Journal of Medicine and Medical Sciences Vol. 1(6) pp. 242-247 July 2010
Available online http://www.interesjournals.org/JMMS

Full Length Research Paper

Safety of daily sedation interruptions in mechanically ventilated inner city patients – an alternative approach

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Accepted 06 June, 2010

Mechanically ventilated patients remain at risk for ventilator-associated pneumonia (VAP). While ventilator bundle implementation, with "sedation vacations" and assessing weaning readiness, has been shown to decrease VAP rates, inadequate sedation is a risk factor for unplanned extubation (UPE). We conducted a before-after observational study after institution of the ventilator bundle with sedation vacations in mechanically ventilated Medical Intensive Care Unit (MICU) patients from January 2006 to December 2007. Patients over 18 years old without contraindications to weaning were included. The primary outcome was UPE rate, and secondary outcomes included days on mechanical ventilation, re-intubation, and 28-day mortality. In 2005, 549 of 1196 MICU patients were mechanically ventilated compared to 1179 of 2553 in the study period. UPE rate remained unchanged (5.3% vs. 4.2%; AR -0.010; 95% CI -0.032 to 0.012). There were non-significant decreases in UPE per 100 ventilator days (1.26 vs. 1.04; RR 0.82; 95% CI 0.51 to 1.35; *P* = 0.40) and duration of mechanical ventilation for patients who had scheduled extubations (3.7 vs. 3.3 days; 95% CI -0.02 – 082; *P* = 0.06). This study suggests that sedation interruptions and assessment for weaning are safe in our unique inner city population and do not result in increased UPE rates.

Keywords: Unplanned extubation, sedation vacation, safety, mechanical ventilation

INTRODUCTION

Patients requiring mechanical ventilation constitute about one-third of all admissions to medical intensive care units (MICUs) (Esteban et al., 2002). In these patients, longer duration of mechanical ventilation is associated with higher rates of complications such as ventilator-associated pneumonia and barotrauma (Ibrahim et al., 2001). Among strategies advocated to reduce days on mechanical ventilation in such patients, is routine assessment of need for ventilation by daily interruptions of sedation infusion or "sedation vacations." This assessment is now included in the “ventilator bundle” strategy recommended by the Centers for Disease Control and the Institute of Health Improvement (Resar Roger et al., 2005). Kress et al. (2000) showed that daily interruption of sedative infusions correlated with reduction in the number of days on mechanical ventilation and MICU length of stay. In addition, a recent study showed that a “wake up and breathe” protocol led to a decrease in days on mechanical ventilation, but also an increase in unplanned extubations (Girard et al., 2008)

Current sedation interruption strategies for weaning assessment require sedation stops at a predetermined time in all mechanically ventilated patients. However, studies show that only approximately a third of mechanically ventilated patients are actually being weaned in MICUs at a given time (Chevron et al., 1998). Patients on mechanical ventilation who are not ready for weaning require adequate sedation and analgesia for comfort and safety, to optimize oxygenation and prevent patient-ventilator asynchrony (Shelly et al., 1997). Inadequate sedation is a risk factor for unplanned extubation in such individuals (Kapadia et al., 2000). In addition, there may be increased potential for pain and anxiety associated with reduction in sedation (Esteban et al., 2000). Therefore, daily interruption of sedation may

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Table 1. Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
Lung injury stable/resolving	Patients on pressors
Hemodynamically stable (HR < 100, MAP > 65)	Impending death
FiO2 requirement < 0.5 with SpO2 > 88	Patients on neuromuscular blockade
PEEP < 8	
Patient able to initiate breaths	

be practical only among selected individuals who are ready for weaning from mechanical ventilation, rather than in all mechanically ventilated subjects. Further, daily interruption of sedative infusions among inner city minority patients who tend to have a greater severity of illness and morbidity than the general population admitted to MICUs is not known.

In view of the lack of evidence and questions about the safety of daily interruption in sedation infusions in this unique group of patients, we studied the safety of a focused sedation interruption strategy among mechanically ventilated patients in our MICU.

METHODS

Design

We conducted a before-after observational performance improvement study of all MICU patients from January 2005 to December 2007 to evaluate the effects of a ventilator bundle strategy including daily interruption of sedation in selected weaning-eligible mechanically ventilated patients. The study covered a period before and after implementation of the ventilator bundle strategy in January 2006. This study was approved by the Hospital Institutional Review Board Committee and informed consent was waived.

Setting

The study was conducted in a university-affiliated hospital serving predominantly an inner city Hispanic and African American population. The MICU is a closed 20-bed unit, staffed around-the-clock by on-site, full-time, board-certified intensivists. The MICU has a nursing ratio of 1:2 and is also staffed around-the-clock by two full-time respiratory therapists.

Inclusion and exclusion criteria

All adult patients aged 18 years or greater who were admitted to the MICU service and required mechanical ventilation during the study period were included. Sedation interruption was ordered by an intensivist through a focused approach for only patients who were weaning-eligible based on standard clinical criteria. Sedation was continued in patients who were not eligible for weaning, such as those in shock; with terminal illnesses; or requiring neuromuscular blockade, high fractional inspired oxygen (> 0.5), or positive end-expiratory pressure > 8 (Table 1).

Data collection

Data for this study was extracted from a detailed critical care clinical database of all patients admitted to the MICU. The data recorded were demographic variables, admission diagnoses, Acute Physiology and Chronic Health Evaluation (APACHE) II scores, patients on mechanical ventilation, days on mechanical ventilation, complications, and outcomes. The director of critical care oversaw the updates to the database daily, and reviewed it monthly with the MICU healthcare team to ensure that errors of omission or data entry were minimized.

Every shift, MICU nurses independently collected data, which included compliance with the components of the ventilator bundle strategy. Data on unplanned extubation, namely, date and time, ventilator support mode, sedation, degree of consciousness, presence and type of restraints, and clinical information were also recorded by the MICU nursing staff as a part of an ongoing performance improvement initiative.

Standard MICU protocols for sedation were followed with assessment of level of sedation using the Ramsey scale. A score of three on the Ramsey scale was considered to be adequate sedation.

Focused planned sedation interruption protocol

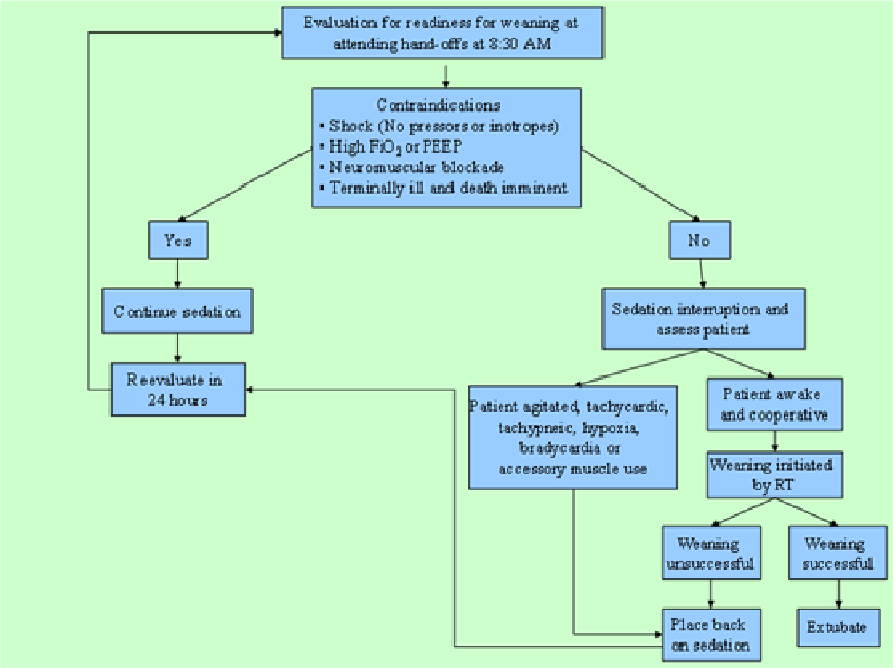
Prior to the implementation of the ventilator bundle, sedation interruption was done at the discretion of the intensive care team. The ventilator bundle (Table 2) was instituted and implemented in the MICU in January 2006. Weaning eligibility was determined according to standardized, predetermined criteria by institutional weaning policy. The decision to stop sedation and evaluate readiness for weaning was made each morning during attending physician rounds at the bedside and was communicated to the nursing staff and respiratory therapist. In weaning-eligible individuals, sedation was stopped by the nurse in charge of the patient. When patients were awake and able to follow instructions, the respiratory therapist initiated weaning. If patients developed sustained agitation, tachypnea, hypoxia, tachycardia, or bradycardia with accessory muscle use, weaning was not attempted and the patient placed back on sedation. The mode of weaning was left to the discretion of the attending intensivist. After a successful weaning trial, these data were reviewed by the intensivist, and the patient was extubated if all standard criteria for extubation were met (Figure 1). Patients who failed weaning using standard criteria were placed back on sedation and full ventilatory support.

Outcomes

The primary safety outcome of interest was unplanned extubation (UPE) rates before and after implementation of the ventilator bundle

Table 2. Ventilator bundle

Head end elevation
Mouth care with chlorhexidine based mouth wash
DVT prophylaxis
GI prophylaxis
Ventilator tube change weekly unless contaminated
Assessment for weaning and Sedation stop in the morning if criteria met for weaning



Abbreviations: FiO2, fraction of inspired oxygen; PEEP, positive end expiratory pressure.
Figure 1. Flow chart outlining the program for weaning and sedation-interruption among mechanically ventilated patients in the medical intensive care unit

strategy including focused sedation interruption. UPE was defined as deliberate removal of an endotracheal tube (ETT) by a patient or accidental removal of the ETT during nursing care or transport. Total UPEs and rates of UPEs per 100 ventilator days were compared before (calendar year 2005) and after (January 2006 to December 2007) implementation of sedation vacation. Secondary outcomes of the study included duration of mechanical ventilation among patients who had scheduled extubations, re-intubation rates following UPE, and 28-day in-hospital mortality in patients with UPE.

Statistical methods

Data are presented as mean ± standard deviation and percentages. Baseline variables were compared using the Student's *t*-test for continuous variables and for categorical data. Risk ratios and absolute risk reductions were calculated from the proportion and number of events in pre- and post-implementation periods of study, respectively. In cases of data involving events per time period, incidence rate ratios, defined as the number of events per unit time, were calculated comparing events in the pre- and post-implementation periods. For all results, 95% confidence intervals are reported. A two-tailed *P*-value < 0.05 was considered statistically significant. The statistical software STATA version 8.0 was used to perform data analyses.

RESULTS

Clinical characteristics

There were 1196 MICU admissions in 2005 and 2553 admissions in 2006-2007 subsequent to implementation of the ventilator bundle and focused sedation interruption strategy. Patient characteristics are shown in Table 3. Patients in the post-implementation group were younger than those in the pre-implementation group (P = 0.001). The two groups did not differ significantly in APACHE scores, gender distribution, or percentage of patients on mechanical ventilation.

Table 3. Clinical characteristics of patients on mechanical ventilation before and after implementation of the sedation vacation strategy

Variable	Without sedation vacation (2005)	With sedation vacation (2006-7)	*P*
MICU admissions	1196	2553	
Patients on Ventilator	549 (46%)	1179 (46%)	0.88
Age, y (median ± SD)	59.8 ± 17.3	54 ± 17.2	0.001
APACHE II Score - ventilated patients	17.6 ± 7.9	18 ± 7.5	>0.99
Total ventilator days	2297	4815	0.61
Patients electively extubated	364 (66%)	826 (70%)	0.12
28-day mortality for ventilated patients	110 (20%)	235 (20%)	0.99

Table 4. Primary and secondary outcomes analysis

Outcome	Without sedation vacation (2005)	With sedation vacation (2006-7)	AR or RR	95% CI	*P*
UPE	29/549 (5.3%)	50/1180 (4.2%)	-0.010 (AR)	-0.032 – 0.012	0.33
UPE /100 ventilator days	1.26	1.04	0.82 (RR)	0.51 – 1.35	0.40
Average days on ventilator -extubated patients	3.7 ± 3.5	3.3 ± 3.2	0.4 (AR)	-0.02 –0.82	0.06*
Re-intubation following UPE	12/29 (41%)	15/50 (30%)	0.73 (RR)	0.40 1.33	0.30
Mortality in UPE patients	1/29 (3.5%)	3/48 (6%)	1.74 (AR)	0.19 – 15.96	0.62*

Abbreviations: UPE, unplanned extubation; AR, absolute risk difference; RR, relative risk ratio. * Unpaired *t*-test

Primary outcomes

UPE rates were 5.3% (29/549) in the pre-implementation period in 2005 and 4.2% (50/1180) in the post-implementation period in 2006-2007 (AR -0.010; 95% CI, -0.032 to 0.012; *P* = 0.33; Table 4). The incidence rate ratio of UPEs per 100 ventilator days was 1.26 in the pre-implementation period and 1.04 during the post-implementation period (RR, 0.82; 95% CI, 0.51 – 1.35; *P* = 0.40; Table 4). Both measures of incidence showed a marginal, non-significant decrease in UPE from the pre- to post-implementation period.

Secondary outcomes

There was a non-significant decrease in the duration of mechanical ventilation among patients who had scheduled extubations in the post- compared to the pre-implementation period (3.3 vs. 3.7 days, respectively; absolute risk difference 0.4; 95% CI -0.02 to 0.82, *P* = 0.06). Re-intubations following UPEs similarly showed a non-significant decrease (41% vs. 30%; RR 0.73 95% CI 0.40 – 1.33; *P* = 0.30). Lastly, mortality among patients who had UPEs did not differ significantly between the groups (3.5% pre- vs. 6% post-implementation; RR 1.74; 95% CI, 0.19 – 15.96; *P* = 0.62; Table 4).

DISCUSSION

Based on this study, daily interruption of sedation as part of the ventilator bundle for inner city patients who were ready for weaning is safe and does not lead to increased UPEs. UPEs before and after implementation of the strategy in our study were well within the range reported in other studies (Ibrahim et al., 2001; Kapadia et al., 2000; Kress et al., 2000).

Initial determination of the readiness to wean prior to sedation interruption was a key component of our ventilator bundle strategy. This is contrary to the practice of daily sedation stops at a pre-designated time in all mechanically ventilated patients irrespective of weaning considerations. Our strategy was readily accepted by all health care providers and helped streamline the process of sedation interruption followed by weaning. We believe

that this multidisciplinary approach with sustained education resulted in successful implementation of the ventilator bundle. The success of the bundling strategy resulted in a significant decrease in ventilator associated pneumonia rates (from 2.17 to 0.62/1000 ventilator days, IRR = 0.27, $P < 0.0001$) in addition to a streamlined weaning assessment and sedation interruption with fewer UPEs (Venkatram et al., 2010).

Contrary to other studies, our study did not reveal a decrease in duration of mechanical ventilation. Of note, days on ventilators in both groups were lower than those reported in other studies (Esteban et al., 2002; Kress et al., 2000; Girard et al., 2008)

The overall planned extubation rates in mechanically ventilated patients was high (70% of all ventilated patients and 90% of survivors) in both groups.

The re-intubation rate following UPE decreased from 41% to 30% with implementation of the strategy, but this was not statistically significant. The re-intubation rates following UPE varies from 25% to 56% in the literature (Pandey et al., 2002; Coppolo et al., 1990; Taggart et al., 1994; Tindol et al., 1994; Vassal et al., 1993; Betbesé et al., 1998; Whelan et al., 1994). None of the patients with UPEs while being weaned required re-intubation, validating observations from earlier studies (Epstein et al., 2000; Pandey et al., 2002). Several studies have reported that predictors of re-intubation include multi-organ failure, altered neurological status, lower blood pH, higher fraction of inspired oxygen, higher ventilator-delivered minute ventilation, and, most importantly, weaning (Whelan et al., 1994; Rashkin et al., 1986; Boulain et al., 1998). Weaning assessment before discontinuation of sedation allowed for screening and elimination of most of these unfavorable factors. This focused approach to linking daily interruptions in sedation to weaning assessment, as part of the ventilator bundle strategy, could have led to a decrease in overall re-intubations and among those with UPEs. Mortality among patients with UPEs did not significantly differ before and after implementation of sedation interruptions. None of the patients with UPEs died due to the UPE itself in either group. Other studies have also shown that UPE is not associated with increased mortality when compared with matched controls (Pandey et al., 2002; Chen et al., 2000)

We noted a significant difference in age between the pre- and post-implementation period, with younger patients in the study period. Younger patients are noted to generally have higher UPE rates (Listello et al., 1994; Whelan et al., 1994). We did not observe this in our study and we speculate that the younger age of patients in the study group may have diminished the reduction in UPEs associated with sedation interruption.

This study has certain limitations. We did not collect data on types and doses of sedation. This was done mainly as a performance improvement initiative for ventilator bundle implementation. In addition, we did not collect data on the use of non-invasive positive pressure ventilation after UPEs. Finally, the study was performed in an MICU and cannot be generalized to surgical ICUs. The closed MICU model with around-the-clock intensivists may have accounted for better clinical outcomes; however, this model was operational both during the pre- and post-implementation periods of our study and therefore had an equivalent impact on outcomes in both phases.

Conclusion

Our results demonstrate that a regular assessment of weaning eligibility linked to daily sedation interruptions in weaning-eligible patients as a part of a ventilator bundle strategy is safe in an inner city MICU setting. This strategy does not result in increased UPEs when conducted by a multi-disciplinary team in a closed MICU setting with round-the-clock coverage by board-certified intensivists.

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