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Original Article

# Six-Month Outcomes After High-Risk Coronary Artery Bypass Graft Surgery and Preoperative Intra-aortic Balloon Counterpulsation Use: An Inception Cohort Study

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*Objective:* To inform the design of a pivotal randomized controlled trial of prophylactic intra-aortic balloon counterpulsation (IABC) in patients undergoing coronary artery bypass graft (CABG) at high risk of postoperative low cardiac output syndrome (LCOS).
*Design:* Inception cohort study.
*Setting:* A total of 13 established cardiac centers in Australia, Canada, New Zealand, and the United Kingdom.
*Participants:* Adult patients were eligible for inclusion if they were listed for CABG surgery and had 2 or more LCOS risk factors (low ejection fraction, severe left main coronary artery disease, redo sternotomy, unstable angina).
*Interventions:* Outcomes of interest were a composite outcome of in-hospital mortality, postoperative acute myocardial infarction (AMI), acute kidney injury (AKI), or stroke as well as 6-month vital status and quality of life using the EuroQol 5-dimensional questionnaire (EQ5D).
*Measurements and Main Results:* The study included 136 participants over a 29-month period. Overall, in-hospital and 6-month mortality occurred in 7 (5%) and 11 (8%) participants, respectively. The composite outcome occurred in 60 (44%). The mean increase in EQ5D summary index at 6 months was 0.10 (standard deviation 0.24, $p = 0.01$). Perioperative AMI, AKI, or stroke significantly decreased the odds of a clinically meaningful improvement in quality of life (odds ratio 0.32; 95% confidence interval 0.13-0.79; $p = 0.014$). Preoperative IABC was used in 39 participants and did not predict postoperative outcomes.
*Conclusions:* The study identified a group of patients at risk of LCOS in whom CABG surgery was associated with a substantial burden of perioperative morbidity. Preoperative IABC use was variable, supporting the need for further research.
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*Key Words:* intra-aortic balloon counterpulsation; low cardiac output syndrome; prophylaxis; high-risk

[**]A complete list of sites, investigators, and research coordinators is provided in the supplementary appendix.

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IN HIGH-RISK PATIENTS undergoing coronary artery bypass graft (CABG) surgery, low cardiac output syndrome (LCOS) remains a common cause of perioperative morbidity and mortality.[1] Recent data suggest that levosimendan prior to CABG surgery in patients with impaired left ventricular ejection does not reduce the risk of LCOS or improve outcomes.[2] There remains an unmet need for effective prophylactic treatments to reduce morbidity and mortality in high-risk patients.

There is some evidence that preoperative intra-aortic balloon counterpulsation (IABC) use in selected patients undergoing CABG may reduce perioperative acute myocardial infarction (AMI) and LCOS and improve short-term survival.[3] However, the quality of evidence is low, and guidelines provide only weak or no recommendations.[4,5] International data on the medium-term outcomes in high-risk patients and the associated effect of preoperative IABC are uncertain and may contribute to the substantial variability in use.[6,7] The generation of definitive evidence to guide preoperative IABC has been identified as a research priority.[8]

As part of a program of research to determine the feasibility of performing a definitive RCT of prophylactic IABC for high-risk patients undergoing CABG surgery, the primary aim of this study was to describe 6-month mortality and quality of life in a cohort of patients undergoing CABG prospectively identified as being at risk of LCOS following CABG surgery and the association with preoperative IABC. In addition, the authors assessed linkage of study data to an established cardiothoracic surgery database and the reported theoretical willingness of the treating surgeon to enroll the participant in a randomized controlled trial (RCT) of preoperative IABC.

## Materials and Methods

This inception cohort study was conducted in 13 centers in Australia, Canada, New Zealand, and the United Kingdom and is reported in accordance with the Strengthening of Reporting of Observational Studies in Epidemiology (STROBE) statement (see supplementary appendix for a full list of study sites, investigators, and research coordinators).[9] Institutional human research ethics committee approval was obtained at all sites prior to initiation of recruitment, and all participants provided informed consent. Adult patients were eligible for inclusion if they were listed for cardiac surgery that included CABG and were identified as at high risk. The criteria from previously published prophylactic IABC RCTs were used to define high risk as any patient with 2 or more of the following characteristics: left main coronary artery stenosis $\geq 70\%$; unstable angina in the 24 hours prior to surgery; redo cardiac surgery; and left ventricular ejection fraction $\leq 30\%$.[10] Patients with a ventricular assist device in situ prior to surgery were excluded.

Adult patients scheduled to undergo CABG surgery at participating centers were screened for study eligibility. After enrolment, study-specific data, including baseline EuroQol 5-dimensional questionnaire (EQ5D3L), were collected by trained study personnel on a prespecified case report form (CRF). At 5 sites, the CRF-specific data collection was limited to only a few key variables with the majority of data provided through linkage with a dataset collected by the existing Australia and New Zealand Society of Cardiac and Thoracic Surgeons Database Program (ANZSCTS DP) managed by the School of Public Health at Monash University, Australia. Linkage was deemed successful if the key variables from the CRF-specific data collection could be linked to the database for all participating ANZSCTS DP sites. The ANZSCTS DP also provided study project management. Surgeon equipoise for theoretical participation in a trial of prophylactic IABC was determined before but as close to time of surgery as possible. Participants were followed up to discharge from index hospitalization. At 6 months, vital status was ascertained and survivors were contacted by phone for repeat EQ5D testing. The timing of IABC initiation was defined as preoperative if it occurred prior to the first surgical incision.

The primary aim was to assess the incidence of high-risk patients and to describe their baseline characteristics, treatments, and outcomes. Secondary outcomes included assessing the association between preoperative IABC use and outcomes. The particular focus was to assess a plausible composite that would encapsulate the potential risks and benefits of preoperative IABC and be feasible to measure in a large-scale RCT. The chosen composite included in-hospital mortality, AMI, acute kidney injury (AKI), or stroke, as well as their individual components. Because quality of life is a key patient-centered outcome that may not be fully captured by the chosen composite, 6-month EQ5D also was collected. The EQ5D summary index was based on the Australian version with the change from baseline based on preoperative measurement and postoperative death scored as zero. A change from baseline of $> 0.08$ was considered a clinically meaningful minimal important difference.[11,12] In addition to collecting data on IABC-related complications, the preoperative reported equipoise of the treating cardiac surgeon for theoretical enrolment of the patient in a RCT of prophylactic IABC was determined by asking the surgeon whether they would have been willing to randomize the patient preoperatively to an RCT of preoperative IABC in addition to standard care versus standard care without preoperative IABC. Postoperative AMI was defined as a peak postoperative troponin more than 5 times the upper limit of normal.[13] AKI was defined as a creatinine increase of 2.5 times or more from preoperative baseline or the initiation of renal replacement therapy in those without pre-existing end-stage renal failure. Stroke was defined as a new neurological deficit persisting for $> 72$ hours according to the ANZSCTS DP. In-hospital morbidity and mortality were censored at 28 days.

### *Statistical Analysis*

Continuous variables were reported as mean and standard deviation (SD) or median and interquartile range (IQR). Between-group differences independent data were analyzed using Student's $t$ test and the Wilcoxon rank-sum test for normally distributed and skewed data, respectively. Paired data were analyzed using paired Student's $t$ test and the Wilcoxon

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