
Systematic Review

Identification and Prevention of Extubation Failure in Adults using an Automated Continuous Monitoring Alert vs Standard Care: A Randomized Controlled Trial

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TITLE PAGE

Title: Identification and Prevention of Extubation Failure in Adults using an Automated Continuous Monitoring Alert vs Standard Care: A Randomized Controlled Trial

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ABSTRACT (300 words)

Background: Post extubation monitoring helps identify patients at risk of developing respiratory failure. This study aimed to evaluate the effect of our standard respiratory therapist (RT) assessment tool versus an automated continuous monitoring alert to initiate RT driven care on the reintubation rate.

Methods: This was a single-center randomized clinical trial of adult subjects who received mechanical ventilation for more than 24 hours and underwent planned extubation in the intensive care unit (ICU) from March 2020 to September 2021. Subjects were assigned to standard RT assessment tool or an automated monitoring alert to identify the need for RT driven care. Primary outcome was need for reintubation due to respiratory failure within 72 hours. Secondary outcomes included reintubation within 7 days, ICU and hospital length of stay (LOS), hospital mortality, ICU cost and RT time associated with patient assessment and therapy provision.

Results: Of 234 randomized subjects, 32 were excluded from the primary analysis due to disruption in RT driven care during the COVID-19 patient surge and 1 due to delay in Integrated Pulmonary Index (IPI) monitoring initiation. Analysis of the primary outcome included 85 subjects assigned to the standard RT assessment group and 116 assigned to the automated monitoring alert group to initiate RT driven care. There was no significant difference between the study groups in reintubation rate, median LOS, mortality, or ICU costs. RT time associated with patient assessment ($p<0.001$) and therapy provided ($p=0.031$) were significantly lower in the automated continuous monitoring alert group.

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Conclusions: In patients receiving mechanical ventilation for more than 24 hours, there were no significant outcome or cost differences between our standard RT assessment tool or an automated monitoring alert to initiate RT driven care. Using an automated continuous monitoring alert to initiate RT driven care saved RT time.

Trial Registration: clinicaltrials.gov Identifier: NCT04231890

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INTRODUCTION

Liberation from mechanical ventilation results in extubation failure in about 10-20% of the patients and extubation failure has been associated with poor clinical outcomes, increased length of hospital stay, morbidity and mortality.^{1, 2} Before extubation, patients undergo a spontaneous breathing trial (SBT) to assess the patient's readiness to breathe with minimal ventilatory support.³ During this breathing trial, patients are routinely monitored and evaluated for signs of respiratory distress. The patient's respiratory frequency, tidal volume, and signs of distress are used to quantify the respiratory status during the SBT and determine the SBT outcome.^{4,5,6} Once extubated, the use of preventive strategies such as non-invasive ventilation is recommended to prevent reintubation but the rate of extubation failure has remained almost the same over the last 15-20 years.⁷ Clinical studies have also demonstrated an independent association between extubation failure and mortality in critically ill patients.^{8,9}

A delay in reintubation and reinstating ventilatory support due to an inability to identify high-risk patients has been shown to be associated with increased mortality.¹ Similar to assessing weaning readiness using SBT, there is no clinically standardized method or early warning index/score that can be utilized to evaluate a patient's ability to sustain spontaneous breathing after extubation. Currently, post extubation management is mainly based upon the clinician's individual assessment. However, literature shows that the accuracy and reliability of clinicians' decisions to determine extubation outcomes is very low due to clinicians' subjectivity in interpreting variables with certain biases.¹⁰⁻¹¹ Furthermore, providing clinical interventions to all patients after extubation may not yield desirable outcomes and may waste resources.

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Continuous respiratory monitoring enables bedside clinicians to detect early signs of respiratory distress so that appropriate clinical therapies can be applied to correct the cause of the deterioration.^{12,13} However, clinicians cannot continuously observe cardiopulmonary monitors, and automated alerts of multiple physiologically monitored variables offers a potential solution to alert clinicians when these variables indicate that the patient's respiratory status is deteriorating. One example of an index that includes various physiologic variables and can be automated to send alerts is Integrated Pulmonary Index (IPI).¹⁴⁻¹⁶ It is an algorithm based, integrated clinical monitoring index that uses fuzzy logic model to combine four vital physiological parameters [end-tidal carbon dioxide (PetCO₂), respiration frequency, heart rate, and oxygen saturation (SpO₂)] to provide an assessment of a patient's overall respiratory status. IPI is displayed as a single indexed value from one to ten.¹⁴ While a declining IPI trend after planned extubation has been identified as a predictor of extubation failure,¹⁵⁻¹⁶ there are no published studies that have evaluated the use of an automated index such as IPI being sent to a clinician to alert them of the respiratory status of a deteriorating patient. The primary aim of this study was to evaluate the effect of an automated continuous monitoring alert compared to standard respiratory therapist (RT) driven assessment tool to initiate RT driven assess and treat protocols, on the reintubation rate due to respiratory failure within 72hours after planned extubation. Secondary outcomes included reintubation within 7 days, intensive care unit (ICU) and hospital length of stay, hospital mortality, ICU cost and RT time associated with patient assessment and therapy provision.

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EXPERIMENTAL DESIGN AND METHODS

This randomized controlled clinical trial (ClinicalTrials.gov: NCT04231890) was conducted at a large, urban academic medical center from March 2020 to September 2021. Adult subjects (18 years and older) who received mechanical ventilation via an endotracheal tube for more than 24 hours and underwent planned extubation based on the medical team approval were included. Any subjects who were pregnant, underwent accidental or terminal extubation, had a tracheostomy tube or do-not-intubate orders, were receiving extracorporeal membrane oxygenation at the time of extubation were excluded. Enrolled subjects that required reintubation were not reenrolled in the study. After achieving the targeted number of subjects in both arms of the study, 32 subjects in the standard of care arm were excluded due to not receiving the RT assessment or RT driven care, because of a disruption in healthcare delivery provided by RTs due to SARS CoV-2 (COVID-19) pandemic creating a surge of patients and staffing crisis during this study period. Therefore, additional 60 subjects were enrolled and randomized to both arms from July 2021 to September 2021 to account for this disruption in care delivered during the peak of the pandemic. The study protocol and amendment were approved by the institutional review board (19080402-IRB01), and a waiver of informed consent was granted.

Randomization

Upon medical approval for planned extubation, subjects were randomized to a standard RT assessment tool¹⁷ or an automated monitoring alert to identify the need for RT driven assess and treat protocols. Computer-generated random numbers were used for the randomization of

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subjects. To protect the assignment sequence until allocation, the sequential numbers were stored in opaque envelopes and were opened in the correct order (allocation concealment).

Experimental Group

Subjects randomized to the automated monitoring alert group were placed on IPI monitoring after extubation. Bedside RTs extubated and connected the subject to EtCO₂ cannula (Medtronic, Minneapolis, MN) and turned IPI monitoring on the cardiopulmonary monitor (Phillips Healthcare, Cambridge, MA). Once activated, the monitor automatically sent IPI information to the subject's electronic medical record (EMR). In a clinical validation study, an IPI ≤ 4 is associated with requiring immediate clinical attention.¹⁴ However, declining IPI values after planned extubation is shown to be a better predictor of extubation failure.¹⁵ Therefore, through the EMR, the hospital pager system was set to automatically alert the study RT for a decrease in IPI by 1 within 1 hour of extubation or IPI ≤ 4 . IPI values were recorded immediately after extubation, 30 minutes and 1 hour after extubation in the IPI flowsheet. The RT assigned to the unit assessed any subject with a true decrease (without any EtCO₂ nasal cannula malfunction or mouth breathing) in IPI by 1 or IPI ≤ 4 after 1 hour of extubation using the Respiratory Assessment and Allocation of Therapy (RAAT) scoring tool and associated assess and treat protocols. The RAAT scoring tool and associated assess and treat protocols have been described in a recent publication.¹⁷ If tolerated, IPI monitoring was continued for up to 72 hours after extubation or until ICU discharge. Subjects who required reintubation were reintubated based on the medical team's clinical decision.

Control Group

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Subjects randomized to the control group received an RT assessment using the RAAT score tool to determine the need to initiate RT driven assessment and treatment protocols. Subjects were assessed within 2 hours after extubation. All subjects were monitored for 72 hours per protocol. Subjects who required reintubation were reintubated based on the medical team's clinical decision.

Measures

Study data were collected and managed using REDCap electronic data capture tools hosted at Rush University Medical Center.¹⁸ Data collection included demographic characteristics (age, gender, race and ethnicity), indication for mechanical ventilation such as hypoxic or hypercapnic respiratory failure, airway protection, cardiac arrest or elective for procedure, diagnosis at admission including acute respiratory failure, neurologic, cardiologic, gastrointestinal, cancer, sepsis, renal, hepatic and others were recorded. Length of mechanical ventilation, rapid shallow breathing index at the end of SBT and the presence or absence of high-risk factors such as: age > 65 years, APACHE II > 12 on extubation day, body mass index > 30, inadequate secretion management (weak cough effort, every one hour suctioning on day of extubation), difficult or prolonged weaning (failure of more than 3 SBT), heart failure as the primary indication for mechanical ventilation, diagnosis of chronic obstructive pulmonary disease, prolonged mechanical ventilation (>7 days on the ventilator), more than two comorbidities, arterial partial pressure of carbon dioxide (PaCO₂) >45mmHg before extubation and Glasgow coma scale (GCS <8) were collected. Vital signs including heart rate (HR), respiratory frequency (*f*), pulse oximeter oxygen saturation (SpO₂), end-tidal carbon dioxide (PetCO₂), fraction of inspired oxygen (FiO₂), and IPI were recorded at 5 minutes, 30 mins and 1

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hour after extubation. IPI, type of respiratory therapy applied, the time between extubation and application of clinical intervention, reintubation within 72 hours and 7 days, time from extubation to reintubation, and causes for reintubation were recorded post-extubation.

Subjects were followed until discharge from the hospital. Length of ICU and hospital stay as well as hospital mortality were collected. RT time associated with respiratory assessments and therapy provided based on documentation was collected. RT time associated with each therapy was obtained from the departmental time standards which allocate fixed time for each therapy based on the American Association of Respiratory Care Uniform Reporting Manual (<https://www.aarc.org/resources/tools-software/standards-development/>, Accessed December 2, 2021). Financial data were obtained from the hospital cost accounting system. ICU direct cost included all expenses posted to the ICU cost centers directly related to patient care, such as supplies, medications, procedures and equipment. ICU total cost included expenses directly related to ICU care plus hospital overhead expenses allocated to the ICU care.

Study Outcome

The primary outcome was reintubation, defined as requiring reintubation and returning to mechanical ventilation due to respiratory failure within 72 hours after the initial ventilator discontinuation. Subjects reintubated due to a procedure and subsequently extubated were not classified as reintubated. Respiratory failure requiring reintubation was defined as the presence of respiratory or cardiac arrest, hypoxic respiratory failure ($SpO_2 < 90\%$ or $PaO_2 < 60\text{mmHg}$ on FiO_2 greater than 40%), hypercapnic respiratory failure ($pH < 7.35$ with $PaCO_2 > 45\text{mmHg}$), clinical signs of respiratory muscle fatigue (f greater than 35/min, use of accessory muscles, paradoxical breathing, and diaphoresis), decreased mental status and inability to clear respiratory

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secretions.¹⁶ The secondary outcomes included reintubation at 7 days, ICU and hospital length of stay (days), ICU mortality, RT time, and total ICU cost.

Statistical Analysis

Past clinical trials have a reported reintubation rate of 10-20% in patients who are intubated for more than 12 hours.^{13,15,16} In this study, to achieve a clinically significant relative reduction of 70% (absolute reduction 14%) in reintubation rate among the automated continuous monitoring alert group at $\alpha=0.05$, power= 0.80, 87 subjects in each group or 174 total subjects were needed. Before analysis, data were examined for missing data, outliers, and normality. Continuous variables are presented as means (SD) if normally distributed or as medians (interquartile ranges [IQR]). Comparison of continuous variables between the two groups was conducted using Student's independent samples t-test for variables with a normal distribution and the Mann-Whitney U test for variables with a non-normal distribution. Categorical variables are presented as proportions and were analyzed with chi-square tests. All reported P values are two-sided, and a p-value < 0.05 was considered significant. Statistical analysis was performed using SPSS 26.0 for Windows (SPSS, Inc., Chicago, IL, USA).

RESULTS

A total of 830 subjects were assessed for study eligibility; of these, 234 underwent randomization and 32 were excluded from the primary analysis due to disruption in RT-driven care during the COVID-19 patient surge and 1 subject was excluded due to delay in IPI monitoring initiation. In the per-protocol analysis of the primary outcome, 85 subjects assigned to the standard RT assessment tool group and 116 subjects assigned to the automated

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monitoring alert group to initiated RT-driven care were included (**Figure 1**). Demographic and clinical characteristics were similar in both groups (**Table 1**).

Primary and Secondary Outcomes

There were no significant differences between the groups in the reintubation rate at 72 hours (16.5% vs 9.5%; absolute difference 6.99 (95% CI -2.3 to 16.3)) or at 7 days (20% vs 14.7%; absolute difference 5.3 (-5.2 to 15.9), **Table 2**). Median time to reintubation was similar with 31 hrs (IQR 11.5-59.9) in the assessment tool initiated group and 28 hours (IQR, 16.1-96.8) in the automated monitoring alert initiated group. In the assessment tool initiated group, 8 (9.4%) patients received tracheostomy compared to 4 (3.4%) in the automated monitoring alert initiated group ($p=0.078$). There was no significant difference in the ICU and hospital lengths of stay between the two groups. Similarly, hospital mortality was not significantly different (12.9% vs 9.5%; $p=0.44$). ICU cost between the two groups were not significantly different either.

After extubation, there was no significant difference in the number of patients who received prophylactic noninvasive ventilation, high flow nasal therapy, airway clearance, and lung expansion therapies in the two study groups. RTs spent significantly longer time (minutes) performing patient assessments (mean 32.7 (SD 15.2) vs 14.2 (SD 17.5); $p<0.001$) and administering therapy (mean 39.8 (SD 84) vs 17.5 (SD 49.8); $p=0.031$) in the RT assessment initiated group compared to the automated monitoring alert initiated group. In the IPI group, each subject received IPI monitoring for median 9.6 (IQR 2.12-23.42) hours.

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RT-Driven Care Versus Non-RT driven Care Post Extubation Respiratory Care Management

In an ad hoc analysis, comparing those who received RT driven care versus those who did not in the standard care group, there was no significant difference in the age, gender, or BMI. Although, the RT assessment initiated group's reintubation rate at 72 hours (16.5% vs 34.4%; $p=0.035$) and 7 days (20% vs 40.6%; $p=0.023$) was significantly lower for subjects who received RT-driven care compared to those who did not (**Table 3**). ICU and hospital length of stay were also significantly shorter for patients who received RT-driven care ($p=0.011$). Additionally, the median direct ICU cost (\$26,522 (IQR 13,348-40,512) vs \$13,608 (7,068-26,017); $p=0.007$) and total ICU cost (\$45,417 (20,820- 62,739) vs 17, 525 (8,051- 33, 853); $p<0.001$) were significantly higher for the subjects that did not receive RT driven care compared to those that did.

DISCUSSION

In this single-center, randomized controlled trial involving adult ICU subjects undergoing planned extubation, the use of post extubation automated monitoring alert to initiate RT-driven care compared with our standard assessment tool initiated RT-driven care did not significantly impact reintubation rates due to respiratory failure. Using an automated monitoring alert to initiate respiratory care significantly reduced RT time, allowing RTs to focus care on patients likely to develop respiratory failure. This finding is important since an automated alert to identify when subjects need RT driven care saves RT time and resources without worsening patient outcomes. Data provided in Table 3 quantifies the impact on subject outcomes when a pandemic disrupts RT driven care. This RT driven care group had lower

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intubation rates, shorter length of stay, and lower ICU costs compared to those that did not receive RT driven care. Since these outcomes are significantly different, intention-to-treat analysis was not done and would bias the study.

This is the first randomized controlled clinical trial assessing the role of an automated monitoring alert in post-extubation subjects. The continuous monitoring score automated to page RTs in this study was IPI. Among patients receiving respiratory support, IPI is shown to have a significant correlation with individual SpO_2 and f values, as well as a correlation between IPI monitored values (SpO_2 and $EtCO_2$) and arterial blood gas measurements (SaO_2 and $PaCO_2$).¹⁹ A recent randomized controlled trial in post-operative patients assessed the utility of IPI monitoring in detecting adverse respiratory events compared to the standard care and found that IPI monitoring led to increased interventions to improve patient's respiratory status leading to a significant reduction of adverse respiratory events per patient, but it did not reduce the number of patients experiencing adverse respiratory events.²⁰ This study utilized the IPI value of 1 as a threshold for nurses to assess and intervene. Previous studies demonstrated that the IPI trend, instead of an individual IPI value, is predictive of extubation failure.^{15,16} Therefore, in this study, we used IPI declining by 1 within an hour as a trigger for respiratory assessment and RT intervention.

Post extubation respiratory deterioration necessitating reinstitution of ventilatory support is an independent risk factor for mortality.⁶ Thus, early identification of patients at risk of developing post extubation failure is of clinical importance. The most common cause of post extubation failure is development of acute respiratory failure due to respiratory muscle fatigue, inability to clear secretions and neurologic dysfunction.²¹⁻²⁶ Standard clinical monitoring

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utilizing vital signs such as, HR, f , and SpO_2 is the usual clinical strategy to identify patients that are experiencing signs of acute respiratory failure such as, tachypnea, tachycardia, and desaturation. Past studies demonstrate that patients often show signs of respiratory compromise hours before reaching a critical level of requiring higher levels of support.²⁷⁻²⁹ In a prospective before and after study, Subbe et al examined the effect of electronic automated advisory vital signs monitoring system on clinical outcome among ward patients and reported a decrease in cardiac arrests, overall mortality, and illness severity among those admitted to the ICU.³⁰ However, of all the vital signs, respiratory frequency is often neglected, under-recorded, and undervalued by bedside clinicians leading to delay in providing appropriate respiratory interventions.³¹ In this study, we demonstrated that timely recognition of at-risk patients using a concise, multiparameter physiological index tool such as IPI is comparable to our RT assessment tool and standard clinician monitoring. The use of such tools has the potential to improve the extubation outcome in a complex healthcare environment.

Early and timely application of clinical interventions such as non-invasive ventilation and high flow oxygen therapy among high-risk patients has been shown to reduce the need for reintubation.^{21,24, 32-33} However, most of these published studies have utilized the presence of at least one pre-extubation high-risk factor to identify this population. In a non-research setting, allocating therapies based on a single high-risk factor may lead to overutilization of resources for patients with no clinical indication for such interventions, resulting in increased patient non-compliance, dissatisfaction, and misuse of hospital resources.^{34,35} In this study, we demonstrated that physiologic automated monitoring alerts to initiate RT driven care could

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provide services to those in need and may reduce the unnecessary application of clinical interventions to those who are not at risk of extubation failure.

A recent pragmatic, randomized controlled trial evaluated the effect of post extubation, protocolized approach (a RT-driven protocol to administer non-invasive ventilation to patients with suspected hypercapnia and high flow nasal cannula to patients without suspected hypercapnia) versus clinician directed post extubation management on the reintubation rate within the 96 hours of extubation.³⁶ In this study, patients in the protocol group received a median of 16 hours of post extubation support as compared to 0 hours in the standard care group. Despite receiving longer post extubation support, reintubation rate in the protocol group was 15.9% as compared to 13.3% in the standard group. This clinical practice led to an over-utilization of resources without improving patient outcomes. Utilizing assessment scoring tools such as the RAAT score to allocate respiratory interventions post extubation are beneficial since therapy resulting in lower scores was associated with avoiding intubation.¹⁷ Our study demonstrated that utilizing automated monitoring alert to initiate RT driven clinical management after extubation was effective in reducing respiratory therapists time performing assessments and treatments with equivalent outcomes compared to our standard assessment initiated RT driven care.

This study has several limitations. First, part of this study was conducted during the peak surge of COVID-19 pandemic which affected the routine standard care administered to patients in this group. After the crisis improved an equal number of additional patients were randomized to both arms to account for the patients who did not receive our standard RT driven care. Next, this was a single-center study that may have different practices regarding

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weaning/extubation and reintubation compared to other institutes. For this study, similar protocols or guidelines were used for mechanical ventilation, SBT, and extubation in all the ICU's. Also, the RTs could not be blinded to the study groups, which may have led subjects in the automated monitoring alert group to receive greater clinical attention. Furthermore, we experienced IPI alarm artifacts due to the malpositioning of EtCO₂ nasal cannula and mouth breathing requiring clinicians to distinguish actual IPI decline from the false ones and instruct patients to wear the nasal cannula correctly and try to breathe through their nose. Lastly, since the difference in reintubation rate between the two groups was lower than what was used in the estimated sample size, the trial was under powered to detect a reintubation rate difference.

CONCLUSION

In patients receiving mechanical ventilation for more than 24 hours, there were no significant outcome or cost differences between our standard RT assessment tool or an automated monitoring alert to initiate RT driven care. Using an automated continuous monitoring alert to initiate RT assess and treat protocols reduces RT time providing care. Larger randomized controlled trials are needed to determine the benefits in clinical outcomes and cost of an automated continuous monitoring alert initiated RT driven care compared to standard of care in different patient populations.

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Extubation Failure Management using Automated Monitoring System

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Quick Look

Current Knowledge

Extubation failure remains a significant factor leading to increased mortality and morbidity among adult patients. Close clinical monitoring after planned extubation can provide early identification of patients potentially developing post extubation respiratory failure.

What This Paper Contributes to Our Knowledge

This randomized controlled trial compared an automated continuous monitoring alert with an RT assessment tool to initiate RT assess and treat protocols post extubation among adult patients receiving mechanical ventilation for more than 24 hours. The study findings showed no significant extubation outcome or cost differences between the standard RT assessment tool or an automated monitoring alert to initiate RT driven care. However, using an automated continuous monitoring alert to initiate RT assess and treat protocols reduced the RT time spent providing patient care.

Figure 1 Study Flow Diagram

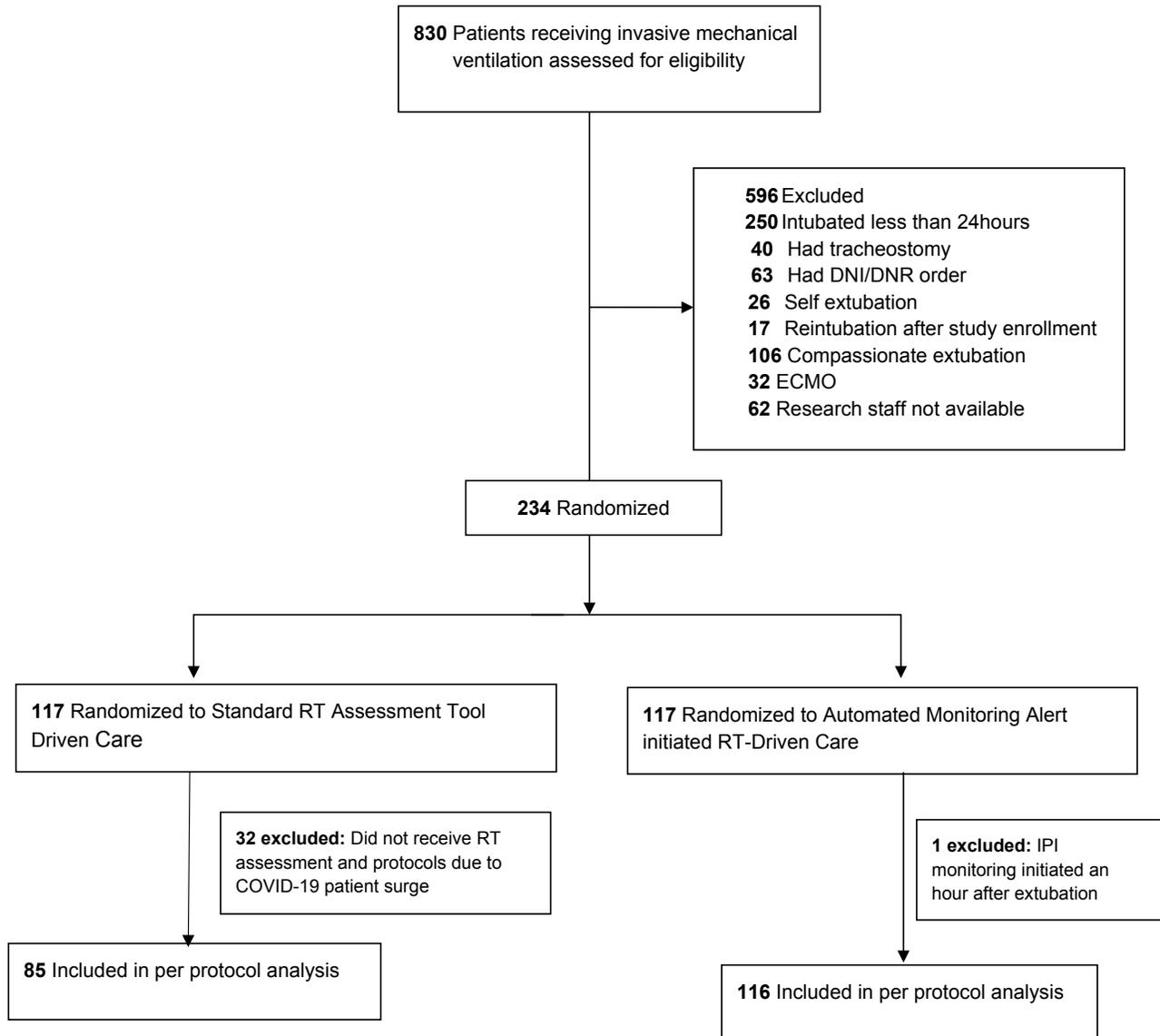


Table 1 Subject Baseline Characteristics

| | Standard RT Assessment Tool Driven Care (n=85) | Automated Monitoring Alert initiated RT-Driven Care (n=116) | p value |
|--|---|--|----------------|
| Age, median (IQR), year | 62 (52-71) | 58.5 (46.2-67) | 0.20 |
| Men, n (%) | 50 (58.8) | 66 (56.9) | 0.79 |
| BMI, median (IQR) | 29.39 (23.97-34.89) | 29.2 (25.45-36.45) | 0.38 |
| Race, n (%) | | | 0.15 |
| White | 33 (38.8) | 35 (30.2) | |
| African American | 23 (27.1) | 46 (39.7) | |
| Hispanic or Latino | 16 (18.8) | 24 (20.7) | |
| Asian | 5 (5.9) | 2 (1.7) | |
| Other | 8 (9.4) | 9 (7.7) | |
| Diagnosis at admission^a, n (%) | | | |
| Acute Respiratory failure | 26 (30.6) | 37 (31.9) | 0.84 |
| Respiratory failure due to COVID-19 | 17 (20) | 23 (19.8) | 0.98 |
| Neurologic | 23 (27.1) | 31 (26.7) | 0.96 |
| Cardiologic | 14 (16.5) | 12 (10.3) | 0.20 |
| Gastrointestinal | 8 (9.4) | 9 (7.8) | 0.68 |
| Cancer | 4 (4.7) | 8 (6.9) | 0.52 |
| Sepsis | 4 (4.7) | 8 (6.9) | 0.52 |
| Renal | 3 (3.5) | 1 (0.9) | 0.31 |
| Hepatic | 1 (1.2) | 8 (6.9) | 0.08 |
| Other | 5 (5.9) | 4 (3.4) | 0.50 |
| Initial Indication for MV, n (%) | | | 0.55 |

| | | | |
|--|-------------------|---------------------|------|
| Hypoxic Respiratory Failure | 29 (34.1) | 44 (37.9) | |
| Hypercapnic Respiratory Failure | 5 (5.9) | 11 (9.5) | |
| Elective | 35 (41.2) | 35 (30.2) | |
| Airway Protection | 14 (16.5) | 23 (19.8) | |
| Cardiac Arrest | 2 (2.4) | 3 (2.6) | |
| Duration of MV, median (IQR), hrs | 62.5 (31.4-143.9) | 69.04 (39.27-120.3) | 0.79 |
| RSBI at end SBT, median (IQR) | 51 (31.75-68.5) | 45 (29.75-59.25) | 0.27 |
| APACHE II on extubation day, median (IQR) | 11 (7.5-14.5) | 12 (8-15) | 0.31 |
| Number of high-risk factors, median (IQR) | 2 (1-3) | 2 (1-3) | 0.58 |
| At least 3 high risk factors present, n (%) | 37 (43.5) | 47 (40.5) | 0.67 |

Abbreviations: IQR, interquartile range; BMI, Body Mass Index; RSBI, rapid shallow breathing index; MV, mechanical ventilation; SBT, spontaneous breathing trial; APACHE II, Acute Physiology and Chronic Health Evaluation II;

* Patients can have more than 1 diagnosis

Table 2 Primary and Secondary Outcomes

| | Standard RT Assessment Tool Driven Care (n=85) | Automated Monitoring Alert initiated RT-Driven Care (n=116) | Absolute Difference Between Groups (95% CI) | p value |
|---|---|--|--|--------------------|
| Primary Outcome | | | | |
| Reintubation due to respiratory failure within 72hours post extubation, n (%) | 14 (16.5) | 11 (9.5) | 6.99 (-2.7 to 16.6) | 0.14 |
| Secondary Outcome | | | | |
| Reintubation due to respiratory failure within 7 days post extubation, n (%) | 17 (20) | 17 (14.7) | 5.3 (-5.5 to 16.1) | 0.32 |
| ICU length of stay, median (IQR), d | 8.08 (4.07-16.33) | 8.02 (4.54-15.89) | | 0.83 |
| Hospital length of stay, median (IQR), d | 15.85 (11.51-25.79) | 17.87 (12.23-30.32) | | 0.28 |
| Tracheostomy received, n (%) | 8 (9.4) | 4 (3.4) | 6 (-1.2 to 13.1) | 0.078 |
| Time to reintubation, median (IQR), h | 31 (11.5-59.5) | 28 (16.1-96.8) | | 0.56 |
| Hospital mortality, n (%) | 11 (12.9) | 11 (9.5) | 3.5 (-5.4 to 12.3) | 0.44 |
| ICU cost, median (IQR), \$ | | | | |
| Direct cost | 13608 (7068-26018) | 12471 (7160-26652) | | 0.78 |
| Total cost | 17525 (8051- | 16713 (8463-38896) | | 0.74 |

| | | | | |
|--|------------------|------------------|--|--------|
| | 33853) | | | |
| Total cost/day | 2537 (1157-2705) | 2559 (1145-2794) | | 0.42 |
| Post Extubation Respiratory Interventions | | | | |
| Prophylactic NIV, n (%) | 12 (14.1) | 11 (9.5) | | 0.31 |
| High Flow High Humidity Nasal Cannula, n (%) | 17 (20) | 18 (15.5) | | 0.41 |
| Airway Clearance therapies, n (%) | 10 (11.8) | 6 (5.2) | | 0.09 |
| Lung Expansion therapies, n (%) | 7 (8.2) | 4 (3.4) | | 0.14 |
| RT time associated with post extubation patient assessment (mins), mean (SD) | 32.7 (15.2) | 14.2 (17.5) | | <0.001 |
| RT time associated with therapy provided post extubation (mins), mean (SD) | 39.8 (84) | 17.5 (49.8) | | 0.031 |

Abbreviations: CI, confidence interval; ICU, intensive care unit; IQR, interquartile range; NIV, non invasive ventilation, SD, standard deviation

Table 3 RT Driven versus Non-RT driven post extubation management

| | Non-RT driven clinical management (n=32) | RT driven clinical management (n=85) | p value |
|---|---|---|----------------|
| APACHE II on extubation day, median (IQR) | 10 (9-15.8) | 11 (7.5-14.5) | 0.48 |
| Primary Outcome | | | |
| Reintubation due to respiratory failure within 72hours post extubation, n (%) | 11 (34.4) | 14 (16.5) | 0.035 |
| Secondary Outcome | | | |
| Reintubation due to respiratory failure within 7 days post extubation, n (%) | 13 (40.6) | 17 (20) | 0.023 |
| ICU length of stay, median (IQR), d | 17.37 (7.03-26.96) | 8.08 (4.07-16.33) | 0.011 |
| Hospital length of stay, median (IQR), d | 24.68 (15.58-32.62) | 15.85 (11.51-25.79) | 0.011 |
| Tracheostomy received, n (%) | 6 (18.8) | 8 (9.4) | 0.20 |
| Time to reintubation, median (IQR), h | 3.5 (1-32.5) | 31 (11.5-59.5) | 0.13 |
| Hospital mortality, n (%) | 6 (18.8) | 11 (12.9) | 0.56 |
| ICU cost, median (IQR), \$ | | | |
| Direct cost | 26522 (13348-40512) | 13608 (7068-26017) | 0.007 |
| Total cost | 45417 (20820-62739) | 17525 (8051-33853) | <0.001 |
| Total cost/day | 2635 (2469-2778) | 2537 (1157-2705) | 0.054 |
| Post Extubation Respiratory Interventions | | | |
| Prophylactic NIV, n (%) | 4 (12.5) | 12 (14.1) | 1.0 |
| High Flow High Humidity Nasal Cannula, n (%) | 11 (34.4) | 17 (20) | 0.10 |
| Airway Clearance therapies, n (%) | 1 (3.1) | 10 (11.8) | 0.27 |

| | | | |
|---|---------------|---------------|--------|
| Lung Expansion therapies, n (%) | 0 | 7 (8.2) | 0.19 |
| RT time associated with post extubation patient assessment, mean (SD), mins | 0 | 32.65 (15.21) | <0.001 |
| RT time associated with therapy provided post extubation, mean (SD), mins | 52.31 (98.31) | 39.77 (84.02) | 0.49 |

Abbreviations: APACHE II, Acute Physiology and Chronic Health Evaluation II; ICU, intensive care unit; IQR, interquartile range; NIV, non-invasive ventilation, SD, standard deviation