Section III

Methods

The focus of the current work was to conduct a retrospective evaluation of risk factors for extubation failure within 30 days in a surgical ICU population. Specific clinical risk factors of extubation failure were identified from the literature, clinical experts, and experience, in order to establish study variables and parameters.

The institutional ACS NSQIP database was utilized to identify surgical and vascular patients, demographic, comorbidities, and specific clinical factors during the hospital operative encounter within the study time period of 30 days observation interval. Additionally, records of patients admitted to the surgical ICU postoperatively with an endotracheal tube in place were identified between July 1, 2013 and December 31, 2015.

Purpose of the Study

The aim of the study was to identify risk factors related to extubation failure in surgical postoperative patients.

Protection of Human Subjects

Prior to commencing the project, institutional review board study approval was received for expedited status: IRB-HSR Protocol # 19111: An Evaluation of Risk Factors for Extubation Failure in Surgical Patients in Intensive Care. Permission for access to data sets was sought from each database authorizing administrator. Approval for the study was obtained from the medical director of the SICU, as shown in Figure 2.

Data files were stored behind two locked doors, on an approved Information Technology server electronic firewalls, on a locked computer requiring password sign on access. Study data files were open on the computer only during active data analysis.

Definition of Measures

Measures utilized in the study are described below.

The **Glasgow Coma Scale** (GCS; Healey et al., 2003) is a score that measures a patient's motor (1-6), verbal (1-5), and eye (1-4) response to stimuli. The score is the sum of the 3 categories evaluated: motor, verbal and eye. The score measures the best response in each category with a total GCS score of 15 as normal.

The **Richmond Agitation-Sedation Scale** (RASS; Sessler et al., 2002) measures level of sedation with arousal metrics including a range of scores for anxiety or agitation from +1 to +4, one score (0) for a calm and alert state, a range of sedation scores from -1 to -5, and one score (-5) for the unarousable state. (Barr et al., 2013).

Definition of Terms

Intubation in this study is defined as the placement of an endotracheal tube to provide mechanical ventilation as needed to support the patient. Extubation is removal of the endotracheal tube. Successful extubation, also described, as successful liberation from mechanical ventilation, is the removal of the endotracheal tube immediately resulting in the ability of the patient to breathe spontaneously and effectively without any further need of mechanical ventilation. Extubation failure is the removal of the endotracheal tube with a subsequent need for replacement of the artificial airway related to the inability to sustain spontaneous breathing. Reintubation is the replacement of the endotracheal tube after a failed extubation. This study defines reintubation as any unplanned intubation following an extubation failure occurring within 30 postoperative days.

Selected established ACS NSQIP Operations Manual (2016) data base definitions and coding were used for applicable demographic, baseline and perioperative variables. The

preoperative variables included: diabetes mellitus requiring therapy with non-insulin agents or insulin, current smoker within one year, dyspnea, functional health status presurgery, ventilator dependent, chronic obstructive pulmonary disease (severe), congestive heart failure within 30 days prior to surgery, hypertension requiring medication, acute renal failure, currently on or requiring dialysis, disseminated cancer, open wound (with or without infection), steroid/immunosuppressant use for a chronic condition, > 10% loss of weight in the six months prior to surgery, and sepsis within 48 hours prior to surgery. The perioperative characteristic variables included: surgical specialty, emergency case, ASA physical status classification, wound classification, duration of surgical procedure and unplanned intubation within 30 postoperative days.

Epic Systems Corporation electronic medical record software (also cited as EPIC data) was used as the primary source for all data elements retrieved from the ACS NSQIP database. In addition EPIC data was foundational to the Clinical Data Repository (CDR), which is an institutional based data repository of clinical documentation and financial information, and the STICU Nurse Practitioner Quality Program database that was a unit based daily collection of clinical data entered by nurse practitioners. The study dataset included data from these three databases.

Study Design

A retrospective comparative study of non-trauma surgical patients who were admitted postoperatively to the SICU with an endotracheal tube in place requiring invasive mechanical ventilation was conducted. Exclusion criteria included SICU trauma and transplant patients, patients younger than 18 years of age, patients not eligible for reintubation that have elected to receive only comfort care and those who expired prior to extubation.

Description of the Sample

The electronic medical records contained in the institutional ACS NSQIP database of general surgical and surgical specialty patients admitted postoperatively to the SICU between July 1, 2013 and December 31, 2015 meeting the prior stated study criteria with an endotracheal tube in place were eligible for entry into the study. Total sample size was 93. Subsets of this sample include demographics, and comorbidities. The total sample contains 59 males and 34 females. Race in this sample was: Whites were 75, Black or African-American were 12. Asian were 1; Unknown were 5. Age in this sample was: < 50 years, 19, >50 years, 74. In Table A2 each candidate descriptor is further itemized into specific demographics and comorbidities, with the following headings: Variable, Total Sample for each variable, Counts, Percentages for Failed and Successful extubations.

Setting

This study was conducted at a university affiliated medical center. This institutional setting has a greater than 600 bed capacity and serves a wide catchment area in the southeastern United States. The SICU is a fifteen-bed unit in which the study population of general surgery and surgical specialty ICU patients reside postoperatively when requiring critical care services. The unit interprofessional team includes: critical care intensivists, resident physicians, pharmacists, acute care nurse practitioners, nurses, respiratory therapists, physical therapists, occupational therapists, surgical nutritionalists, chaplains and social workers.

Procedure

A dataset was created using the ACS NSQIP framework, with study variables identified from a review of literature, national guidelines, and SICU expert consultation to evaluate the primary outcome of extubation failure. Dataset elements included demographic, comorbidities,

perioperative characteristics and surgical ICU clinical factors.

In addition to the ACS NSQIP dataset, postoperative SICU clinical variables retrieved from the CDR during the 24 hours prior to the first ICU extubation for study inclusion were: GCS lowest total score, RASS lowest score, respiratory rate highest, oxygen saturation lowest (SpO_2), temperature maximum, heart rate maximum, blood pressure lowest systolic, blood pressure lowest mean, daily weight in kilograms. The daily weight timeframe was expanded outside the original timeframe to the time the weight was recorded closest to the 24 hours prior to extubation to obtain a more complete data set. Laboratory data reported closest to the extubation time were: pre-extubation ABG (arterial blood gas), white blood cell count, serum sodium, hematocrit, and platelets. Initial Nutrition Support Consult, and Physical Therapy Evaluation, dates were also entered in the database.

The ACS NSQIP database from January 1, 2011 to December 31, 2015 contained 10,825 records of surgical procedure patients. The CDR utilizing the prior stated ACS NSQIP database identified 1396 records for patients admitted to SICU and extracted requested study data. The SICU NP Quality Improvement database containing 1413 records of SICU patients who received mechanical ventilation during the ICU stay was linked to the ACS NSQIP database. Records were excluded when the hospital encounter dates did not match with the initial surgical procedure encounter times. Records were removed when ICU extubation date and time were not identified during the specified encounter time leaving 150 patient records. A hand search was undertaken to identify accuracy in 10% of the cases. Additionally an attempt was made to locate missing data entries. Documentation found in the EPIC record, was manually entered into the study database. After the removal of missing data records 93 records qualified for statistical analysis.

Variables selected for the analysis included: age at time of surgery, highest respiratory rate within 24 hours pre-extubation, preoperative body mass index (BMI), heart rate maximum within 24 hours pre-extubation, temperature maximum within 24 hours pre-extubation, oxygen saturation (SpO_2) lowest within 24 hours pre-extubation, pO_2 lowest within 24 hours pre-extubation, preoperative weight compared to any pre-extubation weight change, sex, and race. Categorical variables were examined using Chi square analysis. Continuous variables were examined using the non-parametric Mann Whitney U test.

After reviewing the literature and discussion with clinical experts ten variables were included in the model for logistic regression: age, gender, race, BMI, spO_2, respiratory rate, heart rate, temperature, pO_2, and weight change.

IBM SPSS Statistics 24 software was used for statistical analysis.

Results

Logistical regression analysis demonstrated a statistically significant relationship between respiratory rate and extubation failure. Respiratory analysis revealed an odds ratio of 1.086, (p = 0.034, CI = 1.006 – 1.172) with a 95% Confidence Interval. Respiratory rate was the only variable in the analysis that reached statistical significance. Statistical analyses revealed that the risk of extubation failure increased by 8.6% for each breath per minute. See logistic regression data in Table A4. A visual inspection of the logistic regression graph reveals a sharp increase in probability of failure for rates > 26 breaths per minute. Refer to Figure A1.

The records of 93 patients were analyzed and grouped by those who were successfully extubated (SE), 70 patients, and those who failed extubation (FE), 23 patients. The descriptive demographics SEs were compared to those in FEs. Of interest are the FE data points noted in the next paragraph.

In the FE group, 73.9% were male, 87% were Caucasian/white. The majority of patients were 50-80 years old. With respect to functional status 78.3% were independent and 21.7% dependent; 13.0% had moderate exertion dyspnea. Preoperative assessment of FE patients with severe COPD was 17.4%. For FE patients with an open wound there were 17.4%. Baseline characteristics were similar for patients who were successfully extubated compared to those who failed extubation with the exception of age and sepsis, see Table A2

Characteristics of the sample were compared (SE to FE). The FE sample surgical specialties were: 87% general surgery, 4.3% gynecology, and 8.7% vascular. ASA classifications reveal the severity of illness with ASA 3 (severe disturbance) and ASA 4 (life threatening) was 88.6 % in the SE group and 78.2 % in the FE group. Further details of the sample are presented in Table A3.

Limitations of the Design

Personal communications with SICU clinical experts in preparing patients for successful extubation in postoperative ICU patients suggested the following list of factors for consideration: fluid status, cough strength, respiratory secretion clearance, and rate. Clinical experts also reported the following additional considerations prior to extubation: (1) improvement in the patient's current health status, (2) degree of difficulty in the reintubation process, (3) if extubation failure occurred would the patient require a tracheostomy and, (4) has the patient requested not to be reintubated. The preceding additional recommendations by the ICU experts may be significant clinical factors for consideration prior to extubation however the data elements were beyond the data retrieval limits of the present study.

Three major limitations of the study are: (1) the retrospective study design was dependent on the quality of the documentation entered in EPIC, (2) data in potentially relevant records was

incomplete, (3) difficulties with data retrieval reduced the sample size and limited analytic options.

Retrospective electronic clinical data entries in EPIC were located in multiple systems, hindering the ability to electronically locate relevant data. Missing expected EPIC data entries resulted in the deletion of incomplete records.

Ability to electronically retrieve identified variables was limited. Consultation with in house EPIC staff was the first method explored to obtain a comprehensive report of clinical factors impacting extubation in surgical ICU patients. Multiple EPIC staff communications provided assistance in identifying specific methods of locating data within the patient record, however the request for an electronic report containing the stated desired variables necessitated a time delay of months.

The search for alternative methods to obtain an electronic report of retrospective record data was pursued. Respiratory Therapy services were consulted to obtain a listing of study population extubation data. The Respiratory Therapy extubation database-which pertained to unplanned extubations in SICU was reviewed, but did not satisfy the electronic data requirements regarding extubations for this study.

CDR staff were amenable to the study request for securing the data and providing an electronic report. A CDR analyst was provided with ACS NSQIP data between January 1, 2011 and December 31, 2015. The study request for clinical data retrieval from patient records was at a clinical depth necessitating education of the CDR analyst so that the analyst could understand the requested clinical data and locate the requisite data in the hospital record. The difficulties in finding the data in the CDR led to the reduction of clinical factors included in the study.

The EPIC system was in the initial transition implementation phase during 2011 limiting data retrieval efforts. The required first extubation date and time in critical care was identified in the SICU NP database that was initiated in July 2013, resulting in limiting the data available for this study from July 1, 2013 to December 31, 2015.

The desired statistical power of the study was not achieved relative to a final sample of 93 records. Data analysis options were also limited relative to the sample size necessitating a restrictive model.

Strengths of the Design

The strengths of the study design are: (1) the ACS NSQIP foundational framework that provided the demographic, operative, and unplanned intubation within 30 postoperative days and (2) the real time data set which provided accurate extubation date and time.

SICU nurse practitioners granted access to their database to obtain the extubation date and time. SICU nurse practitioners recorded the postoperative extubation time and date in near real time (daily except on weekends) in their database from EPIC. The securing of a reliable extubation date allowed creation of a data set that provided the link necessary for additional clinical factor data to be obtained from the CDR. The surgical quality and research expert and project mentor linked SICU NP data records with extubation dates and times with ACS NSQIP records. The joining of the prior databases identified patient records with the needed extubation data thus allowing CDR data retrieval of study specific data elements.

Futhermore, statistical consultation was provided for logistic regression analysis measures. Logistic regression was employed in order to explore the relationship between the reintubation outcomes as a function of candidate risk factors.

Discussion

The respiratory rate during the 24 hours prior to extubation was found to be a statistically significant risk factor in preparing for SE in postoperative surgical ICU patients. This finding identifies a risk factor readily available for clinicians to evaluate and add to the decision process in preparing patients for a SE. Prior to this study the significance of an elevated respiratory rate during the 24 hours preextubation was an underappreciated risk factor in the decision to extubate. The findings add supportive data to the value of the astute monitoring of respiratory rate in the 24 hours prior to extubation by bedside clinicians.

Yet the retrospective sample size limited the power of the study and limits generalizability. Further development of institutional systems for expedient retrieval of clinical data are necessary to attain larger population specific samples. The study framework created a process on which future clinical studies could be conducted utilizing electronic data retrieval systems to identify surgical patients with risk factors for extubation failure in the 24 hours prior to extubation in the ICU. The resulting data analysis could drive improvement in the extubation practice relevant to SE in surgical ICU patients.

In summary, the study data identified respiration rate as a salient risk factor related to extubation failure in this population of postoperative non-trauma surgical ICU patients. Based on this finding, respiratory rate is a factor that should be seriously considered by clinicians in the extubation process. This revelation can be used to guide clinicians as they consider extubations and further studies of more power.