

# Nationwide utilization of cardiopulmonary bypass in cardiothoracic trauma: A retrospective analysis of the National Trauma Data Bank

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<b>BACKGROUND:</b>	The American College of Surgeons Committee on Trauma requires that all level I trauma centers have cardiopulmonary bypass (CPB) capabilities immediately available. Despite this mandate, there are limited data on the utilization and clinical outcomes among trauma patients requiring CPB in the management of injuries. The aim of this study was to evaluate the current use of CPB in the care of trauma patients.
<b>METHODS:</b>	This is a retrospective analysis of the National Trauma Data Bank from 2010 to 2015. Adult patients sustaining cardiothoracic injuries who underwent surgical repair within the first 24 hours of admission were included. Propensity score matching was used to compare outcomes (in-hospital mortality, hospital length of stay (LOS), intensive care unit LOS, and complications) between patients who underwent CPB within the first 24 hours of admission and those with similar injuries who did not receive CPB.
<b>RESULTS:</b>	A total of 28,481 patients who met the inclusion criteria were identified, of whom 319 underwent CPB. Three-hundred three CPB patients were matched to 895 comparison patients who did not undergo CPB. Overall in-hospital mortality was 35%. Patients who were not treated with CPB had a significantly higher in-hospital mortality compared with those treated with CPB (odds ratio, 1.57; 95% confidence interval, 1.16–2.12; $p = 0.003$ ); however, complications were significantly lower in those who did not receive CPB (odds ratio, 0.63; 95% confidence interval, 0.47–0.86; $p = 0.003$ ). Hospital LOS (non-CPB: mean, $13.4 \pm 16.3$ days; CPB: mean, $14.7 \pm 15.1$ days; $p = 0.23$ ) and intensive care unit LOS (non-CPB: mean, $9.9 \pm 10.7$ days; CPB: mean, $10.1 \pm 9.7$ days; $p = 0.08$ ) did not differ significantly between groups.
<b>CONCLUSION:</b>	The use of CPB in the initial management of select cardiothoracic injuries is associated with a survival benefit. Further investigation is required to delineate which specific injuries would benefit the most from the use of CPB. ( <i>J Trauma Acute Care Surg.</i> 2021;91: 501–506. Copyright © 2021 Wolters Kluwer Health, Inc. All rights reserved.)
<b>LEVEL OF EVIDENCE:</b>	Therapeutic, level IV.
<b>KEY WORDS:</b>	Cardiopulmonary bypass; cardiothoracic injury; cardiac injury; vascular injury.

Gibbon<sup>1</sup> first began the development of cardiopulmonary bypass (CPB) in 1932, which led to the first successful procedure using CPB in 1953 to repair an atrial septal defect. Mattox and Beall<sup>2</sup> were among the first to describe the use of CPB in trauma patients with injuries to the cardiac and thoracic aorta in 1976. Since that time, there have been remarkable developments allowing resuscitative CPB to be readily available in emergency situations as a tool in the armamentarium for care of trauma patients, including percutaneous access techniques, heparin-bonded circuitry, portable membrane oxygenators, and

CPB machinery.<sup>2,3</sup> The American College of Surgeons Committee on Trauma now requires that all verified level I trauma centers have CPB capabilities immediately available.<sup>4</sup> The literature to support the use of CPB in trauma patients, however, is limited to case series from busy trauma centers<sup>5–8</sup> and multiple case reports.<sup>9–11</sup> To date, no studies have been conducted on the national scale to investigate the utilization of CPB or clinical outcomes among trauma patients requiring CPB, and no clear survival advantage has thus far been established.

The aim of this study was to evaluate the current use of CPB in surgical trauma care using the National Trauma Data Bank (NTDB). We hypothesized that patients with cardiothoracic injuries requiring emergent surgical repair who were placed on CPB within the initial 24 hours of presentation would have improved in-hospital survival over those where CPB was not used.

## PATIENTS AND METHODS

This is a retrospective analysis using the Research Data Set of the NTDB for years 2010 to 2015, which belongs to and is maintained by the American College of Surgeons. This study underwent review and approval from the Institutional Review Board at Tufts Medical Center (Boston, MA).

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## Study Design and Cohort

The study cohort included adult trauma patients 15 years and older who had sustained at least one cardiothoracic injury, as determined by Abbreviated Injury Scale (AIS) 1998 codes with known severity. Abbreviated Injury Scale 2005 codes were not used for injury identification because they were inconsistently available within the NTDB during the study period, and missing codes were automatically recorded using the AIS 1998 coding system. Patients' demographic information and clinical characteristics including age, sex, race, comorbidities, mechanism of injury (blunt versus penetrating), admission vital signs, and type and region of treating institution were collected. Other sustained injuries with AIS score of  $>2$  severity were also recorded and classified by anatomical region. Patient injuries were further combined into one of three injury pattern groups: thoracic vessel injury, lung and airway injury, and cardiac injury (Supplemental Digital Content, Appendix 1 <http://links.lww.com/TA/C33>). Patients undergoing heart, vessel, or lung repair procedures within the first 24 hours of admission were then identified using the *International Classification of Diseases, Ninth Revision, Clinical Modification* procedure codes (Supplemental Digital Content, [http://links.lww.com/TA/C34Appendix 2](http://links.lww.com/TA/C34Appendix2)). Patients were then classified as having received CPB within the first 24 hours or not having received CPB at any point during their hospitalization. Cardiopulmonary bypass was based on the *International Classification of Diseases, Ninth Revision*, procedure code for extracorporeal circulation auxiliary to open heart (39.61). Patients undergoing extracorporeal membrane oxygenation as identified by *International Classification of Diseases, Ninth Revision, Clinical Modification* for extracorporeal membrane oxygenation (39.61) and percutaneous extracorporeal membrane oxygenation (39.66) were excluded. The primary outcome was in-hospital mortality. Secondary outcomes were hospital length of stay (LOS), intensive care unit (ICU) LOS, types of procedures performed, and complications, as defined by the National Trauma Data Standard.

## Statistical Analysis Propensity Score Model and Matching

Patients who underwent CPB within 24 hours of admission were compared with those who did not undergo CPB (but who received other heart/vessel/lung procedures, as defined above) using 3:1 **propensity score (PS) matching**. The PS model included sex, mechanism of injury (blunt or penetrating), race (White, Black, other, not recorded), year of injury, presence of other chest injuries (heart, lung, vessels, thoracic aorta, pulmonary artery, pulmonary vein, myocardium, pericardium, intra cardiac, coronary artery), severity of chest injury (or worst chest injury, if multiple), presence of associated injuries (head, abdomen, spine, extremities), trauma center level (1–2 vs. other), and region of country (Midwest, Northeast, South, West). These variables were selected based on their role as **confounders** of the treatment-outcome relationship, and their relatively complete capture in the dataset. Using the Statistical Analysis System procedure “psmatch,” each CPB patient was matched with up to three non-CPB patients using a greedy matching algorithm with a caliper equal to 20% of the logit of the PS. Covariate balance before and after

PS matching was assessed using absolute standardized differences, with values  $<0.1$  indicating adequate balance.<sup>12</sup>

## Outcome Models

**Mixed-effects logistic regression**, with treating facility as a random effect, was used to compare in-hospital mortality and complications between treatment groups. Hospital LOS and ICU LOS were compared using **negative binomial mixed-effects regression models** as appropriate for count outcomes. Statistical analyses were performed using **Stata v16.1** (StataCorp LLC, College Station, TX) and **SAS version 9.4** (SAS Institute, Cary, NC), with two-sided tests and  $\alpha = 0.05$ .

## RESULTS

A total of 28,481 patients met the inclusion criteria. Of these, 319 patients underwent CPB within the initial 24 hours. Using 3:1 PS matching, 303 patients who underwent CPB were matched to 895 comparison patients who did not receive CPB. The characteristics of these two groups, both before and after PS matching, are summarized in Table 1. Before matching, the groups showed substantial imbalance across a number of covariates, with standardized differences much larger than 0.10. After matching, however, all standardized differences were below 0.1 except for intracardiac injuries, which was 0.11 (Table 1), indicating adequate balance between the two groups.

The most common surgical procedures performed within the first 24 hours of admission for both matched groups are described in Table 2. In both groups, vessel repair procedures were the most common (non-CPB, 52.5%; CPB, 65.0%), followed by heart repair procedures (non-CPB, 36.0%; CPB, 35.6%) and exploratory thoracotomy (non-CPB, 30.4%; CPB, 16.2%).

The results of the PS-matched analysis are described in Tables 3 and 4. In-hospital mortality among those not treated with CPB was significantly higher than those treated with CPB (odds ratio, 1.57; 95% confidence interval, 1.16–2.12;  $p = 0.003$ ). In contrast, there was a significantly lower rate of complications among those who did not receive CPB (odds ratio, 0.63; 95% confidence interval, 0.47–0.86;  $p = 0.003$ ). The most common complications in both groups were pneumonia (7.6% CPB, 6.8% non-CPB) and cardiac arrest (6.2% CPB, 7.8% non-CPB). Length of hospital (non-CPB: mean,  $13.4 \pm 16.3$  days; CPB: mean,  $14.7 \pm 15.1$  days;  $p = 0.23$ ) and ICU (non-CPB: mean,  $9.9 \pm 10.7$  days; CPB: mean,  $10.1 \pm 9.7$  days,  $p = 0.08$ ) stay did not differ significantly between the treatment groups.

## DISCUSSION

This is the largest study to date investigating the use of CPB in patients with cardiothoracic injuries who were managed with CPB within the initial 24 hours of presentation. Patients who underwent CPB within 24 hours of admission had a significantly lower rate of in-hospital mortality compared with those with similar injuries who did not undergo CPB. However, the use of CPB was accompanied by a significantly higher rate of complications.

Overall, 1.1% (319 of 28,481 patients) of the patients in this series were acutely managed with CPB in the initial 24 hours. Wall et al.<sup>13</sup> reported the management of complex cardiac injuries at the Ben Taub Trauma Center in Houston Texas over a 20-year period and similarly noted a need for CPB in

**TABLE 1.** Baseline Characteristics Before and After Propensity-Score matching

	Before Matching			After Matching		
	No Bypass n = 27,062	Bypass n = 303	Absolute Standardized Difference	No bypass n = 895	Bypass n = 303	Absolute Standardized Difference
Female	5,080 (18.8)	62 (20.5)	0.04	185 (20.7)	62 (20.5)	0.01
Age	38.5 (17.5)	38.9 (18.1)	0.02	40.0 (18.4)	38.9 (18.1)	0.06
Race			0.24			0.03
White	13,980 (51.7)	192 (63.4)		565 (63.1)	192 (63.4)	
Black	7,590 (28.0)	65 (21.5)		197 (22.0)	65 (21.5)	
Other	4,132 (15.3)	33 (10.9)		92 (10.3)	33 (10.9)	
Not recorded	1,360 (5.0)	13 (4.3)		41 (4.6)	13 (4.3)	
SBP	110.9 (42.0)	110.3 (40.5)	0.02	108.9 (43.2)	110.3 (40.5)	0.03
Total GCS	14.0 (3.0, 15.0)	14.0 (3.0, 15.0)	0.03	14.0 (3.0, 15.0)	14.0 (3.0, 15.0)	0.03
ISS AIS	25.0 (16.0, 34.0)	29.0 (25.0, 41.0)	0.49	29.0 (25.0, 41.0)	29.0 (25.0, 41.0)	0.03
Year			0.37			0.06
2010	4,226 (15.6)	68 (22.4)		200 (22.3)	68 (22.4)	
2011	4,537 (16.8)	78 (25.7)		209 (23.4)	78 (25.7)	
2012	4,808 (17.8)	51 (16.8)		160 (17.9)	51 (16.8)	
2013	4,478 (16.5)	36 (11.9)		114 (12.7)	36 (11.9)	
2014	4,508 (16.7)	44 (14.5)		134 (15.0)	44 (14.5)	
2015	4,505 (16.6)	26 (8.6)		78 (8.7)	26 (8.6)	
Mechanism of injury			0.31			0.00
Blunt	12,819 (47.4)	190 (62.7)		562 (62.8)	190 (62.7)	
Penetrating	14,243 (52.6)	113 (37.3)		333 (37.2)	113 (37.3)	
Head injury >2	6,273 (23.2)	47 (15.5)	0.19	156 (17.4)	47 (15.5)	0.05
Abdominal injury >2	8,329 (30.8)	57 (18.8)	0.28	190 (21.2)	57 (18.8)	0.06
Spine injury >2	2,605 (9.6)	22 (7.3)	0.09	75 (8.4)	22 (7.3)	0.04
Other injury >2	17 (0.1)	0 (0.0)	0.04	1 (0.1)	0 (0.0)	0.05
Extremity injury >2	6,782 (25.1)	63 (20.8)	0.10	180 (20.1)	63 (20.8)	0.02
Lung injury	12,211 (45.1)	130 (42.9)	0.04	377 (42.1)	130 (42.9)	0.02
Heart injury	4,064 (15.0)	118 (38.9)	0.56	379 (42.3)	118 (38.9)	0.07
Vessels injury	4,475 (16.5)	179 (59.1)	0.98	529 (59.1)	179 (59.1)	0.00
Thoracic aorta injury	1,378 (5.1)	132 (43.6)	1.00	383 (42.8)	132 (43.6)	0.02
Pulmonary artery injury	396 (1.5)	11 (3.6)	0.14	28 (3.1)	11 (3.6)	0.03
Pulmonary vein injury	178 (0.7)	6 (2.0)	0.12	20 (2.2)	6 (2.0)	0.02
Myocardial + pericardial injury	4,021 (14.9)	113 (37.3)	0.53	366 (40.9)	113 (37.3)	0.07
Intracardiac injury	42 (0.2)	11 (3.6)	0.26	16 (1.8)	11 (3.6)	0.11
Coronary artery injury	77 (0.3)	11 (3.6)	0.24	25 (2.8)	11 (3.6)	0.05
Chest injury severity			1.02			0.03
AIS 1–2	3,209 (11.9)	3 (1.0)		10 (1.1)	3 (1.0)	
AIS 3–4	19,877 (73.4)	131 (43.2)		375 (41.9)	131 (43.2)	
AIS 5–6	3,976 (14.7)	169 (55.8)		510 (57.0)	169 (55.8)	
Trauma center level			0.03			0.01
All other	942 (3.5)	12 (4.0)		38 (4.2)	12 (4.0)	
Levels 1 and 2	26,120 (96.5)	291 (96.0)		857 (95.8)	291 (96.0)	
Region of country			0.19			0.05
Missing	4,767 (17.6)	45 (14.9)		137 (15.3)	45 (14.9)	
Midwest	4,082 (15.1)	60 (19.8)		186 (20.8)	60 (19.8)	
Northeast	3,771 (13.9)	55 (18.2)		168 (18.8)	55 (18.2)	
South	9,025 (33.3)	92 (30.4)		266 (29.7)	92 (30.4)	
West	5,417 (20.0)	51 (16.8)		138 (15.4)	51 (16.8)	

Data are presented as mean (SD) or median (IQR) for continuous measures and n (%) for categorical measures.  
AIS ISS, Abbreviated Injury Scale Injury Severity Score; GCS, Glasgow Coma Scale; SBP, systolic blood pressure.

**TABLE 2.** Surgical Procedures (in First 24 Hours)

	No bypass n = 895	Bypass n = 303
Lung procedure	132 (14.7)	37 (12.2)
Cardiovascular system procedure	5 (0.6)	22 (7.3)
Papillary muscle procedure	0 (0.0)	3 (1.0)
Septal repair procedure	12 (1.3)	9 (3.0)
Revascularization procedure	40 (4.5)	17 (5.6)
Heart repair procedure	322 (36.0)	108 (35.6)
Vessel repair procedure	470 (52.5)	197 (65.0)
Extracorporeal membrane oxygenation	3 (0.3)	3 (1.0)
Percutaneous bypass	2 (0.2)	0 (0.0)
Exploratory thoracotomy	272 (30.4)	49 (16.2)
Sternotomy	60 (6.7)	33 (10.9)

approximately 1% of patients. In contrast to our study, Wall et al.<sup>13</sup> reported the use of CPB over the entire hospital course and noted that, in many of the cases where CBP was used, it was for delayed repair of valvular and septal injuries diagnosed after the index operation. Given the limited available data, this study currently represents the best estimated nationwide rate at which CPB is used for cardiothoracic injuries in the first 24 hours.

To date, there have been inconsistent results as to whether there is a survival benefit among trauma patients treated with urgent CPB. The overall in-hospital mortality rate among patients sustaining cardiothoracic trauma who underwent CPB in our study was 23.8%, which compares favorably with other previously reported rates. Dauphine et al.<sup>7</sup> reported a 31% mortality rate among 16 trauma patients with major cardiothoracic injuries treated with use of CPB at University of Los Angeles Medical Center between 1993 and 2002. In a review of nine selected case reports of CPB use in trauma, Chughtai et al.<sup>3</sup> found an overall mortality rate of 44%. Baker et al.<sup>5</sup> reported only a 55% survival rate for patients with penetrating multichamber cardiac wounds who underwent CPB, whereas Pate et al.<sup>8</sup> describes a 90.9% survival rate among 88 patients treated for traumatic aortic rupture under CPB. Using a PS-matching approach, mortality among the patients in our study who received CBP was significantly lower than those with similar injuries who did not receive CBP (23.8% vs. 32.8,  $p = 0.003$ ). This finding provides the best

**TABLE 4.** Clinical Complications

	No Bypass n = 895	Bypass n = 289
Any complication	314 (35.1)	131 (45.3)
Cardiac arrest	70 (7.8)	18 (6.2)
Myocardial infarction	1 (0.1)	2 (0.7)
CVA	4 (0.4)	11 (3.8)
AKI	8 (0.9)	3 (1.0)
ARDS	16 (1.8)	10 (3.5)
Deep SSI	1 (0.1)	0 (0.0)
DVT	16 (1.8)	10 (3.5)
Organ/space SSI	5 (0.6)	0 (0.0)
Pneumonia	61 (6.8)	22 (7.6)
Pulmonary embolism	21 (2.3)	3 (1.0)
Superficial SSI	6 (0.7)	2 (0.7)
Unplanned intubation	13 (1.5)	6 (2.1)
Osteomyelitis	1 (0.1)	0 (0.0)
Unplanned return to OR	12 (1.7)	8 (3.6)
Unplanned return to ICU	7 (1.0)	1 (0.4)
Severe sepsis	14 (2.0)	5 (2.2)

AKI, acute kidney injury; CVA, cerebrovascular accident; DVT, deep vein thrombosis; OR, operating room; SSI, surgical site infection.

available evidence to date that CPB improves survival in selected severely injured trauma patients.

Not surprisingly, the survival benefit accompanying the use of CPB was associated with an increased complication rate, with 45.3% suffering complications in the CPB group compared with 35.1% in those who did not receive CPB in our study. The most common complications in the bypass group were cardiac arrest, pneumonia, cerebrovascular accident, deep vein thrombosis, acute respiratory distress syndrome (ARDS), and unplanned return to the operating room. Interestingly, the rate of cardiac arrest was similar between the CPB (6.2%) and the non-CPB group (7.8%). In addition, those who received CPB also underwent a greater number of overall procedures, with pulmonary procedures, cardiac procedures, and vascular procedures being the most common.

The data for reported complications in other series among the trauma population are scarce and often lacking. Dauphine

**TABLE 3.** Outcomes

	No Bypass n = 895	Bypass n = 303	Odds Ratio* (95% CI)	$p^*$
Any complication (missing 14)	314 (35.1)	131 (45.3)	0.63 (0.47–0.86)	0.003
In-hospital mortality	294 (32.8)	72 (23.8)	1.57 (1.16–2.12)	0.003
	No Bypass n = 895	Bypass n = 303	Relative Mean Ratio* (95% CI)	$p^*$
Mean hospital days (SD)	13.4 (16.3)	14.7 (15.1)	0.92 (0.80–1.05)	0.23
Mean ICU days (SD)	9.9 (10.7)	10.1 (9.7)	0.99 (0.86–1.13)	0.88

\*Estimates from mixed-effects models to account for clustering within facility. Reference for all models is the bypass group.  
CI, confidence interval.



et al.<sup>7</sup> reported that major complications occurred in 25% of patients with penetrating chest trauma who were managed with CPB, including pneumonia, ARDS, renal failure, and stroke. Pate et al.<sup>8</sup> observed that postoperative complications developed in 72.7% of patients who had repair of traumatic aortic rupture with use of CPB, noting that ARDS and pneumonia were the most common (29.5% of patients). Mattox and Beall<sup>2</sup> reported a total of 28 complications among 26 patients in whom CPB was able to be discontinued but affirmed that, without CPB support, none of the patients would have been salvaged. In addition, complication data were missing from 13 of the patients in the matched cohort, potentially resulting in an underestimation of the risk of complications in the CPB group.

The higher rates of complications observed among patients receiving CPB may be explained by several reasons. It has been well established that CPB generates a widespread inflammatory response that results in coagulopathy and temporary organ dysfunction affecting nearly every organ system. This can result in cardiac dysfunction and arrhythmias, ARDS, renal failure, and cognitive impairment, many of the complications observed in our series.<sup>10</sup> Moreover, a higher complication rate is not unexpected when considering that the emergent use of CPB afforded more surgical opportunities to repair patient injuries, and thus, when temporized with CPB, these patients were able to survive long enough to make it to the operating room for interventions they may not have otherwise received. Therefore, we logically propose that the rate of complications and number of procedures performed would have been lower if patients were not placed on CPB to support the ability to perform these critical procedures and survive to accrue complications.

In patients with cardiothoracic trauma with technically challenging injuries, early initiation of CPB may allow for rapid stabilization and definitive repair, which potentially translates into increased survival.<sup>7</sup> We included only patients who were selected for CPB within the initial 24 hours after sustaining life-threatening injuries in this study. We feel that patients who receive CPB after the initial 24 hours are in a different clinical window and are being placed on CPB for different indications.

We propose that being placed on CPB in the initial 24 hour window confers a survival advantage by several mechanisms. First, in severe cardiothoracic trauma, CPB allows for diversion of blood flow away from the injured cardiopulmonary system, reducing ongoing hemorrhage while allowing for peripheral and cerebral perfusion. This provides critical time for resuscitation to restore circulating blood volume and correction of metabolic disturbances before or during operative intervention for hemorrhage control and repair of injuries. Maintaining peripheral perfusion throughout the operation results in improved hemodynamics and metabolic profile, which can allow the patient to endure longer operative times to enable definitive repair at the index operation rather than relying solely on damage-control techniques. As demonstrated by our results, however, this does not necessarily translate into fewer total procedures performed during the hospital course. Second, similar to how CPB is used in cardiac surgery, it allows the surgeon to operate in a field free of ongoing hemorrhage and facilitates better exposure of the injuries, so definitive repair can be expeditiously performed. It is unclear whether our observed survival advantage with CPB use in the initial 24 hours would continue in

patients who were placed on CPB at later periods during the hospital course or for indications other than initial resuscitation and stabilization. Further exploration in this area is needed.

Our study has several limitations. It is a retrospective analysis of the NTDB, a non-population-based nationwide database of levels 1 and 2 trauma centers. The accuracy and completeness of data in the NTDB rely on the reporting institution. By nature, the NTDB is subject to missing or inaccurate data that cannot be confirmed and also may not capture patient-specific clinically relevant details. In particular, given these limitations of the data set, we were unable to determine the exact indication for CPB in each patient or why it was selected for use in some patients but not others who presented with a similar injury pattern. Furthermore, the NTDB does not account for locoregional or institutional differences in management protocols and resource utilization, which may skew the results. Future studies should be aimed at determining the specific indications for CPB use and to further delineate precisely which injuries would benefit most from the use of CPB.

This study also uses a PS model, which is limited by ensuring inclusion of all confounders in the PS model. There may have been confounding variables unavailable in the NTDB, which may have introduced a patient selection bias that could have explained observed associations. For example, data for vital signs were missing on many patients in the NTDB. To retain as many patients as possible in the analysis, vital signs were thus not included in the PS model. This exclusion may also confer a severity of illness bias; that is, patients with unstable vital signs might have been less likely to receive CPB and more likely to die. Missing data in several other areas of the NTDB, including blood product transfusion requirement and comorbidity burden, may have also contributed to the observed increase rate of complications seen among those undergoing CPB, as these patients may have been a sicker population, which was not revealed in the PS matching.

## CONCLUSION

This is the largest reported study on the use of CPB in trauma patients. Patients who underwent CPB had lower in-hospital mortality and a higher rate of complications compared with patients who did not receive CPB. We believe that the mortality benefit observed in our study indicates that CPB is a critical adjunct in the management of severe cardiothoracic trauma within the initial 24 hours of presentation and is likely underused in the initial resuscitation and management of trauma patients. Further prospective studies are warranted to evaluate the utility of CPB for specific injuries and also to delineate specific indications and timing of use.

## AUTHORSHIP

B.P.J. contributed in the literature search, study design, data analysis, data interpretation, writing, and critical revision. H.M.H. contributed in the study design, data analysis, and critical revision. E.J.M. contributed in the study design, data analysis, and critical revision. D.D. contributed in the literature search, data collection, data analysis, data interpretation, writing, and critical revision. M.K. contributed in the literature search, data collection, data interpretation, writing, and critical revision. C.R. contributed in the literature search, data collection, data interpretation, writing, and critical revision. J.L.B. contributed in the study design, data collection, data interpretation, data analysis, and critical revision. N.B. contributed in the study idea, literature search, study design, data analysis, data interpretation, writing, and critical revision.

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## DISCLOSURE

The authors declare no conflicts of interest. This article was drafted in accordance with the **STROBE checklist** for **retrospective observational** studies.

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