**American Association for the Surgery of Trauma**

**Multi-Institutional Trial Committee**

**New Proposal Application Form**

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**Date:** 7/15/2021

**Title of Proposal:** AAST Multicenter Trial: Utilization of Cardiopulmonary Bypass in Traumatic Injuries

**Hypothesis:** We hypothesize that cardiopulmonary bypass is associated with improved survival in patients with cardio-pulmonary injuries.

**Type of Study:** Retrospective

**Background-**

**Define the Knowledge Gap that Study Addresses:**

The American College of Surgeons Committee on Trauma requires that all verified level I trauma centers have cardiopulmonary bypass capabilities (CPB) immediately available (1). The literature to support the use of CPB in trauma patients is limited to case series from busy trauma centers (2-5) and multiple case reports (6-8). Thus far, no studies have been conducted on the national scale to show utilization and outcomes of trauma patients who required CBP.

Our institution recently performed a retrospective 6-year review using the Research Data Set of the National Trauma Data Bank (NTDB) to determine the outcomes of patients with cardiothoracic injuries who were managed with cardiopulmonary bypass (9). In our review, we found that patients who underwent CPB surgery had higher rates of complications, however had statistically significant lower rate of in-hospital mortality. Unfortunately, inherent limitations of the NTDB did not allow us to characterize the CPB patients in depth. We could not identify the exact indications and timing for the CPB utilization. Additionally, from our review of the NTDB, we have found CPB is infrequently used. Our proposed next step is to fill these knowledge gaps by conducting a multicenter retrospective study that will look further into the utilization of CPB in trauma. Given the infrequent use of CPD, we are not able to conduct a prospective review and instead are limited to a retrospective review.

**Study Aim(s)-**

**Primary Aim:** To describe the adult trauma patient population in whom cardiopulmonary bypass was utilized to manage their cardiovascular and pulmonary injuries, as well as to further demonstrate that cardiopulmonary bypass is associated with improved survival.

**Secondary Aim:**  To report indications, morbidity and mortality of the patients who underwent CPB due to cardio-vascular and pulmonary traumatic injuries.

**Proposed Study Population-**

**Inclusion Criteria:** Adult trauma patients (age ≥ 18 years) who underwent cardiopulmonary bypass to manage their traumatic injuries. Adult trauma patients (age ≥ 18 years) who had similar injuries but did not undergo cardiopulmonary bypass will also be included as our control group.

**Exclusion Criteria:** Pediatric trauma patients (age <18 years) will be excluded.

**Outcome Measures-**

**Primary Outcome:** Survival rates associated with the use of cardiopulmonary bypass in the setting of traumatic injuries.

**Secondary Outcome(s):** In-hospital complications (cardiac arrest, myocardial infarction, cerebrovascular accident, acute kidney injury, acute respiratory distress syndrome, sepsis, deep/superficial surgical site infection, organ/space surgical site infection, deep venous thrombosis, pulmonary embolism, pneumonia, unplanned intubation, unplanned return to OR/ICU); ICU length of stay, days on mechanical ventilation, hospital LOS.

**Data Collection Variables:**

Standard demographic variables (age, gender, race), preexisting conditions (Angina Pectoris, anticoagulant therapy, bleeding disorder, Hypertension, Myocardial Infarction, Congestive Heart Failure, Diabetes Mellitus, Chronic Obstructive Pulmonary Disease, Cerebral Vascular Accident, Venous Thromboembolism, Chronic Kidney Disease, cardiac arrhythmias, Liver Cirrhosis), mechanism on injury (blunt/penetrating), injury type and severity (head/face/neck/thorax/abdomen/pelvic content/spine/ extremity upper/lower AIS, ISS, list of injuries), admission physiology (BP, HR, body temperature, pH, lactate, Base excess, INR), presence of respiratory assistance (mechanical ventilation prior to the admission, mechanical ventilation initiated in the ED before the cardiac repair surgery) surgical management variables (time to CPB operation (from time of the injury, from time of the admission), operative interventions (list of surgical procedures performed with CPB assistance, other non-CPB procedures inotrope/vasopressor use), indications for CPB, blood components transfusion (PRBC, FFP, PLT, Cryoprecipitate, Prothrombin complex concentrate, fibrinogen concentrate), timing of the blood components transfusion (prior to CPB surgery, after CPB surgery up to 1st 24h after admission) total 1st 24h after admission), estimated blood loss during CPB surgery, postoperative outcomes (In-hospital complications: cardiac arrest, myocardial infarction, cerebrovascular accident, acute kidney injury, acute respiratory distress syndrome, sepsis, deep/superficial surgical site infection, organ/space surgical site infection, deep venous thrombosis, pulmonary embolism, pneumonia, unplanned intubation, unplanned return to OR/ICU); discharge GCS, ICU length of stay, days on mechanical ventilation, hospital LOS, discharge disposition, mortality, type of treating institution (academic, trauma level designation).

**Planned Duration of Study:** 10 years (2011-2020)

**Center Participation Goal:** 10 **Patient Recruitment Goal:** 500

**Power Analysis Performed: Yes** [ ]  **No** [x]

**Plan for Statistical Analysis:** This will be a retrospective study comparing patients with cardiovascular and pulmonary injuries who underwent the repair of these injuries using CPB (the study group) and without CPB (control group). From our initial study on the use of cardiopulmonary bypass in trauma, we determined that over the 6-year study period, there were over 200,000 lung injuries and nearly 12,000 heart injuries recorded (9). In order to make this process more feasible for our participating trauma centers, we plan to conduct data collection in 2 stages. First, we will ask participating centers to provide patients with traumatic injuries that required CPB in the first 24 hours. Based on our data from our prior study, we estimate this would be approximately 250 patients over a 10-year period. We will then analyze the data to determine which specific injuries were treated using CPB. Then, we will go back and ask participating centers to provide patients with those specific injuries that did not undergo CPB. In both stages, we will collect specific information on survival, complications, hospital course, and management as per our proposal. By completing our study this way, it will help us accomplish two goals. First, we will be able to perform a descriptive study on the practice patterns of CPB. Second, it will allow us to perform hypothesis testing and determine if utilization of CPB reduces mortality in specific injuries.

Data will be collected using REDCap software that is in compliance with HIPPA regulations. Categorical data such as demographics and clinical characteristics of CPB patients will be summarized and presented as the absolute frequencies and percentages. Continuous variables will be presented either as means with standard deviations or median with interquartile range depending on their distribution patterns. With the aid of our statistician, appropriate statistical tests will be conducted to compare survival between the CPB and control groups, as well to compare our secondary outcomes.

**Define How Findings from this Multi-Center Study Will Serve as the Foundation for Future Studies or Future Funded Research:**

This Multi-Center study is both a descriptive and hypothesis generating study, and a hypothesis testing study to redemonstrate the survival benefit of cardiopulmonary bypass that we have shown in our prior research. The results of this study may identify a subset of patients in which CPB should be used more frequently. Additionally, this study may identify specific injuries in which CPB has a significant benefit, which could then be studied in detail in future research.

**Does Study Require Informed Consent, Describe Rationale:**

Our study does not require informed consent. Additionally, as our study is retrospective it would be impractical to obtain consent.

**Database Development-**

**Do you have independent funding?: Yes** [x]  **No** [ ]

**Does your study require upload of imaging studies?: Yes** [ ]  **No** [x]

**If the cost of development of your database exceeds the allotted financial support from AAST, are you able/willing to fund the difference?: Yes** [x]  **No** [ ]

**Key References-**

1. American College of Surgeons, Committee on Trauma. Resources for optimal care of the injured patient. Chicago, IL: American College of Surgeons; 2014.
2. Baker JM, Battisella FD, Kraut E, Owings JT, Follette DM. Use of cardiopulmonary bypass to salvage patients with multiple chamber heart wounds. Arch Surg. 1998
3. Downing SW, Cardarelli MG, Sperling J, Attar S, Wallace DC, Rodriguez A, Brown J, Whitman GJR, McLaughlin JS. Heparinless partial cardiopulmonary bypass for the repair of aortic trauma. J Thorac Cardiovasc Surg 2000
4. Dauphine C, McKay C, De Virgilio C, Omari B. Selective use of cardiopulmonary bypass in trauma patients. Am Surg. 2005
5. Pate JW, Fabian TC, Walker WA. Acute traumatic repair of the aortic isthmus: repair with cardiopulmonary bypass. Ann Thorac Surg 1995
6. Hendel PN, Grant AF. Blunt traumatic rupture of the heart: successful repair of simultaneous rupture of the right atrium and left ventricle. J Thorac Cardiovasc Surg 1981
7. Moore FO, Berne JD, Turner WF, Villarreal DH, McGovern T, Rowe SA, Norwood SH. Off pump coronary artery bypass is an alternative to conventional cardiopulmonary bypass when repair of traumatic coronary arteries is indicated. Am Surg. 2007
8. Reissman P, Rivkand A, Jurim O, Simon D. Case Report: The management of penetrating cardiac trauma with major coronary artery injury – is cardiopulmonary bypass essential?. J Trauma 1992
9. Johnson BP, Hojman HM, Mahoney EJ, Detelich D, Karamchandani M, Ricard C, Breeze JL, Bugaev N. Nationwide Utilization of Cardiopulmonary Bypass in Cardiothoracic Trauma: A Retrospective Analysis of the National Trauma Data Bank. J Trauma Acute Care Surg. 2021 Jun 16. Epub ahead of print.