Clinical References

CDI OneView™ Monitoring System

Research shows that the largest area under the DO_2 curve (AUC) is an independent risk factor for acute kidney injury (AKI).[1]

Managing indexed oxygen delivery (DO_2i) in relation to oxygen extraction ratio (O_2ER) has been shown to reduce the incidence of hyperlactatemia (HL) during surgery as well as to reduce postoperative serum creatinine, mechanical ventilation time and intensive care unit (ICU) stay.[2]

Terumo's proprietary chemical fluorescent technology and device interconnectivity continuously display up to ***22*** vital patient parameters, including oxygen delivery (DO_2), cardiac index (CI), area under the DO_2i curve, O_2ER, and measured flow.

A substantial volume of peer-reviewed evidence strongly advocates for the monitoring and preservation of optimal levels of DO_2 during cardiopulmonary bypass (CPB).[1-17]

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Major Insights

Maintaining appropriate levels of DO_2 can lead to positive outcomes in various aspects of patient care, including:

- Reduced incidence of AKI [1-2, 7-11, 15-16]
- Improved patient outcomes and lower rates of morbidity and mortality[7, 8-16]
- Shorter stays in the ICU/overall hospital length of stay (LOS)[7, 12-13, 17]
- Decreased hospital costs[10,13-14,17]

Goal-Directed Perfusion

Optimizing red cell mass at the critical period at the onset of CPB through decreased hemodilution, increased flow, and ***continuous*** monitoring of DO_2 is critical.[3, 10]

- Goal-directed therapy is a patient care strategy that is designed to improve patient outcomes. This patient care strategy incorporates aggressive and individualized patient management and monitoring during periods of critical care.[3]
- Goal-directed perfusion aims to use intensive monitoring during CPB to reduce mortality and postoperative complications. Perfusionists have the opportunity to administer therapy to patients intraoperatively, which is one of the most critical times for goal-directed therapy.[3]
- Optimal perfusion requires intensive and focused monitoring to maintain the desired parameters within a very narrow therapeutic range for each individual patient. This goal-directed patient management should be associated with optimal DO_2 and tissue perfusion with reduced inflammatory response, preservation of the coagulation cascade, maintenance of colloid oncotic pressure, and fluid balance. This results in “the best long-term patient outcome in terms of survival and function of all major organ systems” resulting in low morbidity and reduced postoperative recovery periods.[3]

Standards and Guidelines

The European Association of Cardiothoracic Anesthesiology/European Association for Cardio-Thoracic Surgery/European Board of Cardiovascular Perfusion (EACTA/EACTS/EBCP) guidelines recommend goal-directed therapy as a Class 1, Level A (highest level) recommendation "to reduce the rate of postoperative complications and length of hospital stay." Perioperative optimization of the balance between DO_2 and VO_2 is a cornerstone of the management of patients undergoing cardiac surgery.[4]

The American Society of Extra Corporeal Technology (AmSECT) Standards and Guidelines recommend the use of continuous in-line blood gas monitoring.[5, 6]

Acute Kidney Injury

The kidneys are sensitive to the oxygen level in the blood as well as the cardiac output. Less-than-optimal oxygen delivery can cause organ damage. AKI is a sudden or rapid decline in renal filtration function. It is kidney damage/failure that happens within a few hours or days and causes a build-up of waste products in the blood, making it difficult for the kidneys to keep the right balance of fluid in the body. Kidney injury can be chronic or acute and increases morbidity and mortality. AKI results in longer ICU/hospital stays and higher costs, most specifically when the patient requires dialysis.[13]

AKI Prevalence in CPB

Considering that as many as 50% of CPB cases lead to AKI, there exists a significant patient population that could potentially benefit from the continuous monitoring of their DO_2 thresholds.[8,10] The CDI OneView System provides real-time data that can help reduce the incidence of AKI.

- AKI occurs in 2–30% of patients undergoing cardiac surgery, depending on the definition.[7]
- AKI is a common and serious complication with an occurrence rate ranging from 20% to 40% after cardiac surgery with CPB.[1]
- AKI is common after pediatric cardiac surgery, with recorded incidence up to 50%, due to factors directly related to CPB and multifactorial perioperative components.[8]

AKI Clinical Impact

- Preoperative risk models are basically composed by non-modifiable risk factors; conversely, the multifactorial dynamic perfusion index (MDPI) includes a number of modifiable risk factors, like the nadir hematocrit (HCT), the nadir DO_2, the time of exposure to the critical DO_2, the mean arterial pressure, and the use of red blood cell (RBC) transfusion.[9]
- Our analysis demonstrates that the management of DO_2i in relation to O_2ERi was 16% more specific in terms of negative predictive value for HL during CPB compared with the use of CI in relation to SvO_2. The group managed with DO_2i and O_2ERi reported a significant reduction in the incidence of intraoperative lactate peak, correlated with postoperative reduction of serum creatinine value, mechanical ventilation time, and ICU stay, compared with group managed with CI and SvO_2.[2]
- After cardiac surgery, renal function impairment is common, and AKI has an incidence that may reach 50% according to some definitions.[10]
- The early mortality rate in patients with AKI is around 5% but climbs to 50% when renal replacement therapy (RRT) is required.[10]
- Some of the consequences are extended ICU stay, hospital stay, increased need for short- and long-term RRT, progression of chronic kidney disease, including end-stage renal disease, and increased short- and long-term mortality.[7]
- Patients with even mild degrees of AKI have increased mortality and morbidity compared with their matched counterparts. Interventions that prevent or mitigate AKI after cardiac surgery can yield substantial clinical benefits.[11]
- Pediatric patients that developed AKI had worse pre-op ventricular function, longer ischemic times on CPB, longer CPB runs, increased use of intra-op and post-op inotropes, higher albumin administration and higher mean arterial blood pressure (BP) on CPB.[8]

AKI Clinical Importance to Patient Outcomes

- Patients exhibiting symptoms of acute renal failure (ARF) after CPB had a significantly higher mortality rate (11% vs 1.7%; $p = 0.014$), longer ICU stay (5.2 ± 1.2 days vs 2.5 ± 0.9 days; $p < 0.001$), and postoperative hospital stay (15.3 ± 3 vs 7.4 ± 0.2 days; $p < 0.001$) than patients without renal replacement therapy-acute renal failure (RR-ARF).[12]

- We could confirm this critical level of HCT (26%), below which the cardiac surgery-associated acute kidney injury (CSA-AKI) risk linearly increases. Severe hemodilution is per se a risk factor for bad outcomes. In particular, it has been demonstrated that severe hemodilution is deleterious for the microcirculation.[9]

AKI Associated Costs

- AKI after cardiac surgery is one of the major determinants of bad outcomes, with increased early and late mortality rates and a considerable consumption of human and financial resources.[10]
- The ICU and postoperative costs and LOS for patients with AKI are higher than comparable costs for healthy patients, and the gap widens as AKI severity worsens.[13]
- Total and departmental level costs, LOS, and requirement for RRT were higher in AKI patients compared to controls. Statistically significant differences in all costs, mortality rate and requirement for RRT were seen in the patients suffering from AKI post cardiac surgery. Even patients with less severe forms of AKI had a 2.2-fold greater mortality, a 1.6-fold increase in ICU LOS and 1.6-fold increase in total postoperative costs compared to controls.[13]
- At the population level, 1,078,036 individuals underwent major cardiac procedures from 2008 to 2011, with AKI developing in 105,648 (9.8%). Specifically, AKI developed in 8.0% of coronary artery bypass graft (CABG) surgery, 11.4% of valve replacement, and 17.0% of CABG plus valve replacement patients ($p < 0.001$). Death was more common among patients with AKI vs those without (13.9% vs 1.3%, $p < 0.001$). Mean total index hospitalization cost was $77,178 for patients with AKI vs $38,820 for those without ($p < 0.001$). At the national level, the overall incremental annual index hospitalization cost associated with AKI was $1.01 billion.[14]

Goal-Directed Perfusion, DO_2, and AKI

- Severe hemodilution during CPB is associated with an increased AKI risk and is a risk factor for RBC transfusions. Transfusions, in turn, are associated with bad outcomes… CPB techniques may exert a great impact on the degree of hemodilution during CPB.[15]
- It is likely that a comprehensive approach to renal protection, with specific attention to the containment of hemodilution during CPB and the maintenance of adequate DO_2 may represent an effective strategy to limit cardiac operation-induced AKI.[16]
- A GDP strategy during CPB is effective in reducing the risk of minor patterns of AKI (any serum creatinine increase and AKIN stage 1) following cardiac surgery in adult patients.[18]

Monitoring DO_2 and Maintaining a Critical Threshold

- Perfusionists have an important role to play regarding better patient outcomes. The nadir DO_2 level during CPB has been independently associated with postoperative AKI. Since DO_2 during CPB is a modifiable factor through pump flow adjustments, research indicates that goal-directed perfusion management aimed at maintaining the DO_2 level above the identified critical value might limit the incidence of postoperative AKI.[10]
- DO_2 must be considered as one of the most significant determinants of “optimal” perfusion during CPB. Targeting DO_2 levels above a critical threshold… is more important in preserving organ function than targeting individual hematocrit or pump flow values.[3]
- Higher metabolic rates and oxygen demand in children would suggest adult indexed oxygen delivery (DO_2i) reference ranges cannot be used to guide practice.[8]
- Time spent on CPB with a DO_2i under 350mL/min/m^2 is independently associated with AKI in pediatric patients.[8]
- Largest Area Under The Curve (AUC) below the DO_2 threshold (300mL/min/m^2) during CPB is an important and independent risk factor for AKI.[1]
- Data suggests that avoiding a continuous or severe decrease of DO_2 (largest AUC below the DO_2 threshold DO_2^{300} <880) could reduce the risk of AKI after cardiac surgery.[1]

Reducing the Risk Leads to Cost Savings

Maintaining healthy DO_2 during cardiac surgery can lead to cost savings for hospitals. Patients with AKI have longer LOS and consume significant resources beyond those with normal kidney function. AKI increases the resources used by patients by doubling their average length of stay in the ICU.[17]

Maintain an Adequate DO_2 Threshold with CDI OneView Monitoring System

Adopting monitoring technologies provides early warning of dynamic changes during surgery. The CDI OneView System allows constant visibility of DO_2 levels, HCT, hemoglobin (Hgb), venous oxygen saturation (SVO_2),

and other critical parameters such as potential hydrogen (pH), partial pressure of carbon dioxide (pCO_2), partial pressure of oxygen (pO_2), potassium ion (K^+), oxygen consumption (VO_2), O_2ER, CI, measured flow, and visibility of cerebral saturations. Designed to provide a comprehensive view of all relevant information, the CDI OneView System enables users to gain valuable insights, make informed decisions, and drive strategic outcomes.

Summary

Numerous studies have demonstrated that precise management of DO_2 during CPB can significantly decrease morbidity and mortality rates.[10,18] The CDI OneView System accurately measures and displays continuous DO_2, empowering users to maintain levels that are known to reduce the risk of AKI.[19]

Glossary of Acronyms and Abbreviations

AKI	Acute Kidney Injury
AmSECT	American Society of ExtraCorporeal Technology
ARF	Acute Renal Failure
AUC	Area Under the DO_2 Curve
BE	Base Excess
BP	Blood Pressure
CABG	Coronary Artery Bypass Graft Surgery
CI	Cardiac Index
CPB	Cardiopulmonary Bypass
CSA-AKI	Cardiac Surgery-Associated Acute Kidney Injury
DO_2	Oxygen Delivery
DO_2i	Indexed Oxygen Delivery
EACTA	European Association of Cardiothoracic Anesthesiology
EACTS	European Associaction for Cardio-Thoracic Surgery
EBCP	European Board of Cardiovascular Perfusion
GDP	Goal-Directed-Perfusion
HCO_{3-}	Bicarbonate
HCT	Hematocrit
Hgb	Hemoglobin
HL	Hyperlactatemia
ICU	Intensive Care Unit
K^+	Potassium Ion
LOS	Length of Stay
MDPI	Multifactorial Dynamic Perfusion Index
O_2ER	Oxygen Extraction Ratio
pCO_2	Partial Pressure of Carbon Dioxide
pH	Potential of Hydrogen
pO_2	Partial Pressure of Oxygen
RBC	Red Blood Cell
RRT-ARF	Renal Replacement Therapy-Acute Renal Failure
RRT	Renal Replacement Therapy
SaO_2	Arterial Oxygen Saturation
SvO_2	Venous Oxygen Saturation
VO_2	Oxygen Consumption
VO_2i	Indexed Oxygen Consumption

References

1. Oshita, T et al. A Better Predictor of Acute Kidney Injury After Cardiac Surgery: The Largest Area Under the Curve Below the Oxygen Delivery Threshold During Cardiopulmonary Bypass. *J Am Heart Assoc*. 2020;9: e015566. DOI: 10.1161/JAHA.119.015566.
2. Condello, I, etal. Association between oxygen delivery and cardiac index with hyperlactatemia during cardiopulmonary bypass. *JTCVS Techniques*. 2020; Vol 2: 92-99.
3. Dijoy, The History of Goal Directed Therapy and Relevance to Cardiopulmonary Bypass. *J Extra Corpor Technol.* 2015 Jun;47(2):90-4.
4. 2019 EACTS/EACTA/EBCP Guidelines on Cardiopulmonary Bypass in Adult Cardiac Surgery *European Journal of Cardio-Thoracic Surgery* 00 (2019) 1–42 doi:10.1093/ejcts/ezz267.
5. *American Society of ExtraCorporeal Technology Standards and Guidelines for Perfusion Practice*, February 2023* https://www.amsect.org/Portals/0/AmSECT_Perfusion_S%26G_2023%20Ratified%20021023_Digital%20edition.pdf
6. *American Society of ExtraCorporeal Technology Standards and Guidelines for Pediatric and Congenital Perfusion Practice*, May 2019 https://www.amsect.org/Portals/0/AmSECT%20Documents/Pediatric%20and%20Congenital%20Standards%20and%20Guidelines%20Final%20May%202019%20(1).pdf
7. Kramer, et al. Acute Kidney Injury Subsequent to Cardiac Surgery *J Extra Corpor Technol*. 2015 Mar; 47(1): 16–28.
8. Hayward A, et al. Oxygen Delivery in Pediatric Cardiac Surgery and its Association with Acute Kidney Injury using Machine Learning, *The Journal of Thoracic and Cardiovascular Surgery* (2022), doi: https://doi.org/10.1016/j.jtcvs.2022.05.039.
9. Ranucci, M, et al. The Multifactorial Dynamic Perfusion Index: A Predictive Tool of Cardiac Surgery Associated Acute Kidney Injury. *Perfusion*. 2022 Vol. 0(0) 1-9 DOI: 10.1177/02676591221137033.
10. de Somer, et al. O_2 Delivery and CO_2 Production During Cardiopulmonary Bypass as Determinants of Acute Kidney Injury: Time for a Goal-Directed Perfusion Management? *Critical Care* 2011; 15:R192.
11. Elmistekawy, et al. Clinical Impact of Mild Acute Kidney Injury After Cardiac Surgery. *Ann Thorac Surg.* 2014 Sep;98(3):815-22.
12. Ranucci M, Romitti F, Isgro G, et al. Oxygen Delivery During Cardiopulmonary Bypass and Acute Renal Failure After Coronary Operations. *Ann Thorac Surg.* 2005;80:2213-20.
13. Dasta JF, Kane-Gill SL, Durtschi AJ, et al. Costs and Outcomes of Acute Kidney Injury (AKI) Following Cardiac Surgery. *Nephrol Dial Transplant.* 2008;23: 1970-1974.
14. Alshaikh. Et al. Financial Impact of Acute Kidney Injury After Cardioac Operations in the United States. *Ann Thorac Surg.* 2018 Feb;105(2):469-475.
15. Ranucci M, et al. Effects of Priming Volume Reduction on Allogeneic Red Blood Cell Transfusions and Renal Outcome After Heart Surgery. *Perfusion.* 2015;30:120-126.
16. Ranucci M, Aloisio T, Carboni G, et al. Acute Kidney Injury and Hemodilution During Cardiopulmonary Bypass: A Changing Scenario. *Ann Thorac Surg.* 2015;100:95-100.
17. Long, et al., Perfusionist Techniques of Reducing Acute Kidney Injury Following Cardiopulmonary Bypass; An Evidence-Based Review. *Perfusion.* 2014;30(1):1-8.
18. Ranucci, M et al. Goal-directed perfusion to reduce acute kidney injury: A randomized trial. The Journal of Thoracic and Cardiovascular Surgery. 2018 Nov;156(5):1918-1927.
19. Refer to CDI OneView Technical Compendium.

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