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Systems-based-Protocol-Driven Integration study of Surgical and Critical Care in Cardiovascular Patients: Advancing Anesthesia and ICU Monitoring

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# Abstract

**Background:** Cardiovascular surgery remains associated with high rates of perioperative morbidity and mortality. A major contributor to adverse outcomes is variability in anesthetic management and postoperative intensive care unit (ICU) monitoring, leading to inconsistent practices across institutions and clinicians. Recent advances—including goal-directed hemodynamic therapy, cerebral oximetry, depth-of-anesthesia monitoring, multimodal analgesia, point-of-care ultrasonography, and structured fast-track extubation protocols—have each been shown to reduce complications in selected populations. However, integration of these approaches into a unified, protocol-driven perioperative pathway is limited in clinical practice.

**Methods:** This is a prospective, interventional cohort protocol to evaluate integrated anesthesia and ICU monitoring in adult cardiovascular surgical patients. A total of 300 adults undergoing elective or urgent coronary artery bypass grafting (CABG), valve replacement/repair, or aortic surgery will be enrolled at a tertiary cardiac surgical center. Participants will receive either conventional perioperative care or

protocol-driven management, which incorporates goal-directed anesthesia, multimodal analgesia, algorithm-based hemodynamic monitoring, cerebral oximetry, point-of-care ultrasonography, and structured fast-track extubation within 6 hours of surgery. The primary outcome is a composite of 30-day major adverse cardiac and cerebrovascular events (MACCE) and all-cause mortality. Secondary outcomes include intraoperative hemodynamic instability, acute kidney injury (AKI), postoperative delirium, sepsis, duration of mechanical ventilation, ICU and hospital length of stay, 30-day readmission rates, and cost-effectiveness.

Ethics and Dissemination: The protocol has been approved by the Institutional Review Board. Data will be collected prospectively and analyzed on an intention-to-treat basis. Findings will be disseminated via peer-reviewed journals, international scientific conferences, and potentially incorporated into enhanced recovery after cardiac surgery (ERACS) guidelines.

**Conclusion:** This study aims to operationalize guideline-supported perioperative practices into a unified, protocol-driven pathway. By standardizing care, the protocol has the potential to reduce perioperative morbidity, improve recovery, and optimize resource utilization in cardiovascular surgery.

# Introduction

### Cardiovascular Surgery and Perioperative Risk

Cardiovascular surgery is a cornerstone of modern medicine, with procedures such as coronary artery bypass grafting (CABG), valve repair or replacement, and complex aortic operations performed in large volumes globally. Despite significant advances in surgical techniques, perfusion strategies, and myocardial protection, perioperative morbidity and mortality remain unacceptably high. Reported rates of major adverse cardiac and cerebrovascular events (MACCE) range from 15% to 25% in high-risk cohorts, and perioperative mortality after elective CABG remains between 2% and 5% in many registries [1,2]. For valve and aortic procedures, the risks are often higher, reflecting patient complexity and the physiologic stress of surgery [3].

The perioperative phase is particularly vulnerable due to hemodynamic instability, bleeding, ischemia–reperfusion injury, and systemic inflammatory responses induced by cardiopulmonary bypass (CPB). Postoperative complications include myocardial infarction, low cardiac output syndrome, atrial fibrillation, acute kidney injury (AKI), stroke, delirium, pneumonia, and sepsis. Beyond clinical morbidity, these complications translate into prolonged ICU stays, higher hospital costs, and increased readmissions.

### Variability in Perioperative Management

One of the key challenges in cardiovascular perioperative care is variability in anesthetic practices and ICU monitoring. While clinical guidelines from major societies such as the American Heart Association (AHA), American College of Cardiology (ACC), Society of Thoracic Surgeons (STS), and European Society of

Anaesthesiology and Intensive Care (ESAIC) exist, their implementation is inconsistent [4–6].

For example, fluid resuscitation may rely on static measures such as central venous pressure rather than dynamic indices of preload responsiveness, despite evidence favoring the latter. Vasopressor use, analgesic strategies, extubation timing, and hemodynamic monitoring vary widely among practitioners. Such heterogeneity contributes to outcome disparities, particularly in institutions where evidence-based protocols are not standardized.

### Innovations in Anesthesia and Monitoring

In recent decades, several perioperative innovations have shown potential to improve outcomes in cardiovascular surgical patients:

Goal-Directed Therapy (GDT): GDT individualizes fluid and vasopressor therapy using advanced monitoring (stroke volume variation, cardiac output, dynamic preload indices). Meta-analyses demonstrate that GDT reduces complications, shortens ICU stays, and improves organ perfusion [7,8].

**Cerebral Oximetry:** Near-infrared spectroscopy (NIRS) monitors cerebral tissue oxygen saturation, allowing early intervention during hypoperfusion. Studies associate cerebral desaturation with postoperative delirium, stroke, and longer ICU stay [9]. Interventions guided by NIRS reduce neurological morbidity [10,11].

**Depth-of-Anesthesia Monitoring:** Processed electroencephalography (EEG) indices such as bispectral index (BIS) help prevent awareness, minimize anesthetic overdose, and reduce hemodynamic swings. Some trials suggest reduced delirium when depth is optimized [12].

Multimodal Analgesia: Combining opioids with acetaminophen, NSAIDs, regional anesthesia, and gabapentinoids reduces opioid exposure and related adverse effects. Enhanced recovery pathways emphasize opioid-sparing strategies [13].

**Point-of-Care Ultrasonography (POCUS):** Bedside cardiac and lung ultrasound allows rapid evaluation of fluid status, ventricular function, tamponade, and pulmonary congestion. Its role in ICU decision-making is increasingly recognized [14].

**Fast-Track Extubation:** Early extubation (<6 hours) after cardiac surgery reduces ventilator-associated complications, shortens ICU stay, and may improve cardiac performance. Multidisciplinary fast-track programs have proven safe and effective [15–17].

ICU-Level Advances

At the ICU level, structured hemodynamic algorithms, early warning scores, and predictive analytics support timely interventions. Enhanced recovery after cardiac surgery (ERACS) frameworks integrate multimodal analgesia, delirium prevention, glycemic control, and mobilization protocols. These approaches have reduced mechanical ventilation times and ICU length of stay, without increasing reintubation or adverse events [18].

### Rationale for Protocol Integration

While each of these strategies has demonstrated benefit in isolation, implementation is uneven, and integration into a comprehensive perioperative pathway remains rare. Most centers adopt some elements while neglecting others, limiting their potential impact. Moreover, randomized controlled trials often evaluate single interventions, making it unclear how synergistic benefits might be realized when strategies are combined.

This study addresses this gap by evaluating a **protocol-driven integration of anesthesia and ICU monitoring innovations** in adult cardiovascular surgical patients. By standardizing perioperative care, the protocol aims to reduce variability, improve outcomes, and enhance cost-effectiveness.

## Methods

### Study Design and Setting

This is a prospective, interventional cohort study conducted at a tertiary cardiovascular surgical center with an annual volume of over 1000 cardiac procedures. The center has a dedicated cardiothoracic ICU staffed by intensivists, anesthesiologists, perfusionists, and specialized nurses.

The study will be conducted over 24 months: 12 months of recruitment and 12 months of follow-up. Patients will be allocated to either standard care or protocol-driven care based on perioperative team assignment schedules to minimize selection bias.

## **Participants**

#### **Inclusion Criteria:**

Adults  $\geq 18$  years.

Undergoing elective or urgent CABG, valve replacement/repair, or ascending aortic surgery.

#### **Exclusion Criteria:**

Emergency salvage procedures (e.g., rupture, dissection with shock).

End-stage organ failure (dialysis-dependent chronic kidney disease, decompensated cirrhosis, advanced heart failure with mechanical support).

Refusal or inability to provide informed consent.

#### Interventions

#### **Standard Care Group:**

Anesthesia and ICU management at physician discretion.

Routine monitoring (ECG, invasive arterial line, central venous pressure, urine output).

Analgesia and extubation timing based on clinical judgment.

#### **Protocol-Driven Group:**

Goal-Directed Anesthesia and Hemodynamic Monitoring: Use of advanced monitoring devices (esophageal Doppler or arterial waveform analysis) to guide fluid and vasopressor therapy. Targets: stroke volume variation <13%, mean arterial pressure >65 mmHg, cardiac index >2.2 L/min/m<sup>2</sup>.

**Cerebral Oximetry and Depth-of-Anesthesia Monitoring:** Continuous NIRS with predefined thresholds for intervention (e.g., >20% drop from baseline). Processed EEG to titrate hypnotics.

**Multimodal Analgesia:** Intraoperative acetaminophen, regional techniques (paravertebral block or erector spinae block where feasible), reduced opioid dosing. Postoperative regimen includes acetaminophen, NSAIDs (if renal function allows), and adjuncts.

**ICU Hemodynamic Algorithms:** Standardized protocols for inotropes, vasopressors, and fluid responsiveness testing.

**Point-of-Care Ultrasonography:** Daily POCUS assessments of cardiac function and lung status to guide fluid and ventilatory management.

**Fast-Track Extubation:** Target extubation within 6 hours if hemodynamically stable, with criteria for readiness (adequate oxygenation, normothermia, low bleeding risk).

**Early Mobilization and Delirium Prevention:** Daily sedation interruption, delirium screening (CAM-ICU), and physiotherapy.

#### Outcomes

#### **Primary Outcome:**

Composite of 30-day MACCE (myocardial infarction, stroke, cardiac arrest, or need for reintervention) and all-cause mortality.

#### **Secondary Outcomes:**

Intraoperative hemodynamic instability (episodes of MAP <55 mmHg >5 min, or lactate >4 mmol/L).

Acute kidney injury (KDIGO criteria).

Delirium (CAM-ICU positive).

Sepsis (Sepsis-3 definition).

Duration of mechanical ventilation (hours).

ICU and hospital length of stay (days).

30-day readmissions.

Cost-effectiveness (incremental cost-effectiveness ratio).

## Sample Size

Assuming a complication rate of 25% in standard care and expecting reduction to 15% with protocol-driven management, with  $\alpha$ =0.05 and 80% power, the sample size required is 270. Allowing for 10% attrition, the final target is 300 patients (150 per group).

#### Data Collection

Data will be collected prospectively using standardized case report forms and entered into a secure electronic database. Variables include demographics, comorbidities, EuroSCORE II, intraoperative hemodynamics, ICU monitoring data, complications, and economic outcomes.

Statistical Analysis

Primary analysis: Intention-to-treat.

Categorical variables:  $\chi^2$  or Fisher's exact test.

Continuous variables: Student's t-test or Mann–Whitney U test.

**Survival analysis:** Kaplan–Meier curves with log-rank tests.

**Confounder adjustment:** Multivariate logistic regression including age, EuroSCORE II, surgery type.

Economic evaluation: Incremental cost-effectiveness ratio (ICER) per quality-adjusted life-year (QALY) gained.

#### Ethical Considerations

The protocol has Institutional Review Board approval. Informed consent will be obtained preoperatively. Confidentiality will be maintained, with data anonymized prior to analysis. Adverse events will be monitored by an independent safety committee.

## Discussion

## Expected Benefits

This protocol is designed to integrate evidence-based perioperative innovations into a structured pathway. The expected benefits include:

- 1. **Reduced MACCE:** Optimized hemodynamic management and cerebral oximetry are expected to lower myocardial infarction and stroke rates.
- 2. **Improved Organ Protection:** GDT and POCUS-guided fluid therapy may reduce AKI and sepsis.
- 3. **Enhanced Recovery:** Fast-track extubation and early mobilization should shorten ICU stay.
- 4. **Cost-Effectiveness:** Standardized care may reduce readmissions and hospital resource utilization.

#### Comparison to Prior Studies

Previous RCTs have demonstrated the benefits of GDT [7,8], cerebral oximetry [9–11], and fast-track extubation [15–17]. However, these interventions have rarely been implemented simultaneously. The novelty of this protocol lies in operationalizing multiple evidence-based strategies in a single system-level approach.

## <u>Strengths</u>

Real-world applicability in a high-volume center.

Multidisciplinary design including anesthesiologists, surgeons, intensivists, and nurses.

Evaluation of both clinical and economic outcomes.

## Limitations

Single-center design may limit generalizability.

Strict protocol adherence may be challenging in urgent cases.

Advanced monitoring technologies may not be universally available.

## Knowledge Translation

If successful, this protocol could inform updates to ERACS guidelines, influence STS and EuroSCORE benchmarking, and serve as a model for global implementation. The integration of monitoring and care pathways aligns with the shift toward value-based care in cardiovascular surgery.

#### Future Directions

Expansion into multicenter randomized trials.

Incorporation of machine learning algorithms for hemodynamic prediction.

Adaptation of the protocol for thoracic or transplant surgery.

# Conclusion

This prospective, interventional cohort study evaluates a protocol-driven integration of anesthesia innovations and ICU monitoring in cardiovascular surgery. By standardizing perioperative care, the protocol seeks to reduce MACCE and mortality, improve organ protection, shorten ICU stays, and enhance cost-effectiveness. If validated, this approach may serve as a template for global perioperative cardiac care pathways and advance the field toward safer, more consistent outcomes.

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