Critical Care Explorations

Correlation Between Restraint Use and Engaging Family Members in the Care of ICU Patients

To the Editor:

Postintensive care syndrome, including impairment in cognition, mental health, and activities of daily living, is pervasive among ICU survivors, however effective interventions remain inadequate. Frequently implemented inpatient strategies, such as use of mechanical restraints, can adversely affect post-ICU outcomes, contributing to immobility and delirium. The assessment of safe and nonpharmacologic interventions, including increased family engagement at the bedside, is crucial to augmenting ICU patient recovery. We evaluate the correlation between family member bedside engagement and ICU patient exposure to restraints via a retrospective cohort analysis of adult ICU patients at one academic medical center. Comparing a cohort of patients exposed to increased family engagement ($n = 77$) with a cohort of patients not exposed to the same ($n = 67$), we demonstrate a clinical, but not statistically significant, reduction in the duration of restraint use. The adjusted difference via multivariable linear regression was –2.20 hours (95% CI, –5.15 to 0.76 hr). Similar results were obtained (–2.16; 95% CI, –4.80 to 0.47) with a stepwise regression model including variables that affected the outcome by 10% or more. This analysis suggests that the theory behind family engagement at the bedside as a means to reduce potentially restraint exposure and delirium should be explored in a prospective manner.

Mechanical restraint use is prevalent among mechanically ventilated adults managed with a sedation protocol in the ICU (1). Although frequently intended for patient or clinician safety, mechanical restraints can lead to adverse physical and psychologic consequences, including immobility, agitation, and delirium (2, 3). This is incongruent with current guidelines that emphasize minimizing sedation, enhancing mobility, and reducing iatrogenic harms in the ICU (4). In particular, the ICU Liberation Bundle is becoming an essential evidence-based guide to steer greater awareness toward interactive care, optimal pain control, and early mobilization, leading to significant improvements in ICU patient outcomes (5). A key component of the ICU Liberation Bundle lies in enhancing family engagement and empowerment. Although both providers and family members feel that family involvement is important for patient care, there is minimal objective research examining how family involvement in care affects patient outcomes (6), specifically how restraint use is impacted. As the absence of family visitation and use of restraints are known to be individual risk factors for delirium in the ICU (7), we hypothesized that engagement of families in the bedside care of patients would correlate with reduced restraint exposure in the ICU.

We performed a retrospective cohort analysis via chart review of 145 patients admitted to the medical ICU (MICU) at Rhode Island Hospital, each with a critical care attending predicted ICU mortality of greater than 30%. These patients had been previously enrolled in a family participation study, conducted between October 2015 and March 2017, which sought to empower family members to participate in the care of patients admitted to the ICU (8). In the primary study, Amass et al (8) demonstrated that offering family members the opportunity to participate in patient care was associated with increased engagement with the patient and reduced symptoms of post-traumatic stress disorder in the family members 90 days after patient death or discharge from the ICU. Additional details regarding the intervention and results of that study are described elsewhere (8). Here, we compare the cohort of patients exposed to increased family engagement (intervention) with the cohort of those not exposed to the same (control) and evaluated for duration of restraint use. As Rhode Island Hospital MICU has an open visitation policy, family members were not restricted by visiting hour policies or isolation concerns. Human subject approval was obtained from the local Institutional Review Board for this retrospective chart review.

We defined the primary outcome variable as the hours of restraint exposure per number of days exposed to restraints (restraint use/restraint days) to account for variable length of ICU stay. As per standard of care, nurses were required to document initiation and cessation of restraints. Chart abstraction was completed by one researcher (S.J.H.), and the abstracted data were confirmed by a separate author (T.H.A.) for validity and accuracy. Based on the available literature (3, 9), we defined several covariables to account for confounding between the groups, focusing on variables known to increase risk for restraints or those associated with delirium. The covariables included length of stay in the ICU, Acute Physiology and Chronic Health Evaluation (APACHE) II score at admission to the ICU, age of the patient at enrollment, patient gender, level of education, family-reported patient race, patient history of substance abuse, recorded delirium via the Confusion Assessment Method ICU score (9, 10), and exposure to paralytics, mechanical ventilation, and vasopressors. Finally, to consider agitation, we defined a covariate based on the Richmond Agitation-Sedation Scale (RASS) score, calculated as the sum of hours of RASS score greater than 1 or less than 1 (representing either agitation or sedation) divided by the number of hours in the ICU, compared with the number of hours with an RASS score of 0 (no agitation or sedation) divided by the number of hours in the ICU. The control and intervention groups were compared using a two-sided t test or chi square, dependent on the variable,

to generate *p* values with an alpha significance level of 0.05. Multivariable linear regression was then used to generate adjusted outcomes with two-sided 95% CIs. All covariates were initially included to generate an adjusted outcome variable, and then a sensitivity analysis was performed to evaluate which covariables adjusted the outcome by 10% or more. A stepwise regression analysis was then performed, sequentially including those variables that affected the outcome by 10% or more, presented as an additional model of confounding.

The patients in both cohorts were similar with regard to demographics and the defined covariates, as presented in **Table 1**. For the primary outcome of restraint hours per restraint day, there was an unadjusted difference of –1.72 hours between the control and intervention groups, though this was not statistically significant

TABLE 1. Patient Demographics

Patient Demographics	Control (*n* = 67)	Intervention (*n* = 77)	*p*
Mean age (SD)	65.48 (2.21)	64.19 (2.06)	0.67
Gender, % male (*n*)	50.75 (34)	46.75 (36)	0.63
Mean Acute Physiology and Chronic Health Evaluation II (SD)	27.91 (1.00)	27.61 (1.02)	0.84
Level of education % (*n*)			
Primary or elementary	1.49 (1)	1.30 (1)	0.30
Secondary or junior high	11.94 (8)	12.99 (10)	
High school	32 (48)	58.44 (45)	
College or university	14 (21)	20.78 (16)	
Advanced degree	8.96 (6)	5.19 (4)	
Did not attend school	1.49 (1)	1.30 (1)	
None given	7.46 (5)	0 (0)	
Race %, (*n*)			
White	74.63 (50)	87.01 (67)	0.19
Black or African American	7.46 (5)	2.60 (2)	
Other	14.9 (11)	10.4 (8)	
None given	2.99 (2)	0 (0)	
Country of birth, % United States (*n*)	77.61 (52)	84.42 (65)	0.297
Mean days of delirium (SD)	4.01 (3.79)	3.66 (3.75)	0.58
Mean total ICU hours (SD)	116.93 (16.95)	107.22 (10.28)	0.61
Mean days exposed to paralytic (SD)	0.55 (0.12)	0.86 (0.32)	0.40
Mean days intubated (SD)	2.99 (0.48)	3.14 (0.46)	0.81
Mean days exposed to vasopressors (SD)	1.94 (0.30)	1.96 (0.36)	0.97
Mean days exposed to sedation (SD)	1.85 (0.35)	2.61 (0.43)	0.18
Alcohol abuse history, % yes (*n*)	14.93 (10)	18.18 (14)	0.27
Substance Abuse, % yes (n)	7.46 (5)	10.39 (8)	0.37
(Total hours RASS below −1 + total hours RASS above 1)/(total ICU hours)	0.39 (0.05)	0.46 (0.05)	0.25
(Total hours RASS = 0)/(total ICU hours)	0.24 (0.03)	0.24 (0.035)	0.87
Mean total restraint hours (sd)	30.25 (6.01)	28.25 (5.16)	0.80
Mean ICU LOS, d (SD)	5.85 (0.72)	5.23 (0.45)	0.46
Mean days exposed to restraints (SD)	1.88 (0.32)	1.78 (0.27)	0.81
Mean total restraint hours/LOS (SD)	4.91 (0.79)	4.76 (0.69)	0.88
Mean total restraint hours/mean days exposed to restraints (SD)	14.78 (0.82)	13.06 (0.89)	0.19

LOS = length of stay, RASS = Richmond Agitation-Sedation Scale.

(14.78 SD 0.82 hr vs 13.06 SD 0.89 hr, $p = 0.19$) (Table 1). The adjusted mean difference between the control and intervention cohorts was also not significant when analyzed via multivariable linear regression including the defined covariates (–2.20 hr; 95% CI, –5.15 to 0.76; $p = 0.142$) or via stepwise regression (–2.16 hr; 95% CI, –4.80 to 0.47; $p = 0.106$) (**Table 2**). This stepwise regression included variables that affected the outcome by 10% or more, which were race, APACHE II score, days of sedation, level of education, and days exposed to paralytic.

Our results do not demonstrate a statistical difference in mean restraint exposure between the cohorts of patients exposed to increased family engagement compared with the patients not exposed to the same. However, in both the unadjusted and adjusted models, we observed an apparent reduction in restraint hours, which may offer clinical significance in reducing restraint time. These results are limited by several important factors. First, by design, a retrospective cohort study cannot account for all confounding variables; there are likely unmeasured confounders that affected the analysis. In an effort to mitigate this limitation, covariates were clearly defined given the data available within the original data set, data via chart abstraction, and based on previous literature. Second, the two cohorts were each composed of relatively small numbers of patients. Although Table 1 demonstrates that the groups were well-balanced and likely representative of the general tertiary-care adult ICU population, the relatively small sample size limits the analysis. Restraint use practices may also vary between different hospital ICUs, so the single study nature of this study cannot account for institutional differences. Additionally, the outcome variable was dependent on accurate documentation of restraint time in the patient's medical record. Although variable documentation practices likely influenced the outcome, this could not be accounted for in our statistical modeling. Finally, as a novel intervention of engaging family members in the hands-on care of the patients, there may have been an unmeasured impact of nursing trust or lack of trust with the families. Meaning, if given more time exposed to an intervention such as this, it is possible that the bedside nurses may have allowed more, or less, restraint-free time with family present and engaged. If a future trial considers a restraint exposure outcome prospectively, it would be important to engage nursing to understand the impact of such an intervention on their willingness to place or remove restraints.

In spite of the limitations outlined above, this cohort analysis suggested a reduction in restraint exposure in the patients whose families were encouraged to participate in their care. Additional prospective analysis is needed to evaluate the impact of increased bedside family engagement as a safe intervention to reduce delirium and improve patient recovery.

TABLE 2. Results

	Adjusted Mean Difference in Restraint Time Between Control and Intervention Groups[a] (hr)	Adjusted *p*
All variables	−2.20 (95% CI, −5.15 to 0.76)	0.142
Stepwise regression[b]	−2.16 (95% CI, −4.80 to 0.47)	0.106

[a]The adjusted mean difference in restraint time between the control and intervention cohorts was performed via multivariable linear regression including the defined covariates, which are outlined in Table 1. For comparison, the unadjusted difference (hr) was −1.72 (95% CI, −4.23 to 0.80).

[b]The stepwise regression included variables that affected the outcome by 10% or more, including race, Acute Physiology and Chronic Health Evaluation II, days of sedation, level of education, and days exposed to paralytic.

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