in the discharge record: 518.5 (Pulmonary insufficiency following trauma and surgery), 518.81 (Acute respiratory failure), 518.82 (Other pulmonary insufficiency not elsewhere classified), or 518.84 (Acute and chronic respiratory failure). ICD-9-CM code 518.5 was expanded to 518.51 (Acute respiratory failure following trauma and surgery), 518.52 (Other pulmonary insufficiency, not elsewhere classified, following trauma and surgery), and 518.53 (Acute and chronic respiratory failure following trauma and surgery) in 2012 and were included in our data as well. MV was defined as any discharge with one of the following ICD-9-CM procedure codes listed in the discharge record: 96.70 (Continuous mechanical ventilation of unspecified duration), 96.71 (Continuous invasive mechanical ventilation for less than 96 consecutive hours), and 96.72 (Continuous mechanical ventilation for 96 hours and greater consecutively). For tracheostomy we used ICD-9-CM code 31.1 (Temporary tracheostomy).

We excluded patients younger than 18 years old as the pediatric population has different outcomes, pathophysiology, and clinical need compared to adult patients. This age definition excluded missing ages. We also excluded discharges with head and neck cancer defined as Clinical Classification Software (CCS) code 11 in their indication(s) for, procedural requirements of, and outcome of tracheostomy. Practically, patients with head and neck cancer represent a different patient population than those with acute respiratory failure requiring temporary tracheostomy which was our target population for this analysis.

The Clinical Classification Software (CCS) is one of the tools provided by HCUP. The CCS clusters ICD-9-CM codes into smaller, manageable, clinically meaningful groups [32]. The CCS collapses over 14,000 diagnosis codes to 285 smaller categories, and approximately 3,900 procedure codes to 231 categories. We used CCS code 11 to identify all ICD-9-CM codes for head and neck cancer to ensure we are comprehensively including all the ICD-9-CM codes for head and neck malignancy, and to allow for more practical statistical coding and analysis.

Outcomes

Incidence and number of cases

In order to describe the national epidemiology and utilization patterns of tracheostomy in ARF-MV we calculated the total, weighted, annual number of ARF-MV with tracheostomy cases, annual number of tracheostomies per 1,000 ARF-MV cases, annual number of tracheostomies per 1,000 hospital discharges, and annual number of tracheostomies per 100,000 U.S. adults (those ≥18 years old) based on U.S. Census Bureau data.

Patient and hospital-level characteristics

<u>Demographics</u>

Our study measures included the patient demographics of age, race/ethnicity (White, Black, Hispanic, Asian or Pacific Islander, Native American, and other), sex, and expected primary payor (Medicare, Medicaid, private insurance, self-pay, no charge, and other). In analyses, age was used as a continuous variable and was categorized into groups: 18-30, 31-40, 41-50, 51-60, 61-70, 71-80, and ≥81 years.

Elixhauser Comorbidity Measures

For clinical variables, we included assessment of several medical comorbidities based on the Elixhauser comorbidity measures, which include 30 separate comorbid conditions found to independently predict hospital mortality and LOS. Developed in 1998 through review of adult, nonmaternal inpatient records from over 400 acute care hospitals in California using the HCUP's Statewide Inpatient Database (SID), researchers identified 30 comorbidities that were found to independently predict patient outcomes such as increased mortality and longer LOS [33]. They used the ICD-9-CM codes to distinguish pre-existing comorbidity from primary diagnosis or primary reason for admission. These comorbidity measures' ability to predict poor patient outcomes were tested in a heterogeneous population with a variety of reasons for hospital admissions, as well as a subset homogeneous population with specific diseases. They were however not validated in other data systems, conditions, and populations. The comorbidity list includes the following diagnoses: Acquired Immune Deficiency Syndrome (AIDS), alcohol abuse, deficiency anemia, arthritis (rheumatoid/collagen vascular diseases), chronic blood loss anemia, cardiac arrhythmias, congestive heart failure (CHF), chronic pulmonary disease, coagulopathy, depression, diabetes mellitus (DM) with complications, DM without chronic complications, drug abuse, hypertension (combined complicated and uncomplicated), hypothyroidism, liver disease, lymphoma, fluid and electrolytes disorders, metastatic cancer, other neurological disorders, obesity, paralysis, peripheral vascular disorders, psychoses, pulmonary circulation disorders, renal failure, solid tumor without metastasis, peptic ulcer disease (excluding bleeding), valvular disease, and weight loss [34].

The Elixhauser comorbidities are identified from NIS hospital discharges using HCUP's comorbidity software. The comorbidity software dichotomizes responses to 'not present' and 'present'. Cardiac arrhythmia was removed from the comorbidity software given that it is mostly an acute diagnosis rather than a pre-existing condition, as well as concerns for reliability, leaving 29 comorbidity measures [34, 35].

Severity of Illness and Mortality Risk Subclasses

We included the severity of illness and risk of mortality subclasses based on the All Patients Refined Diagnosis Related Groups (APR-DRG) classification system. The APR-DRG system groups patients based on their reason for hospitalization, mortality risk, and severity of illness, and resource intensity [36]. For severity of illness subclasses, the categories include no class specified, minor, moderate, major, and extreme loss of function. Similarly, for mortality risk subclasses the categories include no class specified, minor, moderate, major, and extreme likelihood of dying.

Hospital variables

For hospital-related variables we included hospital region (Northeast, Midwest, South, and West), bed size (small, medium, and large), and location/teaching status (rural, urban nonteaching, and urban teaching).

Clinical Outcomes

Other clinical variables included in this study were median LOS, in-hospital mortality rate based on vital status reported as 'died', admission status as elective vs non-elective, and disposition of patients at discharge which includes routine, transfer to short-term hospital, transfer other (includes Skilled Nursing Facility [SNF], Intermediate Care Facility [ICF], another type of facility), home health care, discharged against medical advice (AMA), died (used for in-hospital mortality rate), and discharged alive but destination unknown.

Analytic plan

We used SAS 9.4 (by SAS Institute Inc., Cary, NC, USA) *survey* procedures to account for the complex multi-stage NIS sampling design and produce national estimates. We estimated the number of hospitalizations with a diagnosis code of ARF, MV, and tracheostomy and produced national estimates using weighted frequencies. We used the U.S. Census Bureau annual population estimates for ages ≥18 years to determine tracheostomy rates per 100,000

U.S. adults. We calculated proportions for categorical variables and medians for continuous variables. We chose median over mean because it is less sensitive to outliers. We calculated standard errors and 95% confidence intervals (CI) for all our variables. Statistical significance was defined as non-overlapping 95% CI. Variables with >10% missingness were not included in our analyses. We did not include missing values in our analyses.

Results

Incidence and number of cases

From 2002-2014, there were an estimated 482,872,255 hospital discharges from all causes. After excluding 81,098,410 hospital discharges that were coded for age <18 years (n=79,422,672) or head and neck cancer (n=1,675,738), we identified an estimated 9,324,928 hospital discharges coded for ARF and MV. Of these, an estimated 860,699 discharges had a code of tracheostomy, representing 9.2% of the ARF with MV population (Figure 1).

From 2002 to 2014, the total annual estimates of ARF-MV with tracheostomy cases increased from 45,551 (95% CI 41,527-49,574) to 73,200 (95% CI 69,546-76,853) (Figure 2). From 2002 to 2014, while the incidence of tracheostomies per 1,000 ARF-MV cases remained stable from 90.6 (95% CI 82.6-98.7) to 82.2 (95% CI 78.1-86.3) (Figure 3), incidences of tracheostomy per 1,000 hospital discharges increased from 1.3 (95% CI 1.1-1.4) to 2.1 (95% CI 2.0-2.2) (Figure 4). Lastly, incidence of tracheostomy per 100,000 U.S. adults increased from 21.2 (95% CI 19.3-23.1) to 29.9 (95% CI 28.4-31.4) cases from 2002 to 2014 (Figure 5).

Patient and hospital-level characteristics

Clinical Variables

Demographics

From 2002 to 2014, the median age of patients with tracheostomy among ARF-MV decreased from 65.7 years (95% CI 64.6-66.8) to 61.2 years (95% CI 60.8-61.6). Over the study period the proportion of patients from age groups 51-60 and 61-70 years old increased from 16.0% (95% CI 15.1-16.8) to 21.8% (95% CI 21.1-22.5), and 20.8% (95% CI 19.7-21.8) to 25.1% (95% CI 24.4-25.9), respectively. In contrast, the proportion of patients from age groups 71-80 and ≥81 years old decreased from 26.2% (95% CI 24.8-27.5) to 18.9% (95% CI 18.1-19.7), and 14.3% (95% CI 13.2-15.4) to 9.0% (95% CI 8.4-9.6), respectively. The proportion of males increased from 53.8% (95% CI 52.4- 55.1) to 56.3% (95% CI 55.4-57.2). The most common expected primary payor was Medicare followed by private insurance and Medicaid. The proportion of patients with expected primary payor as Medicare decreased from 56.3% (95% CI 54.1-58.6) to 50.4% (95% CI 49.3-51.5), while the proportion of patients with whose expected payor was Medicaid increased from 11.8% (95% CI 10.6-12.9) to 18.6% (95% CI 17.7-19.5). The proportion of patients with expected payors of private insurance, on self-pay, no charge, and other payer remained unchanged from 2002 to 2014. Race was not included in our analysis given >10% missingness in most years. See Table 1 for comparison of patient demographics in 2002 and 2014.

Elixhauser Comorbidity Measures

The proportion of tracheotomy patients with coagulopathy, obesity, paralysis, pulmonary vascular disease, and weight loss significantly increased, while the proportion of patients with chronic lung disease significantly decreased. There was no change in the proportion of patients with AIDS, CHF, lymphoma, metastatic cancer, neurological abnormality, and valvular disorder. See Table 2 for complete list of Elixhauser comorbidities.

Severity of Illness and Mortality Risk Subclasses

For illness severity subclasses, most patients had extreme loss of function, followed by major loss of function. The proportion of patients with extreme loss of function severity increased from 73.5% (95% CI 71.8-75.2) to 87.4% (95% CI 86.7-88.0), while those with major loss of function decreased from 23.3% (95% CI 21.8-24.7) to 11.8% (95% CI 11.2-12.5). The APR-DRG risk classification of patients categorized patients as having extreme or major likelihood of dying in the majority of cases. Those with extreme likelihood of dying increased from 42.8% (95% CI 40.5-45.1) to 67.4% (66.2-68.6), while those with major likelihood of dying decreased from 40.1% (95% CI 38.3-41.4) to 26.9% (95% CI 25.9-27.8). See Table 2 for comparison of clinical variables of tracheostomy patients for 2002 and 2014.

Hospital variables

The proportion of patients from small hospitals increased from 7.1% (95% CI 5.3-8.9) to 10.6% (95% CI 9.5-11.8), while those from large hospitals decreased from 71.4% (95% CI 67.7-75.1) to 63.5% (95% CI 61.3-65.6). The proportion of patients from urban-teaching hospitals increased from 57.0% (95% CI 52.9-61.2) to 79.4% (95% CI 77.9-80.9), while those from urban non-teaching and rural hospitals decreased from 38.1% to (95% CI 34.1-42.0) to 18.4% (95% CI 17.0-19.7), and 4.9% (95% CI 3.4-6.4) to 2.2% (95% CI 1.7-2.7), respectively. See Table 3 for comparison of hospital-level variables of tracheostomy patients for 2002 and 2014.

Clinical Outcomes

From the beginning to end of the study period, the median LOS decreased from 31.9 (95% CI 30.9-32.8) to 25.9 days (95% CI 25.4-26.4). In-hospital mortality decreased from 25.2% (95% CI 23.8%-26.6%) to 14.7% (95% CI 14.0%-15.3%). At least 50% of patients have skilled nursing facilities (SNFs) and intermediate care facilities (ICFs) as their disposition after discharge. The proportion of patients with disposition of SNFs and ICFs increased from 53.4% (95% CI 51.2-55.5%) to 67.7% (95% CI 66.7%-68.8%). Those with routine discharge decreased from 8.6% (95% CI 7.0%-10.1%) to 6.1% (95% CI 5.5%-6.6%). The proportion of patients with discharge disposition of short-term hospitals, home health care, AMA, and destination unknown were stable throughout the study period. See Table 4 for comparison of clinical outcomes of tracheostomy patients for 2002 and 2014.

Discussion

In this project we report the trends in incidence of tracheostomy procedures performed in patients with ARF-MV and describe associated clinical and hospital characteristics, and clinical outcomes from 2002-2014. To examine annual incidence, we started by looking at the overall number of cases of ARF-MV patients who received tracheostomy to assess tracheostomy utilization. Then we examined tracheostomy cases in the context of the total number of inpatient hospitalizations, inpatient hospitalizations for ARF-MV, and based on annual estimates of the adult U.S. population. We found that the overall number and incidence rates of tracheostomy increased from 2002-2014 similar to prior studies [3, 37]. In addition, we found that the temporal trend in annual tracheostomy rates demonstrated an increase from 2002-2010, followed by plateau until the end of the study period, similar to study done by Mehta et al [37]. Interestingly the incidence per 1,000 ARF-MV cases showed stable trend during the entire study period. To our knowledge this has not been shown in prior studies. This result may suggest that the rise in tracheostomy incidence is primarily driven by the increase in the total number of ARF-MV hospitalizations.

Regarding clinical and hospital characteristics and outcomes, we found several notable findings. First, the median age decreased which like the tracheostomy incidence, occurred between 2002-2010, followed by a plateau. When age was categorized, we observed increasing proportion of tracheostomy patients in middle age groups and declining proportion in the advanced age groups. Second, we saw increasing trends in comorbidities such as bleeding disorders, obesity, and paralysis, and decreasing trend in chronic lung disease and solid tumor. The proportion of tracheostomy patients with higher severity of illness and mortality risk, as well as those with discharge location documented as SNFs and ICFs increased. Lastly, clinical outcomes such as median LOS and in-hospital mortality decreased during the study period.

Our study is descriptive therefore our explanations and conclusions are purely speculative. Changes in our database sampling design as well as our reliance physician coding to obtain our cases also require interpreting our results with caution. In terms of our results regarding tracheostomy incidence, this may be due to the increasing incidence of the underlying ARF and MV population as mentioned above, [2, 4] earlier recognition of complications from prolonged ETT use which lead to earlier placement of tracheostomy [3, 9, 38], as well as newer techniques such as PDT which allows tracheostomy to be done at the bedside. Tracheostomy performed percutaneously lends itself to patients with higher acuity of illness which may preclude surgical tracheostomy which would require patients be transferred to/from an operating room. Additionally, given perceived lower risk of bleeding, PDT may be more readily performed in patients with bleeding disorders [19]. Another potential reason for the rise as already mentioned is the increasing number of specialists who can perform tracheostomy.

The latter plateau in trend from 2010 to 2014 has been demonstrated in prior studies [37]. This may be due to stricter patient selection that would go along with decreasing median age of these patients, and perhaps greater collaboration with palliative care physicians and earlier initiation of goals of care discussion which would be expected to limit procedural interventions in critically ill subjects near death [39, 40]. The increasing proportion of patients with comorbidities, and higher illness severity and likelihood of death subclasses indicate a changing patient population requiring intensive care and tracheostomy. Patients receiving tracheostomy have, on average, higher acuity of illness in more recent data in our study. The temporal increase in comorbidities may be from greater recognition of these diseases which result in increased coding and reporting but the fact that other comorbidities, especially chronic lung disease, demonstrated a decrease argue against this. This finding is not completely surprising and points to our decreased likelihood of performing this procedure on patients who are unlikely to be weaned from MV and tracheostomy.

The decreasing median LOS could represent true improvement in patient management and overall outcomes, or from removal of LTACs from the source dataset. Average LOS from LTACs is >30 days and removal of these long-term facilities from the HCUP-NIS dataset would be expected to reduce the mean LOS of the study population [41]. Alternatively, shorter LOS could be attributed to improved implementation of multidisciplinary teams that facilitate safe and efficient discharge out of the hospital [42, 43], but it is worth mentioning that despite decreasing hospital LOS, these patients may possibly be staying longer in other facilities such as SNFs and ICFs. The decreased in-hospital mortality follows the same rationale—either we are truly improving patient outcomes given the improving care in ARF and MV patients [8, 44, 45], or they are dying somewhere else. Most tracheostomy patients are getting discharged to other facilities which again represent the uniquely complex needs of these patients that are unable to be provided at home. It also reinforces that after acute hospitalization, these patients face a long road to recovery that calls for ongoing 24-hour medical care provided by medical staff including subspecialists, registered nurses, respiratory therapists, physical and occupational therapists, case managers, and social workers.

Our study has several strengths. Using the HCUP-NIS we were able to generate nationally representative estimates of tracheostomy incidence and outcomes over a 13-year period. Another strength is that we reported a comprehensive list of variables such as demographics, clinical and hospital-related variables, and clinical outcomes which allowed us to better understand tracheostomy patients. Ours is the first study to our knowledge that examined outcomes in tracheostomy among those with ARF-MV. Lastly, all our variables had <10% missingness, except for race. There are also some limitations to our study. First, this is a retrospective study so as mentioned earlier our interpretations of results and trends are based on conjecture. For example, as this is a cross-sectional study, we cannot establish causation and temporality between tracheostomy and improving outcomes. Since we are measuring tracheostomy incidence rates and mortality at the same time, we are unable to determine if tracheostomy leads to improving outcomes or people with higher likelihood of surviving are more likely to receive tracheostomy. We will need a prospective study to establish if tracheostomy leads to improving mortality, but this will be extremely challenging and costly given the heterogeneous characteristics of critically ill patients with ARF and MV, as well as the significant mortality of these population. Second, it is possible that our analysis underestimated tracheostomy counts as we could only use ICD coding. Since early 1990s, procedures such as tracheostomy can be coded using a different coding system called Current Procedural Terminology (CPT) codes [46, 47] which are not available in HCUP-NIS. It is unclear when exactly CPT codes became mandated and uniformly adapted for coding tracheostomy procedures. Third, our database only contains data from inpatient stays and does not collect follow up data after discharge. Since most patients with ARF-MV are discharged to other facilities after their acute index hospitalization, capturing their outcomes in those settings would be paramount to comprehensive understanding of this population's specific care needs and mortality after ARF-MV with or without tracheostomy. While the data available for this study is unable to estimate outcomes beyond the index hospitalization, better understanding of outcomes of these patients after discharge would inform the community need for resources, including whether any subgroup requires specialized needs, and may promote better collaboration between inpatient and outpatient healthcare teams to allow smoother transition of tracheostomy patients after hospital discharge. Knowledge about patients' mortality after discharge would also improve patient selection for tracheostomy and avoid invasive procedures on those at highest risk of death after discharge. Lastly, because there are no data elements to indicate the type of community hospital contributing to the discharge counts, we are unable to report the contribution of LTAC and the impact of its exclusion starting in 2012.

Our study has several implications: First, we may see a continued rise in tracheostomy incidence given the aging population, ongoing expected rise on the incidence of ARF incidence and increased MV use, and greater procedural comfort by clinicians from various specialties. Second, despite taking care of a sicker patient population, in-hospital LOS and mortality are improving, likely attributable to more careful patient selection and better management of ARF and MV patients. However, it is unclear if tracheostomy directly contributes to these improved outcomes as studies comparing tracheostomy versus non-tracheostomy patients are lacking. Third, studies that can report outcomes of tracheostomy patients from LTACs will be essential epidemiologic data that can have major impact in further improving these patients' care.

Conclusion

Overall, our study informs the characteristics of patients requiring tracheostomy for ARF-MV as well as detailing the temporal trends between 2002 and 2014. The rising incidence of tracheostomy among ARF-MV as well as the increasing proportion of patients with comorbidities suggest that severe ARF with prolonged MV will likely continue to be a public health and health resource burden. It will require careful attention to make sure our health systems are able to accommodate this growing complex, resource-intensive population over a long period of time. Further research is needed to analyze the trend in the last few years to better illustrate if incidence has really plateaued or simply a limitation of our dataset. We plan future additional analyses focused on comparing clinical and hospital characteristics, and outcomes for patients with and without tracheostomy among those with ARF-MV. This will further evaluate whether the trends observed in this report are truly from the changes in tracheostomy patients or changes in the underlying ARF-MV population.

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Figures and Tables

Figure 1: Cohort Derivation

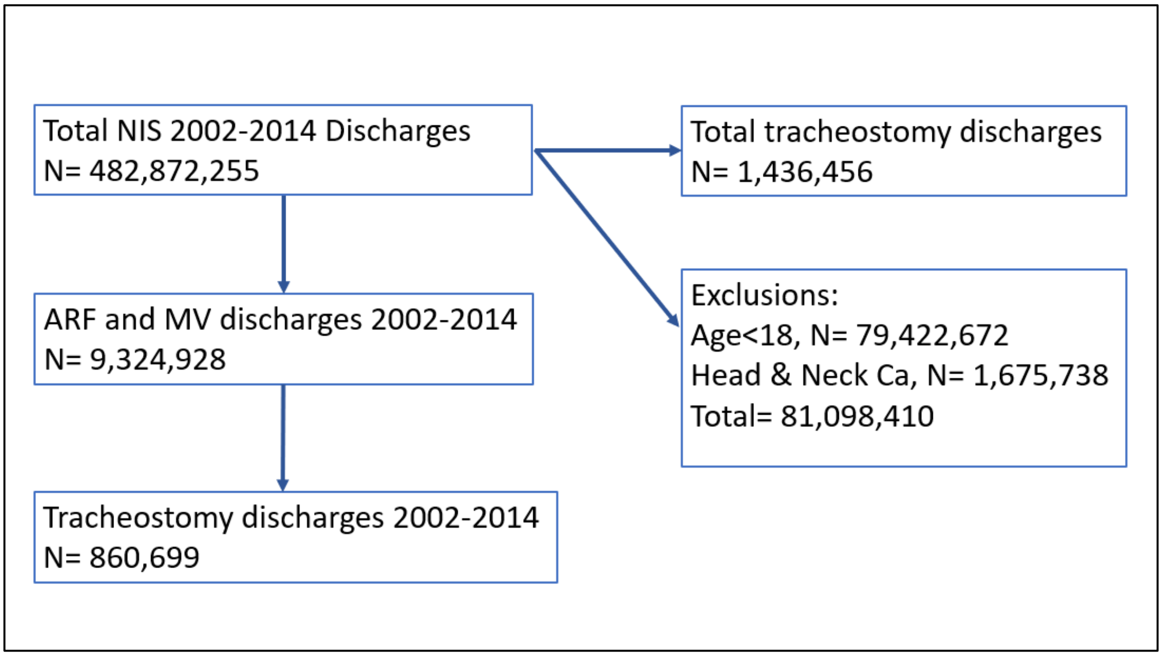

Figure 2: Total No. of ARF-MV with Tracheostomy Cases from 2002-2014

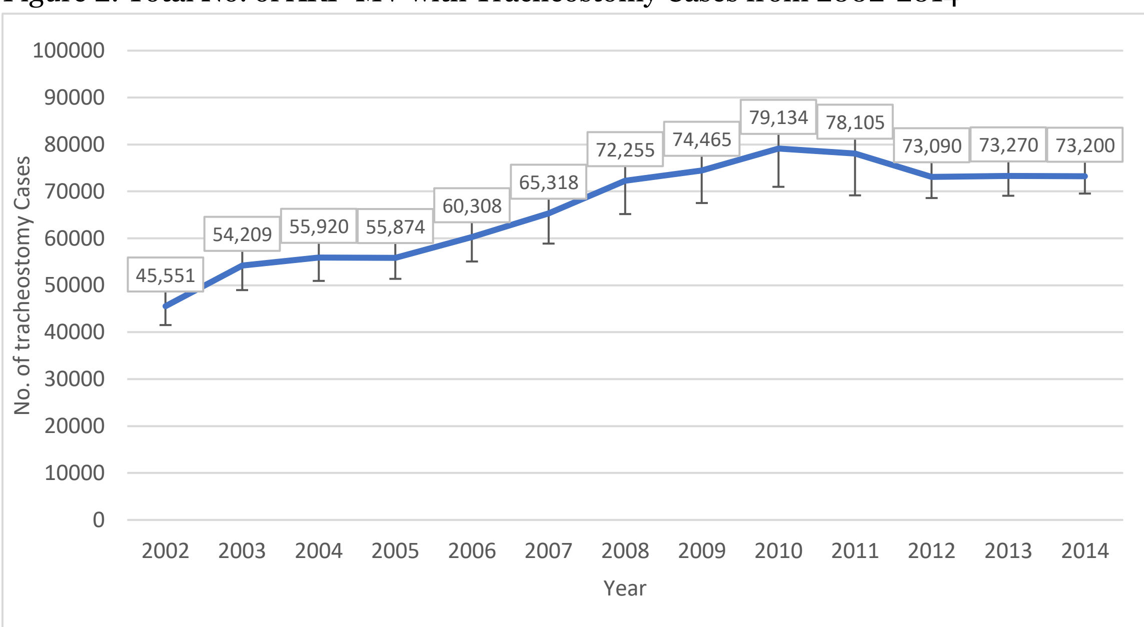

Figure 3: Incidence of Tracheostomy per 1,000 ARF-MV cases from 2002-2014

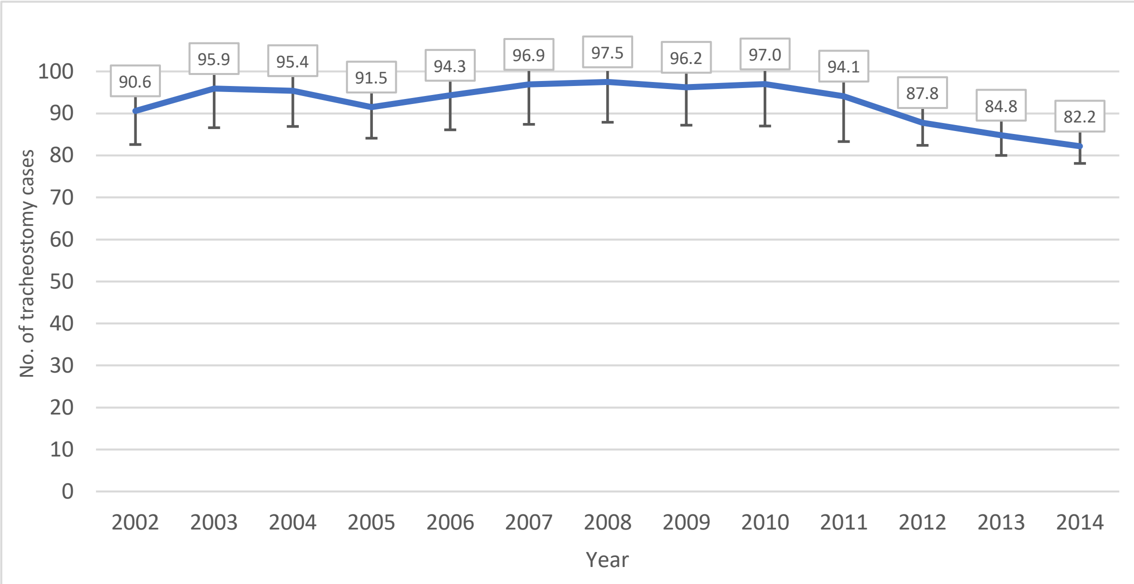

Figure 4: Incidence of Tracheostomy per 1,000 Discharges from 2002-2014

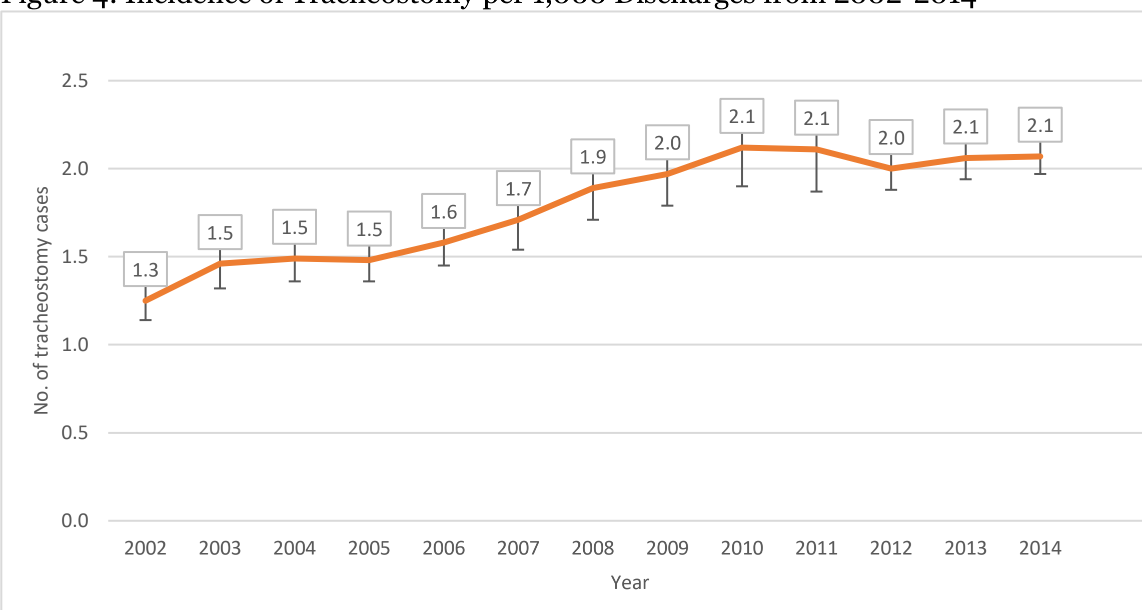

Figure 5: Incidence of Tracheostomy per 100,000 US Adults from 2002-2014

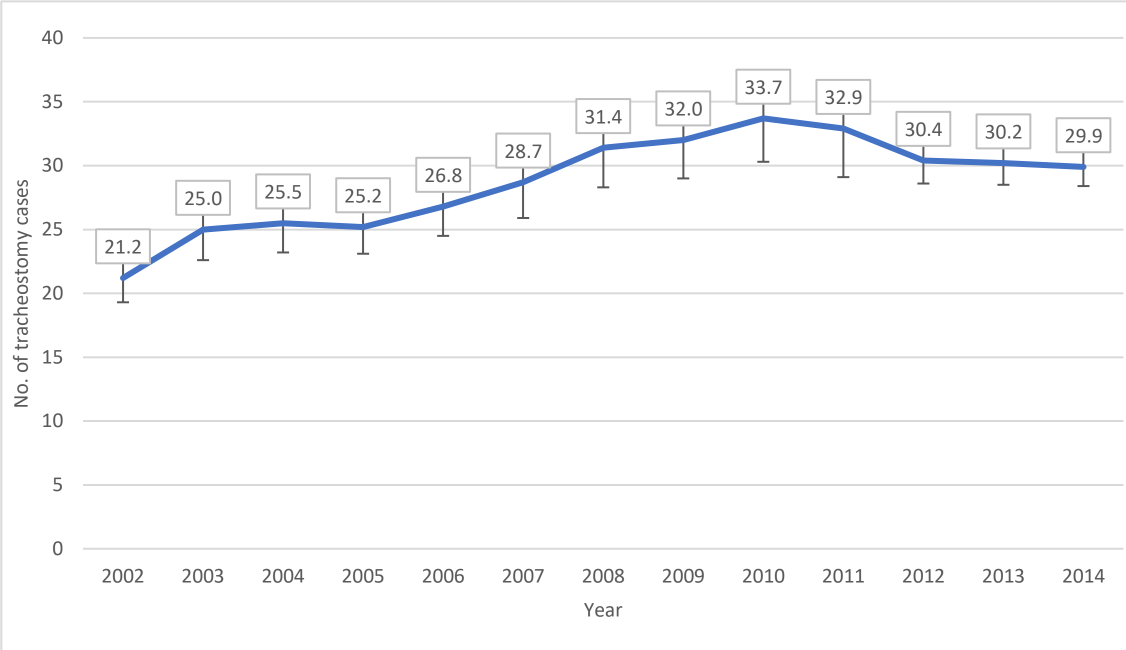

Table 1: Patient Demographics of Tracheostomy Patients in 2002 and 2014

	2002		**2014**	
Variable	**%/median (SE)**	**95% CI**	**%/median (SE)**	**95% CI**
Age (years)	65.7 (0.6)	64.6, 66.8	61.2 (0.2)	60.8, 61.6
Age category				
18-30 years	5.1 (0.4)	4.3, 5.9	7.1 (0.3)	6.6, 7.6
31-40 years	6.8 (0.4)	6.1, 7.5	6.7 (0.3)	6.2, 7.2
41-50 years	10.9 (0.4)	10.1, 11.6	11.4 (0.3)	10.9, 12.0
51-60 years	16.0 (0.4)	15.1, 16.8	21.8 (0.4)	21.1, 22.5
61-70 years	20.8 (0.5)	19.7, 21.8	25.1 (0.4)	24.4, 25.9
71-80 years	26.2 (0.7)	24.8, 27.5	18.9 (0.4)	18.1, 19.7
≥81 years	14.3 (0.6)	13.2, 15.4	9.0 (0.3)	8.4, 9.6
Sex				
Male	53.8 (0.7)	52.4, 55.1	56.3 (0.5)	55.4, 57.2
Female	46.2 (0.7)	44.9, 47.6	43.7 (0.5)	42.8, 44.6
Expected Primary Payor				
Medicare	56.3 (1.2)	54.1, 58.6	50.4 (0.6)	49.3, 51.5
Medicaid	11.8 (0.6)	10.6, 12.9	18.6 (0.5)	17.7, 19.5
Private insurance	25.6 (0.9)	23.9, 27.3	23.2 (0.4)	22.4, 24.1
Self-pay	2.8 (0.3)	2.2, 3.5	4.0 (0.3)	3.5, 4.5
No charge	0.4 (0.2)	0.1, 0.7	0.4 (0.1)	0.2, 0.5
Other	3.1 (0.4)	2.4, 3.8	3.4 (0.2)	3.0, 3.8

Table 2: Clinical Variables of Tracheostomy Patients in 2002 and 2014

	2002		2014	
Variable	**% (SE)**	**95% CI**	**% (SE)**	**95% CI**
Comorbidities				
AIDS[A]	0.3 (0.1)	0.2, 0.4	0.4 (0.1)	0.3, 0.5
Alcohol	6.8 (0.4)	6.1, 7.5	9.5 (0.3)	9.0, 10.0
Anemia (deficiencies)	13.2 (1.0)	11.2, 15.1	28.8 (0.6)	27.6, 30.0
Arthritis	1.4 (0.1)	1.1, 1.6	2.7 (0.1)	2.4, 2.9
Blood loss anemia	2.9 (0.3)	2.3, 3.5	1.5 (0.1)	1.3, 1.8
CHF[B]	29.8 (1.0)	27.8, 31.8	27.4 (0.5)	26.4, 28.5
Chronic lung disease	33.1 (1.0)	31.0, 35.1	27.8 (0.5)	26.8, 28.7
Coagulopathy	11.5 (0.6)	10.4, 12.6	21.6 (0.4)	20.7, 22.5
Depression	3.1 (0.2)	2.6, 3.5	9.0 (0.3)	8.5, 9.6
DM[C] w/o complications	13.4 (0.6)	12.2, 14.7	22.8 (0.4)	22.0, 23.7
DM[C] w/complications	4.2 (0.3)	3.6, 4.8	6.3 (0.2)	5.8, 6.8
Drug Abuse	2.3 (0.2)	1.9, 2.7	5.6 (0.2)	5.1, 6.0
Hypertension	20.8 (1.0)	19.0, 22.7	55.2 (0.6)	54.0, 56.4
Hypothyroidism	3.8 (0.3)	3.2, 4.4	9.3 (0.3)	8.8, 9.8
Liver disease	2.9 (0.2)	2.5, 3.3	5.3 (0.2)	4.9, 5.7
Lymphoma	0.9 (0.1)	0.7, 1.0	1.1 (0.1)	0.9, 1.2
Electrolytes abnormality	44.5 (1.4)	41.8, 47.2	73.9 (0.7)	72.6, 75.2
Metastatic cancer	3.2 (0.2)	2.7, 3.6	2.6 (0.1)	2.3, 2.9
Neurological abnormality	21.5 (0.8)	20.0, 23.1	22.2 (0.4)	21.3, 23
Obesity	4.5 (0.3)	3.8, 5.1	20.8 (0.4)	20.0, 21.7
Paralysis	6.7 (0.5)	5.8, 7.6	15.9 (0.4)	15.2, 16.6
PVD[D]	3.4 (0.3)	2.8, 4.0	9.1 (0.3)	8.6, 9.7
Psychiatric disorders	2.8 (0.2)	2.4, 3.2	6.1 (0.2)	5.7, 6.5
Pulmonary vascular disease	3.3 (0.4)	2.6, 4.0	11.0 (0.3)	10.5, 11.6
Renal failure	9.6 (0.5)	8.6, 10.6	19.7 (0.4)	18.9, 20.6
Solid tumor	4.4 (0.3)	3.9, 5.0	2.1 (0.1)	1.8, 2.3
Ulcer (peptic)	1.2 (0.1)	0.9, 1.4	0.1 (0.0)	0.0, 0.1
Valvular disease	7.5 (0.5)	6.5, 8.5	7.0 (0.3)	6.4, 7.5
Weight loss	19.9 (1.5)	16.8, 22.9	38.1 (0.8)	36.6, 39.6
Disease severity				
Minor loss of function	0.2 (0.0)	0.1, 0.3	0.1 (0.0)	0.0, 0.1
Moderate loss of function	3.0 (0.2)	2.6, 3.5	0.7 (0.1)	0.6, 0.9
Major loss of function	23.3 (0.7)	21.8, 24.7	11.8 (0.3)	11.2, 12.5
Extreme loss of function	73.5 (0.9)	71.8, 75.2	87.4 (0.4)	86.7, 88
Mortality Risk				

Minor likelihood of dying	3.7 (0.3)	3.1, 4.4	1.2 (0.1)	1.0, 1.4
Moderate likelihood of dying	13.3 (0.5)	12.3, 14.3	4.5 (0.2)	4.1, 4.9
Major likelihood of dying	40.1 (0.7)	38.3, 41.4	26.9 (0.5)	25.9, 27.8
Extreme likelihood of dying	42.8 (1.2)	40.5, 45.1	67.4 (0.6)	66.2, 68.6
Elective Admission				
Non-elective	87.9 (0.9)	86.1, 89.6	90.6 (0.3)	90.0, 91.3
Elective	12.1 (0.9)	10.4, 13.9	9.4 (0.3)	8.7, 10.0

[A]*Acquired Immunodeficiency Syndrome;* [B]*Congestive Heart Failure;*
[C]*Diabetes Mellitus;* [D]*Peripheral Vascular Disease;*
Cardiac arrhythmia was removed from the comorbidity software leaving only 29 comorbidities.

Table 3: Hospital Variables of Tracheostomy Patients in 2002 and 2014

	2002		**2014**	
Variable	**% (SE)**	**95% CI**	**% (SE)**	**95% CI**
Hospital region				
Northeast	23.3 (1.8)	19.8, 26.8	18.2 (0.9)	16.5, 19.9
Midwest	21.8 (2.2)	17.5, 26.2	19.7 (0.9)	18.0, 21.4
South	39.5 (2.2)	35.3, 43.8	43.0 (1.3)	40.4, 45.6
West	15.3 (1.3)	12.7, 17.9	19.2 (0.8)	17.5, 20.8
Hospital bed size				
Small	7.1 (0.9)	5.3, 8.9	10.6 (0.6)	9.5, 11.8
Medium	21.5 (1.7)	18.1, 24.9	25.9 (1.0)	24.0, 27.8
Large	71.4 (1.9)	67.7, 75.1	63.5 (1.1)	61.3, 65.6
Location/teaching status				
Rural	4.9 (0.8)	3.4, 6.4	2.2 (0.3)	1.7, 2.7
Urban non-teaching	38.1 (2.0)	34.1, 42.0	18.4 (0.7)	17.0, 19.7
Urban - teaching	57.0 (2.1)	52.9, 61.2	79.4 (0.7)	77.9, 80.9

Table 4: Clinical Outcomes of Tracheostomy Patients in 2002 and 2014

	2002		2014	
Variable	**%/Median (SE)**	**95% CI**	**%/Median (SE)**	**95% CI**
LOS[±] (days)	31.9 (0.5)	30.9, 32.8	25.9 (0.3)	25.4, 26.4
Mortality rate	25.2 (0.7)	23.8, 26.6	14.7 (0.3)	14.0, 15.3
Disposition after discharge				
Routine[a]	8.6 (0.8)	7.0, 10.1	6.1 (0.3)	5.5, 6.6
Transfer to short term hospital[b]	7.0 (0.5)	5.9, 8	5.8 (0.4)	5.0, 6.5
Other transfers: SNF and intermediate care[c]	53.4 (1.1)	51.2, 55.5	67.7 (0.6)	66.7, 68.8
Home health care[d]	5.6 (0.4)	4.7, 6.4	5.4 (0.2)	4.9, 5.8
AMA[e]	0.2 (0.0)	0.1, 0.2	0.2 (0.0)	0.1, 0.2
Destination unknown[f]	0.2 (0.1)	0.1, 0.3	0.2 (0.1)	0.1, 0.3

[±] *Length of Stay;*
[a] *Discharged to Home or Self Care (Routine Discharge), Court/Law Enforcement, Still a patient (allowable value for outpatient data starting in data year 2016), Home or Self Care with a Planned Acute Care Hospital Inpatient Readmission (Effective 10/1/13), Court/Law Enforcement with a Planned Acute Care Hospital Inpatient Readmission (Effective 10/1/13)*
[b] *Effective 10/1/07: Discharged/transferred to a Designated Cancer Center or Children's Hospital, Admitted as an inpatient to this hospital - valid only on outpatient data, Discharged/transferred to a Federal Health Care Facility, Critical Access Hospital (CAH), Short Term General Hospital for Inpatient Care with a Planned Acute Care Hospital Inpatient Readmission (Effective 10/1/13), Designated Cancer Center or Children's Hospital with a Planned Acute Care Hospital Inpatient Readmission (Effective 10/1/13), Federal Health Care Facility with a Planned Acute Care Hospital Inpatient Readmission (Effective 10/1/13), Critical Access Hospital (CAH) with a Planned Acute Care Hospital Inpatient Readmission (Effective 10/1/13)*
[c] *Discharged/transferred to a Skilled Nursing Facility (SNF), Intermediate Care Facility (ICF), Hospice - Medical Facility, Medicare approved Swing Bed, Inpatient Rehabilitation Facility (IRF) including Rehabilitation Distinct part unit of a hospital, Medicare certified Long Term Care Hospital (LTCH), Nursing Facility certified by Medicaid, but not certified by Medicare, Psychiatric Hospital or Psychiatric distinct part unit of a hospital, Designated Disaster Alternative Care Site (Effective 10/1/13), (for complete list see* https://www.hcup-us.ahrq.gov/db/vars/dispuniform/nisnote.jsp)
[d] *Discharged/transferred to Home under care of Organized Home Health Service Organization, Home IV Provider, Hospice-Home, Home Under Care of Organized Home Health Service Organization with a Planned Acute Care Hospital Inpatient Readmission (Effective 10/1/13)*
[e] *Left Against Medical Advice or Discontinued Care*
[f] *Expired at home, Expired in a Medical Facility, Expired - place unknown, Discharged alive, destination unknown*