Impact of an early mobilization protocol on outcomes in trauma patients admitted to the intensive care unit: A retrospective pre-post study

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BACKGROUND: Prolonged immobility has detrimental consequences for critically ill patients admitted to the intensive care unit (ICU). Previous work has shown that early mobilization of ICU patients is a safe, feasible and effective strategy to improve outcomes; however, few of these studies focused on trauma ICU patients. Our objective was to assess the impact of implementing an ICU early mobilization protocol (EMP) on trauma outcomes.

METHODS: We conducted a retrospective pre-post study of adult trauma patients (>18 years old) admitted to ICU at a Level I trauma center over a 2-year period prior to and following EMP implementation, allowing for a 1-year transition period. Data were collected from the Nova Scotia Trauma Registry. We compared outcomes (mortality, length of stay [LOS], ventilator-free days) between patients admitted during pre-EMP and post-EMP periods, and assessed for factors associated with outcomes using binary logistic regression and generalized linear models.

RESULTS: Overall, 526 patients were included in the analysis (292 pre-EMP, 234 post-EMP). Ages ranged from 18 years to 92 years (mean, 49.0 ± 20.4 years) and 74.3% were men. The post-EMP group had lower ICU mortality (21.6% vs. 12.8%; $p = 0.009$) and in-hospital mortality (25.3% vs. 17.5%; $p = 0.031$). After controlling for confounders, patients in the post-EMP group were less likely to die in the ICU (odds ratio, 0.43; 95% confidence interval, 0.24–0.79; $p = 0.006$) or in-hospital (odds ratio, 0.55; 95% confidence interval; 0.32–0.94; $p = 0.03$). In-hospital LOS, ICU LOS, ICU-free days, and number of ventilator-free days were similar between the two groups.

CONCLUSION: Trauma patients admitted to ICU during the post-EMP period had decreased odds of ICU mortality and in-hospital mortality. This is the first study to demonstrate a significant reduction in trauma mortality following implementation of an ICU mobility protocol. (*J Trauma Acute Care Surg.* 2020;88: 515–521. Copyright © 2020 Wolters Kluwer Health, Inc. All rights reserved.)

LEVEL OF EVIDENCE: Therapeutic, level III.

KEY WORDS: Early mobilization protocol; intensive care unit; outcomes.

Advances in the management of critically ill patients have improved survival rates[1]; however, patients stabilized in an intensive care unit (ICU) setting often develop other issues, which impact their long-term outcome.[2,3] Neuromuscular weakness and functional impairment are common adverse events following ICU admission and are associated with immobility.[4–7] Factors that can impede mobilization in the ICU include patient illness, sedative and analgesic medications, mechanical ventilation, and vascular attachments.[8–11]

Intensive care unit-acquired weakness (ICUAW) refers to pronounced weakness identified during ICU admission without an identifiable etiology except for critical illness.[12,13] This complication has been reported in 26% to 65% of the ICU population,[14] and is associated with longer duration of mechanical ventilation,[5,15] greater ICU and hospital length of stay (LOS),[13] and increased mortality.[14,16] Reducing the duration of immobilization can help minimize ICUAW and associated sequelae.[7] Early mobilization of ICU patients has been demonstrated to be a safe, feasible, and effective strategy to improve patient outcomes.[17–26] Investigations of early mobilization in the ICU setting have shown improvements in ICU LOS, ventilator-free days, delirium, and functional mobility at hospital discharge.[5,25]

While there have been previous studies of early mobilization in the general ICU setting,[17–26] few studies have investigated the impact of an early mobilization protocol (EMP) on outcomes in the critically ill trauma population.[27,28] Trauma patients tend to be younger and healthier than the general ICU population and often require specialized management for injuries to multiple organ systems.[29] The objective of this study was to examine whether implementation of an EMP in the ICU at a tertiary trauma center had an effect on the outcomes of major trauma patients.

METHODS

Setting, Design, and Eligibility Criteria

The Queen Elizabeth II Health Sciences Centre (QEII HSC) is an academic Level I trauma center and the only adult

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trauma referral center in Nova Scotia. All adult trauma patients from across the province who require critical care are admitted to the medical-surgical-neuro (MSN) ICU at the QEII HSC. The MSN ICU is a closed model where consultant services round on patients but decisions concerning patient care are made by the ICU attending.

We performed a retrospective pre-post study on a sample of consecutive major trauma patients (>18 years old) who were admitted to ICU at the QEII HSC over a 2-year period prior to implementation of an EMP (pre-EMP phase, April 1, 2012 to March 31, 2014) and following EMP implementation (post-EMP phase, April 1, 2015 to March 31, 2017), allowing for a 1-year transition period. All trauma patients admitted to ICU during the study period were eligible. We excluded pediatric patients (<18 years) and any trauma patients admitted to ICU during the transition period (April 1, 2014 to March 31, 2015). Ethical approval was obtained from the Nova Scotia Health Authority (NSHA) Research Ethics Board (File 1023317) in Halifax. This study was performed in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology guidelines for reporting observational studies.[30]

Mobility Protocol Implementation

Prior to EMP implementation, mobilization was performed on an ad hoc basis by ICU allied health providers (nurses and respiratory therapists) and physiotherapists. Although physical therapy could be ordered as part of routine care, a standardized approach to patient mobilization was not in place. As part of an initiative to improve outcomes for ICU patients at the QEII HSC, the Department of Critical Care developed a mobility protocol based on current literature and best practices,[31] and allocated funding for full-time physiotherapy coverage. The protocol involves a multidisciplinary, stepwise approach to patient mobilization (Supplemental Digital Content 1, Fig. 1, http://links.lww.com/TA/B552). Under the protocol, ICU clinicians evaluate patient readiness for participation in mobilization activities using a four-level system. The patient's level of consciousness is assessed using the Richmond Agitation-Sedation Scale score. For unconscious patients, mobility sessions consist of passive range of motion activities. As patients regain consciousness, physical therapy and progressive resistance exercises are introduced. Physiotherapists and the clinical team decide which of the mobilization activities listed in the protocol are appropriate to use on a case-by-case basis.

Prior to implementing the mobility protocol, multidisciplinary staff meetings were held to develop and adapt the EMP and to plan the implementation process. Evidence supporting the benefits of early mobilization were presented and ICU staff were educated on the mobility protocol to ensure compliance and garner a pro-mobility environment within the ICU setting. Sedation practices, ventilator weaning, and patient care decisions in the pre-EMP and post-EMP periods were at the discretion of the treating clinician.

Data Collection

Data were collected from the Nova Scotia Trauma Registry (NSTR), a population-based provincial trauma registry under the Nova Scotia Department of Health and Wellness, which includes information on all major traumas in Nova Scotia. The NSTR is maintained by the staff of the provincial trauma program (Trauma Nova Scotia [TNS]). Trained data collectors enter data in the registry according to standardized coding protocols. The NSTR has quality control procedures in place to ensure that data entry is accurate and complete. The TNS definition of "major" trauma includes any injury with an Injury Severity Score (ISS) ≥ 12 and an appropriate International Classification of Diseases (ICD) External Cause of Injury Code, as well as penetrating injury cases with an ISS ≥ 9, trauma-related deaths (at scene, in emergency department [ED], or within 24 hours of admission), and any trauma team activations regardless of ISS. Excluded are all injuries which do not meet the above criteria, medical errors, and discharges from the ED which were not trauma team activations.

Data on demographic characteristics (age, sex), injury type, injury cause (identified with ICD-10-CA codes), injury severity (Glasgow Coma Scale [GCS] at the scene, GCS on ED arrival, maximum Abbreviated Injury Scale Head score, ISS 2005), ICD-10-CA comorbidities, and National Trauma Registry (NTR) comorbidities were collected. We grouped data on cause of injury and ICD-10-CA comorbidities into appropriate categories. We also collected information on mortality (ICU, in-hospital), LOS (ICU, in-hospital), and need for mechanical ventilation (in days). Any patients with missing data were excluded from the analysis.

Outcome Measurements

The primary outcome of interest was in-hospital mortality. Secondary outcomes included ICU mortality, ICU LOS, hospital LOS, and ventilator-free days.

Statistical Analysis

Patients were grouped based on ICU admission during the pre-EMP or post-EMP period. We used proportions, means, standard deviations, medians, and interquartile ranges to describe patient characteristics and outcomes. Continuous variables were compared using Student *t* test and categorical variables were compared using χ^2 analysis. Medians were compared using the median test in SPSS. We created binary logistic regression models to assess for factors associated with mortality, and we used generalized linear models to assess for factors associated with LOS and ventilator-free days. The following independent variables were included in the models: period (pre-EMP, post-EMP), age (continuous), sex (male, female), ISS (continuous), scene GCS (continuous), cause of injury (motor vehicle collision, fall, other), and ICD-10-CA comorbidities (yes, no). A sensitivity analyses was performed to evaluate the consistency of observed results regarding mortality on a subset of patients with blunt or penetrating injuries. All analyses were performed using IBM SPSS Statistics Version 24 (Armonk, NY: IBM Corp). Adjusted odds ratios (ORs) with 95% confidence intervals (CIs) are reported for the measurement of effect size.

RESULTS

Patient Characteristics

The selection of study participants is shown in Figure 1. Overall, there were 526 adult major trauma patients admitted to ICU during the study period (292 pre-EMP, 234 post-EMP).

The study population ranged in age from 18 years to 92 years (mean age, 49.0 ± 20.4 years), and 74.3% of patients were men. Table 1 shows the characteristics of patients in each group. The pre- and post-EMP groups were similar in age, sex, cause of injury, and injury severity. There were some differences in injury mechanism between the two groups, with fewer cases of penetrating trauma and more cases of burns/drownings/asphyxias in the pre-EMP group. Regarding comorbidities, a larger proportion of post-EMP patients had a cardiovascular-related comorbidity (16.4% vs. 23.5%; $p = 0.042$), respiratory disease (3.8% vs. 8.5%; $p = 0.021$), or impaired sensorium (2.1% vs. 7.3%; $p = 0.004$). A smaller proportion of patients in the post-EMP group did not have any NTR comorbidities (37.3% vs. 26.9%; $p = 0.011$).

Outcomes

Table 2 shows the outcomes of trauma patients admitted to ICU before and after implementation of the mobility protocol. The post-EMP group had lower mortality in the ICU (21.6% vs. 12.8%; $p = 0.009$) and in-hospital (25.3% vs. 17.5%; $p = 0.031$) compared with pre-EMP patients. No differences were observed in hospital LOS, ICU LOS, or ventilator-free days.

Effect of an EMP on Patient Outcomes

We used regression analysis to assess the effect of implementing an EMP on trauma ICU patient outcomes after controlling for potentially confounding variables (Table 3). Compared with the pre-EMP period, trauma patients admitted to ICU following protocol implementation were less likely to die in the ICU (OR, 0.43; 95% CI, 0.24–0.79) and in-hospital (OR, 0.55; 95% CI, 0.32–0.94). Results were similar following a sensitivity analysis limited to patients with blunt or penetrating injuries (Supplemental Digital Content 2, Table 1, http://links.lww.com/TA/B553). In-hospital mortality was also associated with increasing patient age (OR, 1.06; 95% CI, 1.04–1.08), increasing ISS (OR, 1.09; 95% CI, 1.06–1.12), and decreasing scene GCS score (OR, 0.82; 95% CI, 0.77–0.88). Similarly, these factors were also associated with ICU mortality. Implementation of the EMP had no effect on in-hospital LOS, ICU LOS, or the number of ventilator-free days.

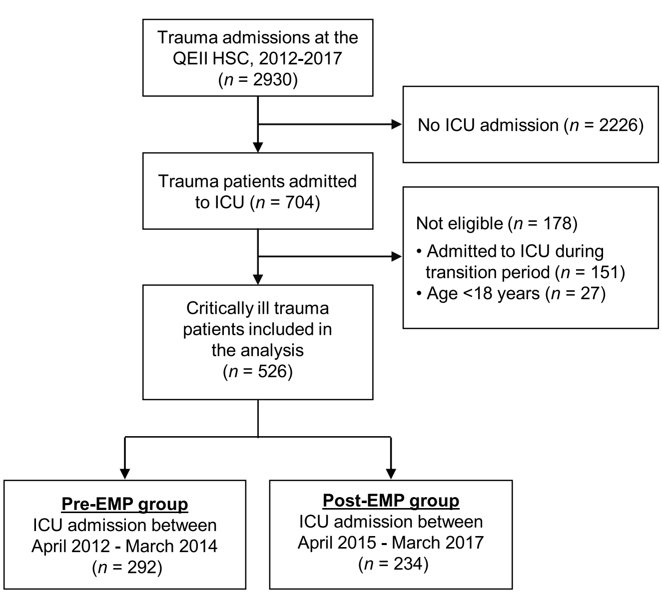

Figure 1. Flow chart of trauma patients included in the study. QEII HSC, Queen Elizabeth II Health Sciences Centre.

DISCUSSION

This study represents one of the largest investigations to date on the impact of a structured progressive mobility protocol on outcomes in the critically ill trauma population. Major trauma patients who were admitted to ICU in our Level I trauma center following implementation of an EMP had reduced in-hospital mortality and ICU mortality. After controlling for confounders, these patients had decreased odds of ICU mortality (OR, 0.43) and in-hospital mortality (OR, 0.55). There was no difference between the pre-EMP and post-EMP groups with respect to in-hospital LOS, ICU LOS, or ventilator-free days. Our study is the first to demonstrate a significant reduction in trauma mortality after the implementation of an ICU mobility protocol.

Early mobilization of general patients admitted to an ICU is an important therapeutic strategy to improve patient outcomes.[31,32] An understanding of the negative long-term effects of bed rest and the high prevalence of immobility among ICU patients has provided sound rationale for mobilization strategies within the ICU setting.[7,13,14] Despite considerable interest in research on the mobilization of critical care patients, the impact of mobilization in the trauma ICU population has not been extensively studied.[28] The principles of critical care for trauma patients are similar to those for general ICU patients; however, injuries to multiple organ systems can complicate diagnosis and delivery of necessary care.[29] Although trauma patients are typically younger, healthier, and have fewer comorbidities than the general ICU population,[29] it may be challenging to introduce progressive mobility tasks in these patients due to their complex injuries.[28,33] In particular, trauma patients often have extensive orthopedic and neurologic injuries, which create unique barriers to mobility.[34] Despite these challenges, mobility strategies employed in the ICU setting must be inclusive for trauma patients. Trauma patients that survive the acute insult may be more likely to have good long-term outcomes due to their healthy baseline status.[35]

Our findings support existing evidence that early mobilization of trauma ICU patients can improve patient outcomes. In our study, mortality was significantly lower for trauma patients who engaged in early mobility activities. This improvement in mortality was not accompanied by a concomitant decrease in ICU LOS or number of ventilation days in the post-EMP group, which we hypothesize may be attributable to the high utilization of non-ICU beds in the step down units and wards at the QEII HSC. Although previous studies have investigated the link between early mobilization and mortality in other ICU populations,[5,21,36] ours is the first to demonstrate a significant decrease in mortality among trauma patients admitted to ICU. A previous study of 2,176 patients admitted to a trauma and burn ICU (TBICU) found lower mortality following implementation of an EMP; however, this difference was not significant (13.2% vs. 11.8%; $p = 0.33$).[27] Similarly, another study of 405 burn patients admitted to a TBICU found a non-significant reduction in mortality after initiation of an EMP (5.6% vs. 4.0%; $p = 0.46$).[37] These studies were limited to subgroups of the trauma population

TABLE 1. Characteristics of ICU Trauma Patients Before and After EMP Implementation

Characteristics	Pre-EMP (n = 292)	Post-EMP (n = 234)	*p* Value
Age, mean ± SD	48.9 ± 20.2	49.1 ± 20.6	0.91
Sex, n (%)			0.68
Male	215 (73.6)	176 (75.2)	
Female	77 (26.4)	58 (24.8)	
ISS 2005, mean ± SD	22.4 ± 10.5	23.5 ± 10.4	0.21
Max AIS head score, n (%)			0.25
1	33 (11.3)	15 (6.4)	
2	7 (2.4)	11 (4.7)	
3	52 (17.8)	38 (16.3)	
4	42 (14.4)	31 (13.2)	
5	61 (20.9)	49 (21.0)	
6	0 (0)	n < 5	
Unavailable	97 (33.2)	n > 5	
GCS scene, mean ± SD	10.7 ± 4.8	10.8 ± 4.5	0.91
GCS arrival, median [IQR]	15.0 [2.0]	15.0 [5.0]	0.31
Injury Type, n (%)			0.004
Blunt	254 (87.0)	205 (87.6)	
Penetrating	16 (5.5)	24 (10.3)	
Burn/drowning/asphyxia	22 (7.5)	5 (2.1)	
ICD-10-CA cause of injury, n (%)			0.05
MVC	106 (36.3)	96 (41.0)	
Fall	90 (30.8)	51 (21.8)	
ATV/snowmobiling	16 (5.5)	26 (11.2)	
Exposure	26 (8.9)	13 (5.6)	
Violence/assault/firearms	18 (6.2)	18 (7.7)	
Self-harm	14 (4.8)	10 (4.3)	
Other	22 (7.5)	20 (8.5)	
ICD-10-CA comorbidities,* n (%)			
Cardiovascular	48 (16.4)	55 (23.5)	0.042
Neuro	31 (10.6)	36 (15.4)	0.10
Respiratory	14 (4.8)	21 (9.0)	0.06
Infectious disease	19 (6.5)	11 (4.7)	0.37
Renal	14 (4.8)	12 (5.1)	0.86
Neoplastic	12 (4.1)	6 (2.6)	0.33
Other	85 (29.1)	86 (36.7)	0.06
None	149 (51.0)	101 (43.2)	0.07
NTR comorbidities,* n (%)			
Current smoker	86 (29.4)	74 (31.6)	0.59
Hypertension requiring medication	83 (28.4)	73 (31.2)	0.49
Alcoholism	54 (18.5)	31 (13.2)	0.10
Diabetes mellitus	21 (7.2)	24 (10.3)	0.21
Drug use	21 (7.2)	12 (5.1)	0.33
Respiratory disease	11 (3.8)	20 (8.5)	0.021
Bleeding disorder	14 (4.8)	19 (8.1)	0.12
Impaired sensorium	6 (2.1)	17 (7.3)	0.004
ADD/ADHD	5 (1.7)	10 (4.3)	0.08
Other	25 (8.6)	19 (8.1)	0.86
None	109 (37.3)	63 (26.9)	0.011

AIS, Abbreviated Injury Score; IQR, interquartile range; MVC, motor vehicle collision; ATV, all-terrain vehicle; ADD/ADHD, Attention Deficit Disorder/Attention Deficit Hyperactivity Disorder; SD, standard deviation.

* Some patients had more than one comorbidity.

which may explain differences in overall mortality. Other studies of trauma ICU patients did not find a difference in mortality rates following implementation of mobilization protocols.[33,38] While investigations have demonstrated ICUAW is associated with substantial morbidity, mortality and increased health care needs in survivors of critical illness,[13,14,16] the mechanism by which early

TABLE 2. Patient Outcomes Before and After Implementation of an ICU EMP

Outcomes	Pre-EMP (n = 292)	Post-EMP (n = 234)	*p* Value
ICU mortality, n (%)	63 (21.6)	30 (12.8)	0.009
In-hospital mortality, n (%)	74 (25.3)	41 (17.5)	0.031
ICU LOS days			
Mean ± SD	6.9 ± 8.5	7.0 ± 9.1	0.90
Median [IQR]	4 [7]	4 [7]	0.73
Hospital LOS days			
Mean ± SD	28.7 ± 46.5	30.2 ± 45.1	0.71
Median [IQR]	17 [30]	18.0 [25]	0.79
Ventilator-free days			
Mean ± SD	22.5 ± 2.7	24.0 (2.8)	0.71
Median [IQR]	12 [27]	12 [22]	0.97

mobilization reduces mortality in trauma ICU patients remains unclear.

Survivors of acute critical illness are at risk of deconditioning and associated sequelae due to long periods of immobility. Several studies have identified additional benefits of early mobilization in the ICU setting. Needham et al.[39] studied the effects of mobilizing mechanically ventilated medical ICU patients and found improvements in sedation status, greater functional mobility, and reductions in ICU LOS and in-hospital LOS.[39] In the first randomized controlled trial to study the impact of an ICU mobility program, Schweickert et al.[20] demonstrated shorter duration of delirium, greater ventilator free days and greater return to independent functional status at hospital discharge; no improvements were observed in ventilation days, ICU LOS or in-hospital LOS. Finally, Clark and colleagues[27] examined the impact of an early mobility program on patients admitted to a TBICU and found a significant decrease in deep vein thrombosis among mobilized patients; however, they did not observe a difference in mortality, ventilator days, ICU LOS or in-hospital LOS. Prospective outcome studies are required to determine the long-term effects of early ICU mobilization efforts in the trauma population.

Overall, the early mobilization of critically ill trauma patients represents a safe, feasible, and potentially effective strategy for optimizing outcomes and decreasing the burden of in-hospital patient care needs. From our experience at the QEII HSC, there were several factors that contributed to successful implementation of an EMP in the ICU.[40] These included the presence of physician champions who partnered with hospital leadership, along with high levels of engagement from physiotherapists and bedside nurses. We lobbied to increase physiotherapist allotment from a few hours/day on select days to 7.5 hours/d every day of the week. Buy-in and engagement from ICU physicians on a daily basis helped promote the culture of mobility which continues today. Both formal and informal education sessions were regularly offered and guided by nurses and physiotherapist requirements. With respect to financing this initiative, the only additional costs incurred were for the increase in salary for the physiotherapists.

There are several important limitations to this study that must be considered when interpreting the results. As a retrospective analysis of an existing data set, these results cannot be used to imply causality. There are inherent limitations with the pre-post study design, and it is possible that institutional changes and/or advances in general ICU care may have contributed to the observed difference in outcomes between the two groups. Throughout the study period, there were quality improvements in all facets of ICU care including monitoring/identifying delirium

TABLE 3. Regression Results Evaluating Mortality, Length of Stay, and Ventilator-Free Days

Variables	ICU mortality*	In-Hospital mortality**	ICU LOS (Days)†	Hospital LOS (Days)‡	Ventilation-Free days§
Admitted post-EMP (reference: Pre-EMP)	0.43 (0.24–0.79), 0.006	0.55 (0.32–0.94) 0.03	0.99 (0.84–1.18), 0.97	0.98 (0.80–1.20), 0.82	0.98 (0.79–1.21), 0.86
Age	1.05 (1.03–1.07), <0.001	1.06 (1.04–1.08), <0.001	1.00 (0.995–1.005), 0.98	1.007 (1.001–1.013), 0.014	1.012 (1.005–1.018), <0.001
Male (reference: female)	1.32 (0.68–2.58), 0.41	0.98 (0.54–1.78), 0.94	0.95 (0.78–1.16), 0.64	1.14 (0.90–1.43), 0.27	1.05 (0.82–1.34), 0.71
ISS	1.10 (1.07–1.14), <0.001	1.09 (1.06–1.12), <0.001	1.025 (1.015–1.035), <0.001	1.011 (0.999–1.023), 0.06	1.024 (1.011–1.037), <0.001
Scene GCS	0.81 (0.76–0.87), <0.001	0.82 (0.77–0.88), <0.001	1.02 (0.99–1.04), 0.06	0.99 (0.97–1.01), 0.40	0.95 (0.92–0.97), <0.001
Cause of injury (reference: other)					
MVC	0.29 (0.13–0.60), 0.001	0.35 (0.17–0.69), 0.003	1.10 (0.90–1.35), 0.35	1.62 (1.26–2.07), <0.001	1.53 (1.18–1.99), 0.001
Fall	0.63 (0.30–1.31), 0.21	0.55 (0.28–1.11), 0.95	0.83 (0.66–1.04), 0.11	1.11 (0.85–1.47), 0.44	1.20 (0.88–1.63), 0.24
ICD-10-CA comorbidities (reference: no)	1.26 (0.70–2.27), 0.45	0.95 (0.55–1.66), 0.87	1.08 (0.91–1.29), 0.39	1.22 (0.99–1.50), 0.06	1.04 (0.83–1.30), 0.71

Data are presented as OR (95% CI), *p* value.
* Likelihood ratio χ^2 = 116.10 (df = 8, p < 0.001); deviance = 315.78 (df = 443).
** Likelihood ratio χ^2 = 35.58 (df = 8, p < 0.001); deviance = 591.29 (df = 445).
† Likelihood ratio χ^2 = 41.15 (df = 8, p < 0.001); deviance = 412.64 (df = 445).
‡ Likelihood ratio χ^2 = 123.06 (df = 8, p < 0.001); deviance = 358.19 (df = 443).
§ Likelihood ratio χ^2 = 67.18 (df = 8, p < 0.001); deviance = 347.37 (df = 326).

and minimizing use of sedative medications. Moreover, the NSTR does not capture data on quantity of mobilization received during ICU stay or whether a given patient was mobilized. Thus, we could not report on compliance with the EMP and were unable to account for the possibility that some patients in the pre-EMP group received ad hoc mobilization or that some patients in the post-EMP group could not be mobilized due to their clinical condition. Furthermore, we were unable to analyze certain factors that could have influenced the capacity of trauma patients to benefit from early mobilization (e.g., presence of orthopedic injuries, need for intubation, frailty measures). It was not possible to compare other outcomes that may have been impacted more by EMP implementation (e.g., functional outcomes, drug free days) as these were not available in the NSTR. Finally, our study was conducted at a single Level I trauma center; thus, our findings may not be generalizable to other institutions with mobility protocols or programs that differ substantially from the EMP at the QEII HSC.

CONCLUSION

In summary, major trauma patients who were part of a progressive ICU mobility program had improved survival compared with patients admitted to ICU prior to EMP implementation. After controlling for confounders, patients admitted to ICU during the post-EMP period had decreased odds of ICU mortality and in-hospital mortality. Further research is required to corroborate our findings and to investigate the timing and amount of mobility that trauma patients receive during their ICU stay to optimize mobility interventions.

AUTHORSHIP

S.J.C., M.E., S.D.H., R.S.G. contributed to designing the study. M.E. analyzed the data. All authors contributed to interpretation of the study results. All authors critically reviewed the article for important intellectual content and approved the final article.

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DISCLOSURE

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