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Outcomes of Extracorporeal Membrane Oxygenation in Acute Respiratory Distress Syndrome Following Traumatic Injury: A Propensity-Matched Analysis

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OBJECTIVES: The purpose of this study is to evaluate the overall occurrence of inhospital mortality in trauma patients who were placed on extracorporeal membrane oxygenation following the complication of the acute respiratory distress syndrome.

DESIGN: Observational cohort study.

SETTING: The data of all patients who were traumatically injured and developed the complication of acute respiratory distress syndrome were accessed from the Trauma Quality Improvement Program database from the calendar years of 2013 to 2016.

PATIENTS: Patients 16 years old and less than 90 years old were included in the study. Variables included patient demography, Injury Severity Score, Glasgow Coma Scale score, Abbreviated Injury Scale score, and outcomes.

INTERVENTIONS: Extracorporeal membrane oxygenation.

MEASUREMENTS AND MAIN RESULTS: Propensity-matched analysis was performed between two groups: patients placed on extracorporeal membrane oxygenation and patients placed on conventional mode of ventilation. The primary outcome was inhospital mortality. Out of 6,121 patients who developed acute respiratory distress syndrome, 118 patients (1.93%) were placed on extracorporeal membrane oxygenation. The pair matched analysis showed significant difference between the two groups (extracorporeal membrane oxygenation vs conventional mode of ventilation) for overall inhospital mortality (35.6% vs 14.4%; $p < 0.001$). There were significant differences found between the two groups for the median hospital length of stay (41 [35–49] vs 27 [24–33]), ICU days (35 [30–41] vs 19 [17–24]), and ventilator days (30 [27–34] vs 15 [13–18]). All p values are less than 0.001.

CONCLUSIONS: Approximately 2% of acute respiratory distress syndrome patients were placed on extracorporeal membrane oxygenation. The overall inhospital mortality remained high despite patients being placed on extracorporeal membrane oxygenation.

KEY WORDS: extracorporeal membrane oxygenator; mortality; severe acute respiratory distress syndrome; trauma

Trauma is a leading cause of death among young adults (age < 45 yr) (1), and it is estimated that one patient dies every 3 minutes due to an injury (2). Many advancements and interventions in trauma care have

not impacted immediate and early death, however, they have resulted in the reduction of deaths at the late stage (3, 4). The development of acute respiratory distress syndrome (ARDS) during hospitalization is one of the leading causes of late-stage deaths (5, 6).

Almost a half of a century since ARDS was first described as a complication, numerous strategies have been added to the critical care armamentarium for curtailing the occurrence of ARDS (7).To date, the mortality rate remains very high (8). Several interventions have been adopted to reduce mortality, but the main treatment involves mechanical ventilation (9) with the goal of providing adequate gas exchange with minimal ventilation-induced lung injury (10). Some strategies include lung protective ventilation, high peek end-expiratory pressure, early prone positioning, and extracorporeal membrane oxygenation (ECMO) (11–15).

Two recent randomized trials involving ECMO in ARDS patients provided conflicting results when compared with the conventional mode of mechanical ventilation (15–17). Mortality as an outcome variable has been studied in trauma patients who underwent ECMO and has shown both increased and decreased rates (18, 19). Furthermore, recent guidelines acknowledged the paucity of knowledge regarding making the recommendation for the use of ECMO in severe ARDS (20, 21).

There are no standardized criteria for the use of ECMO in ARDS. Although there are recommendations for hospitals using ECMO in trauma patients. There is no accreditation process, and as a result, practice patterns can vary greatly. With the majority of ECMO studies in trauma patients consisting of case series with variable results (18, 22–25), we are conducting this study by querying the Trauma Quality Improvement Program (TQIP) data set in order to evaluate the mortality outcomes of trauma patients throughout the U.S. population who were treated with ECMO for ARDS.

METHODS

The study was exempted from the review as per policy of the Hackensack Meridian Institutional Review Board (IRB); therefore, no IRB review was necessary, and thus, no number was assigned because it did not fall under the broad guidelines as human subjects research.

The information of all patients between 16 and 89 years old who developed ARDS were accessed from the American College of Surgeon TQIP database for the calendar years 2013–2016. The data are prospectively collected and deposited to the database. Currently, more than 800 institutions in the United States are participating in the program (26). TQIP provides feedback twice a year to participating institutions regarding their performance on certain key outcomes. In order to keep the data entry correct, TQIP also provides educational opportunities to the hospital staffs through TQIP annual meeting and regular web-based conferences. ARDS is defined as bilateral opacities on chest imaging, which cannot be fully explained by other known conditions (effusions and lobar/lung collage or nodules, and results in respiratory failure, which is not fully explained by cardiac failure and fluid overload and cannot be excluded by objective assessment [e.g., echocardiography]). ARDS is further classified into three categories based on Pao_2/Fio_2 ratio. Mild ARDS means Pao_2/Fio_2 less than or equal to 300 mm Hg, moderate Pao_2/Fio_2 less than 200 mm Hg, and severe Pao_2/Fio_2 less than 100 mm Hg on continuous positive pressure ventilation (26). These characteristics must be consistent with the 2012 Berlin definition (27).

The patients who were placed on ECMO (ECMO+) were compared with patients who were not placed on ECMO (ECMO–) for demographics, mechanism of injury, Injury Severity Score (ISS), Glasgow Coma Scale (GCS), presence of hypotension (systolic blood pressure < 90 mm Hg), Abbreviated Injury Scale (AIS) score, infection complications, and severe acute kidney injury. Infectious complications are described by trained infection control staff as pneumonia (including ventilator-associated pneumonia), urinary tract infections (UTIs) (including catheter-related UTI), blood-borne infections (including central line-related infections) and/or sepsis, and follow the strict guidelines of the TQIP data dictionary (26). Severe AKI is defined as an abrupt decrease in kidney function (defined as three times the serum creatinine [SCr] from baseline or a SCr ≥ 4.0 mg/dL [≥ 353.6 μmol/L]), initiation of renal replacement therapy, or anuria greater than or equal to 12 hours (28).

The primary outcome of the study is overall inhospital mortality, while secondary outcomes are hospital length of stay, ICU days, ventilator days, infective complications, and discharged disposition.

Patient demographic data and outcomes were summarized using summary statistics (median with interquartile range [first quartile–third quartile] for continuous variables, and frequency and percentage for categorical

variables). Since propensity score matching is one of the better methodology for an observational study to find the casual inference (29), we opted to perform the analysis based on estimated propensity score. The propensity score for ECMO was calculated for each subject. The variables used for calculating the propensity score were age, race (White vs nonwhite), gender, hypotension, ISS, GCS, mechanism of injury, and AIS greater than or equal to 3 of the brain, thorax, abdomen, and pelvic body regions. Then one-to-one matching, using the "nearest neighbor," with a caliper of 0.25 SD, was performed to pair ECMO+/ECMO– subjects. The propensity score matching was performed using the R package "MatchIt" (version 3.0.2, R Foundation for Statistical Computing, Vienna, Austria) (30). Summary statistics were performed after matching as described above, and the Wilcoxon signed-rank test was used to compare continuous variables between the matched groups. If the level of a categorical variable was two, the McNemar's test was used to compare the categorical variables between matched groups (31). If the level of a categorical variable was greater than two, the Stuart-Maxwell test was used (31). For the length of total hospital stay, ICU days, and ventilator days, the Kaplan-Meier procedure was used to estimate the median time, and the SE was estimated using the Greenwood's formula (31). The Kaplan-Meier curves were generated with number at risk at several time points. The log-rank test was used to compare the time (Kaplan-Meier curves) between groups (31). The two-sided p value was reported for each test. A p value of less than 0.05 was considered an indication of statistical significance. The reported p values are not adjusted for multiple comparisons. Statistical analysis was performed using the R language (version 3.5.0, R Foundation for Statistical Computing) (32).

RESULTS

Out of 6,121 patients who suffered from ARDS, 118 patients (1.93%) were placed on ECMO. Propensity score matching created 118 pairs. There was significant improvement in standardized mean difference of variables between the groups after propensity matching (**Supplement Fig. 1**, http://links.lww.com/CCX/A613).

There were no significant difference found between the two groups, ECMO versus no ECMO, regarding median age 27 (20–44) versus 28.5 (23–43; p = 0.65), race (White) 70.35% versus 69.5% (p > 0.99), sex (male) 88.1% versus 84.7% (p = 0.58), ISS score 28

(19–38) versus 27 (22–38), GCS score 13.5 (3–15) versus 11 (3–15), and blunt mechanism of injury 87.3% versus 88.1%. Approximately 75% of patients sustained chest trauma and found no difference between the two groups. Approximately 20% of the patients initially presented with hypotension (**Table 1**).

The mortality was significantly higher in the ECMO group, 35.6% versus 14.4% (p < 0.001). There were no significant differences found between ECMO versus no ECMO groups regarding the complications except higher occurrences of severe sepsis, AKI, and UTI were found in ECMO group (**Table 2**). The hospital length of stay, ICU days, and ventilator days were prolonged in the ECMO+ group compared with the ECMO– group (41 [35–49] vs 27 [24–33], 35 [30–41] vs 19 [17–24], and 30 [27–34] vs 15 [13–18]). All p values were less than 0.001 (**Figs. 1–3**). However, there was no significant difference found between the groups in the disposition of patients, who survived at the time of discharge, to rehabilitation centers and skilled nursing facilities (17.1% vs 19.8%), and (43.4% vs 33.7%; p = 0.604) (**Table 3**).

Further analysis showed that there were 80 patients out of 118 who were placed on venous thromboembolism (VTE) prophylaxis. The majority of patients received low-molecular-weight heparin, and other received unfractionated heparin. More than 78% of these patients received prophylaxis within the first 5 days of the hospital admission. There was no significant difference found between the groups, ECMO versus conventional mode of ventilation (CMV), regarding the use of the VTE prophylaxis in this patients' cohort. There was no significant difference between the two groups: ECMO versus CMV regarding occurrence of severe head injury (29.7% vs 32.2%; p = 0.749) and severe thoracic injury (74.6% vs 75.4%; p > 0.99). Please see Table 1.

The timing of the ECMO intervention was available in 83 out of 118 patients. The subgroup analysis showed 55.9% of patients were placed on ECMO less than or equal to 8 days of hospital admission and 44.09% of patients' were placed on ECMO greater than 8 days. There was no significant difference in mortality whether patients were placed on ECMO less than or equal to 8 days or more than 8 days (53.33% vs 46.67%; p = 0.215).

DISCUSSION

Approximately 2% of the patients who suffered from ARDS were placed on ECMO. Our study found

TABLE 1.
Comparison of Extracorporeal Membrane Oxygenation Versus No Extracorporeal Membrane Oxygenation Groups After Propensity Matching

Variable	All Patients (n = 236)	No ECMO (n = 118)	ECMO (n = 118)	p
Age, yr, median (Q1–Q3)	27 (21–44)	28.5 (23–43)	27 (20–44)	0.650
Race (White), n (%)	165 (69.9)	82 (69.5)	83 (70.3)	> 0.99
Sex, n (%)				0.584
Female	32 (13.6)	18 (15.3)	14 (11.9)	
Male	204 (86.4)	100 (84.7)	104 (88.1)	
Hypotension, n (%)	48 (20.3)	24 (20.3)	24 (20.3)	> 0.99
Systolic blood pressure mm Hg, median (Q1–Q3)	118 (93.8–142)	119 (92.3–148)	118 (94.3–135.8)	0.476
Injury Severity Score, median (Q1–Q3)	27 (22–38)	27 (22–38)	28 (19–38)	0.723
Glasgow Coma Scale, median (Q1–Q3)	12 (3–15)	11 (3–15)	13.5 (3–15)	0.620
Type of injury, n (%)				> 0.99
Blunt	207 (87.7)	104 (88.1)	103 (87.3)	
Penetrating	29 (12.3)	14 (11.9)	15 (12.7)	
Mechanism of injury, n (%)				0.001
Bicycle hit by	2 (0.8)	1 (0.8)	1 (0.8)	
Fall	15 (6.4)	7 (5.9)	8 (6.8)	
Gunshot wound	27 (11.4)	14 (11.9)	13 (11)	
Machinery	2 (0.8)	1 (0.8)	1 (0.8)	
Motorcycle	32 (13.6)	15 (12.7)	17 (14.4)	
Motor vehicle traffic accident	139 (58.9)	73 (61.9)	66 (55.9)	
Other transport	6 (2.5)	2 (1.7)	4 (3.4)	
Pedestrian hit by	11 (4.7)	5 (4.2)	6 (5.1)	
Stab wound	2 (0.8)	0 (0)	2 (1.7)	
Abbreviated Injury Scale ≥ 3, n (%)				
Brain	73 (30.9)	38 (32.2)	35 (29.7)	0.749
Thorax	177 (75)	89 (75.4)	88 (74.6)	> 0.99
Abdomen	71 (30.1)	35 (29.7)	36 (30.5)	> 0.99
Pelvic fractures	5 (2.1)	3 (2.5)	2 (1.7)	> 0.99

ECMO = extracorporeal membrane oxygenation, Hypotension = systolic blood pressure < 90 mm Hg, n = number of patients.

TABLE 2.
Mortality and Complications Between the Groups, Extracorporeal Membrane Oxygenation Versus No Extracorporeal Membrane Oxygenation

Variable, n (%)	No ECMO (n = 118)	ECMO (n = 118)	p	OR (95% CI)	Absolute Risk Difference (95% CI)
Blood born infection	3 (2.5)	3 (2.5)	> 0.99	1 (0.017–59.275)	0 (−0.049 to 0.049)
Urinary tract infection	17 (14.4)	6 (5.1)	0.037	0.353 (0.063–0.859)	−0.093 (−0.18 to −0.007)
Pneumonia	53 (44.9)	50 (42.4)	0.801	0.909 (0.527–1.547)	−0.025 (−0.166 to 0.115)
Severe sepsis	9 (7.6)	25 (21.2)	0.005	3.667 (1.603–21.5)	0.136 (0.043–0.228)
Acute kidney injury	21 (17.8)	37 (31.4)	0.038	1.889 (1.062–3.825)	0.136 (0.01–0.261)
Mortality	17 (14.4)	42 (35.6)	0.001	3.083 (1.663–7.75)	0.212 (0.094–0.33)

ECMO = extracorporeal membrane oxygenation, OR = odds ratio.

p values are not adjusted for multiple comparisons.

significantly higher inhospital mortality, longer hospital length of stay, ICU days, and ventilator days in patients who were placed on ECMO.

Although the first description of ARDS was in a traumatically injured patient (33), most of the literature about the use of ECMO in adult patients who develop ARDS has come from patients who developed ARDS following sepsis. Sepsis-induced ARDS has an occurrence greater than 10 times the occurrence of ARDS associated with trauma (34). The most common injury of patients who develop ARDS is thoracic injury leading to pulmonary dysfunction (35). Studies vary in multiple aspects pertaining to using ECMO in ARDS patients, including the methods of venovenous or venoarterial, inclusion and exclusion criteria, initiation timing, strategies, weaning, patient management staff, and indications for transferring patients to specialized ECMO centers (36–39).

Two randomized trials about the benefit of the use of ECMO in severe ARDS patients had variable results and have made the utilization of ECMO more complicated (15, 16). The utility of ECMO in trauma patients exponentially increased from 2008 to 2012 (25). Cordell-Smith et al (22) reported a case series of 28 trauma patients who developed severe ARDS following a blunt chest injury and/or long bone fractures. It showed a favorable survival outcome by placing the patients on ECMO. Ahmad et al (23) reported a series of 46 trauma patients who were placed on ECMO due to severe ARDS. Seven of the patients were placed on venoarterial ECMO, and the remaining patients were placed on venovenous ECMO. There was
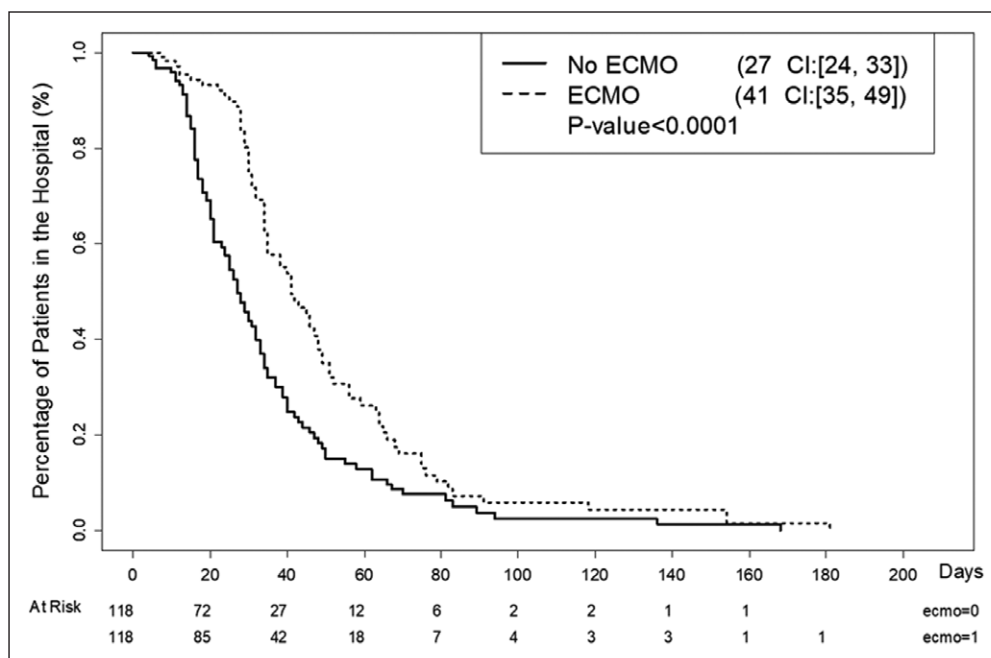
Figure 1. The Kaplan-Meier curves of hospital length of stay with number at risk. ECMO = extracorporeal membrane oxygenation.
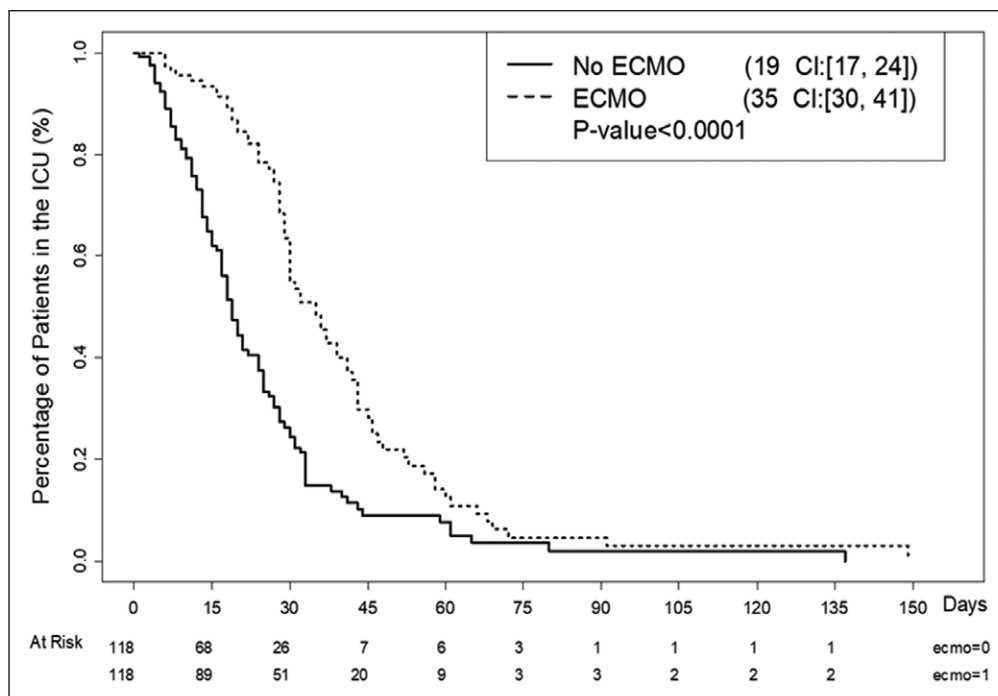
Figure 2. The Kaplan-Meier curves of intensive care days with number at risk. ECMO = extracorporeal membrane oxygenation.
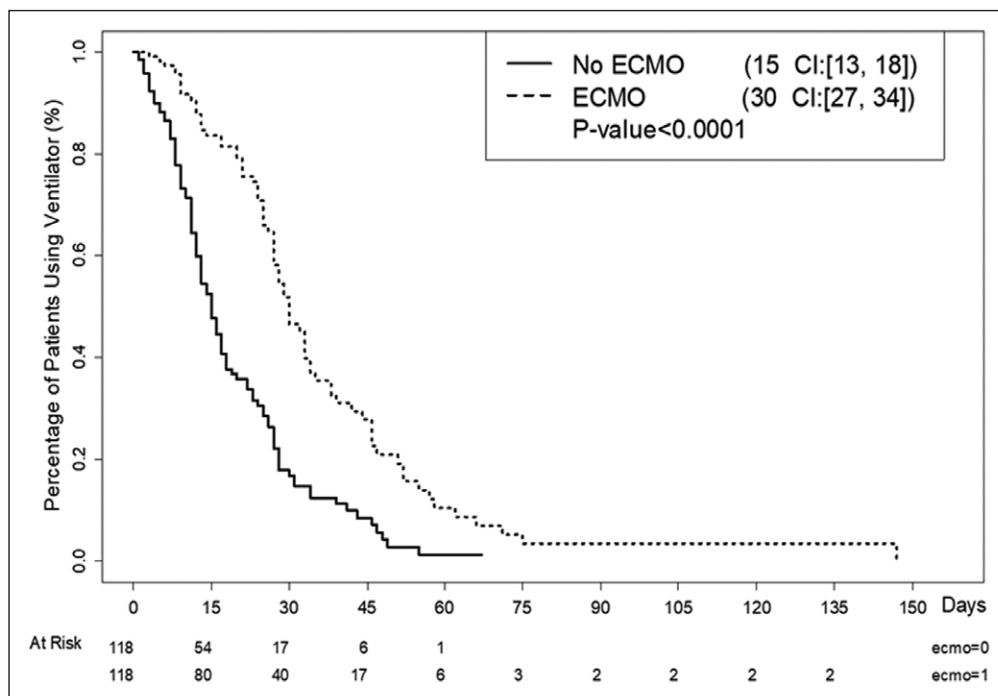
Figure 3. The Kaplan-Meier curves of ventilator days with number at risk. ECMO = extracorporeal membrane oxygenation.

a 100% mortality among venoarterial ECMO patients. The overall mortality for patients placed on venovenous ECMO was 56%, which was consistent with the other study (24). Patients who did not survive had a significantly higher median ISS compared with patients who survived (41 [26–50] vs 25 [18–32]; p = 0.03). A recent study presented a case series of 15 patients who were placed on ECMO for severe ARDS after a trauma and compared them with CMV (18). The patients were placed on ECMO very early. The median time for the development of ARDS was (5.0 d [2.0–9.0 d]), and the average timing of placing patients on ECMO after ARDS was (1.9 ± 1.4 d). The significant reduction in mortality (13.3% vs 64.3%; p = 0.01) in the ECMO patients was a favorable outcome; however, the study had a very small sample size. Furthermore, a lack of information about prone positioning patients before selecting ECMO raises a question about the maximum utilization of conventional measures (13). Hu et al (25) used the National Inpatient Sample database from 2000 to 2012. They reviewed all trauma patients who were placed on ECMO and included more than 1,400 patients in their study. The majority of the patients suffered from chest trauma. Rib fracture was the most common injury. The median hospital length of stay was 26 days. The overall mortality of ECMO patients was 48%.

In this study, we used the TQIP database and compared all ARDS patients, who were placed on ECMO, with patients who were on conventional modes of ventilation and found that approximately 2% of the ARDS patients were placed on ECMO. We conducted

TABLE 3.

Disposition of Patients Who Survived at the Time of Discharge From the Hospital

Variable	No ECMO (*n* = 101)	ECMO (*n* = 76)	*p*
Hospital disposition, n (%)			0.604
Another hospital	8 (7.9)	8 (10.5)	
Home: Healthcare	8 (7.9)	2 (2.6)	
Home: No services	26 (25.7)	19 (25)	
Hospice care	2 (2)	1 (1.3)	
Intermediate care	2 (2)	0 (0)	
Left against medical advice	1 (1)	0 (0)	
Long-term care	20 (19.8)	13 (17.1)	
Skilled nursing care	34 (33.7)	33 (43.4)	

ECMO = extracorporeal membrane oxygenation.

a retrospective observational study and calculated the estimated propensity score of all patients who were placed on ECMO and paired them with the patients who remained on a CMV to reduce selection bias and improve the balance between the two groups. We included variables in the propensity score matching that can impact the decision of putting patients on ECMO. The majority of our patients' (~75%) suffered from severe thoracic injury followed by severe head injury in ~30% of cases (Table 1). Our study did show a significant difference in the mortality outcome in patients who were placed on ECMO versus the CMV (35.6% vs 14.4%; $p = 0.001$). The reason for lower mortality rate in CMV group in our study may be the patients in CMV group were not severely hypoxic. Further analysis of the ECMO patients who received ECMO early (≤ 8 d) did not show any survival benefit when compared with the patients who were placed on ECMO after a week. Our study, showed a prolonged hospital course in patients who were placed on ECMO, including median hospital length of stay (41 [35–49] vs 27 [24–33]; $p < 0.001$), ventilator days (30 [27–34] vs 15 [13–18]; $p < 0.001$), and ICU days (35 [30–41] vs 19 [17–24]; $p < 0.0001$). When compared the morbidities between the two groups, ECMO group had significantly higher occurrence of severe sepsis, UTI, and AKI that is consistent with other

published report (5). The question remains whether to place a severe ARDS trauma patient on ECMO or not. It depends upon the availability of resources and expertise of the clinical team. A continued high mortality rate may result from ECMO being used as a last resort. Perhaps early intervention may provide better results (18).

There are several limitations in our study. We used the TQIP database that is designed for risk-adjusted benchmarking to provide hospitals with accurate national comparisons. Not all trauma centers report to TQIP, and it does not include nontrauma centers. The database also does not provide detailed information about respiratory mechanics and the results of blood gases including Pao_2 and Fio_2 information. Furthermore, the lack of standardization in the ECMO intervention leads to practice variability. Therefore, there is a possibility of selection bias in the placement of patients on ECMO. To address these limitations, we performed estimated propensity score matching to remove selection bias and included all the possible variables available from the dataset in our analysis, which may have contributed to the selection of patients on ECMO. However, propensity-matching analysis does not take into account any unknown or unmeasured factors that may have contributed to immortal time bias and influenced the results.

CONCLUSIONS

A fraction of patients with ARDS were placed on ECMO. Mortality associated with ARDS in trauma victims remains high despite placing the patients on ECMO. Patients who were on ECMO had a prolonged hospital length of stay. The results from our study should be interpreted with caution.

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