Original Article

The use of perioperative Impella 5.5 support in high-risk cardiac surgery: a retrospective cohort study

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Background: Although the Impella device has an established role in high-risk percutaneous intervention and cardiogenic shock, its role in open cardiac surgery remains unclear. We undertook this study to better understand the role of Impella support in cardiac surgical intervention.

Methods: This is a retrospective cohort study of consecutive patients who underwent cardiac surgery with surgically placed Impella 5.5 device support from October 2020 through June 2023. Patient charts were identified and systematically reviewed for relevant information. The primary outcome for this study was patient survival to discharge. Secondary outcomes included intraoperative survival, 30-day survival and 1-year survival.

Results: From 2020–2023, ten patients underwent open cardiac surgery with Impella 5.5 support. Five patients were male and the median age was 56.5 years [interquartile range (IQR), 52–63.8 years]. Three patients (30%) presented for isolated revascularization, 3 patients (30%) presented for single valve surgical intervention, 3 patients (30%) presented for revascularization and valve intervention, and 1 patient (10%) presented for multivalve intervention. The median ejection fraction (EF) of patients was 25% (IQR, 21.25–32.5%), the median Society of Thoracic Surgeons risk score was 4.32% (IQR, 1.73–11.06%). Of the patients, 40% underwent axillary cannulation while 60% had central cannulation. Intraoperative survival was 100%, survival to discharge was 90% and 30-day survival was 80%.

Conclusions: Our study suggests the use of surgical Impella in high-risk cardiac surgical patients is associated with acceptable survival regardless of site or timing of cannulation. However, Impella usage is associated with significant morbidity. Further investigation is warranted to better understand which patients benefit perioperative Impella support.

Keywords: Impella; temporary mechanical support; adult cardiac; perioperative care

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Introduction

Temporary mechanical circulatory support (tMCS) is a well-established treatment modality in patients with poor cardiac function. Since the development of cardiopulmonary bypass in 1953, there have been significant advancements in the devices used for tMCS and the application of this treatment (1). Each type of support system has specific treatment strategies, advantages and disadvantages (2). Despite improvements, the need for tMCS has been documented as a poor prognostic factor. This is especially apparent in patients suffering from cardiogenic shock (CS) secondary to heart failure (3). Although the SHOCK-II trial demonstrated no significant difference in mortality associated with intra-aortic balloon pump placement in patients undergoing urgent revascularization who suffered from CS secondary to myocardial ischemia, the concept of CS as a spectrum has since evolved (4). Subsequently, the use of tMCS in pre-shock states coupled with appropriately timed intervention has been discussed as a key adjunct in preventing and treating cardiogenic shock (5,6). These concepts bring the role of prophylactic tMCS as an adjunct to high surgical risk patients requiring intervention into the discussion as a treatment modality.

A newer device, the Impella, a transvalvular, microaxial flow device, was first approved for use for mechanical circulatory support (MCS) in 2008. Utilization has increased since its introduction, reaching a peak of 31.9% of MCS devices in 2016, however results from the early iterations of this device were varied (7). More recent literature has shown benefit of Impella support as a bridge to cardiac surgery opposed to extracorporeal membrane oxygenation support, however the role of perioperative support of surgical Impella is not well understood (8). The most recent iteration of the device, the Impella 5.5 (Abiomed, Danvers, MA, USA), was released for commercial use in September 2019. Due to the device construction and improved length of use this device has been used successfully as a bridging device to cardiac function recovery or heart transplant (9). Due to promising early results seen in international studies the use of the device has expanded rapidly (10-12). However, the use of the Impella 5.5 for tMCS within the realm of cardiac surgery, is not well understood. In general, the use of tMCS as an adjunct to cardiac surgery has been shown to be associated with greater inpatient mortality, however this is likely due to the high-risk nature of the patients requiring perioperative MCS. While the percentage of patients who require perioperative MCS is low, this is not an insignificant contingent of patients and improvements in perioperative MCS would likely translate to improved outcomes (13). Previous reports have discussed the use of both the Impella 5.5 and 5.0, largely the 5.0, in elective high-risk cases with improved results, however we sought to evaluate the effect of perioperative support using only the Impella 5.5 in high-risk patients and we report our findings below (14). We present this article in accordance with the STROBE reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-24-194/rc).

Highlight box

Key findings

- Impella 5.5 supported high-risk cardiac surgery may be a feasible approach.

What is known and what is new?

- Previous reports have demonstrated acceptable perioperative results with older device generations. However, experiences with newer devices and understanding of post-hospital outcomes are limited.
- We demonstrate excellent perioperative survival and acceptable 90-day survival during high-risk cardiac surgery supported by the Impella 5.5 device.

What is the implication and what should change?

- Use of the Impella 5.5 may be a feasible strategy in high-risk cardiac surgery patients.
- Future studies will be important to better assess the effectiveness of this approach.

Methods

Impella 5.5 with SmartAssist system

The Impella 5.5 (Abiomed, Danvers, MA, USA) is a surgically placed, temporary left ventricular assist device which received Food and Drug Administration approval September 24, 2019 for use in cardiogenic shock following acute myocardial infarction, cardiac surgery, or in the setting of decompensated left ventricular failure refractory to optimal medical therapy and conventional treatment measures. The device consists of a 19 Fr micro-axial pump and 21 Fr cannula mounted on a 9 Fr driveline/bearing purge delivery catheter. The automated impella controller (AIC) is the primary user control interface for system performance, monitoring for alarms and displaying real-time hemodynamic and catheter position information. The device pump is designed to pull blood from the left ventricle into the ascending aorta, reduce ventricular distention, workload and myocardial oxygen consumption to allow

recovery and assessment of residual cardiac function. It is capable of flowing up to 5.5 L/min and can be inserted via either axillary artery, the innominate artery or the ascending aorta.

Implant technique

Device placement at our center (Baylor Scott and White The Heart Hospital Plano, Plano, TX, USA) included both peripheral (vascular graft to right axillary artery) and central (vascular graft to innominate artery or ascending aorta) methods. The right axillary artery is exposed, controlled and a vascular graft is then beveled at 45 degrees and sewn in an end to side fashion to the artery. The graft is de-aired and a vascular sheath is then inserted into the graft. The aortic valve is crossed with a guidewire and pigtail catheter. The Impella 5.5 is then exchanged for the catheter and advanced over the guidewire into the left ventricle. Placement is confirmed with transesophageal echocardiography prior to initiating device flows. Heparin is administered to achieve an activated clotting time >160–180 seconds. The device is secured within the graft with silk ties and then to the patient. The central method is performed in a similar manner; however, vessel exposure is done via median sternotomy and the graft is tunneled out superior to the clavicle. Placement strategy is determined by surgeon preference and specific case, however, in general, our preference is for direct central placement. In most cases, we proceed with cardiac surgery as planned and will attempt to wean off bypass while evaluating the response of the heart. In cases where we feel Impella support is warranted, we will place a side biting clamp on the ascending aorta approximately 7 cm above the plane of the aortic valve. This can be done either on or off cardiopulmonary bypass. A 10 × 30 mm graft is then beveled at 45 degrees and anastamosed to the ascending aorta using 5-0 running prolene. The graft is tunneled out above the right clavicle, and the Impella 5.5 inserted through the graft. If needed, the aortic valve can be compressed posteriorly to render it incompetent and allow easier passage. If this part of the procedure is performed on bypass, we will lower the flow to allow the heart to eject and the valve to open. If we have difficulty crossing the aortic valve, a J wire and a pigtail catheter can be used to cross the valve. This is then exchanged for the Impella insertion wire before placing the Impella over the wire. This tactic is especially useful in the setting of a bioprosthetic aortic valve. The Impella is then secured per the Instructions for Use, bypass is weaned, and the chest can be closed. This is performed in our main cardiac operating rooms with the use of C-arm fluoroscopy if needed. Following implantation, in the absence of significant bleeding, we use bicarbonate in the purge fluid and a systemic heparin infusion for a target partial thromboplastin time of 50–70 seconds. For patients with active bleeding or are considered high risk for bleeding, we forgo any anticoagulation. Device removal in both methods is performed after support has been weaned and tolerated well be the patients. This may take place in either the operating room or intensive care unit (ICU). After weaning flows, device securing sutures are removed, the Impella is mobilized, graft is clamped and then divided with a 30 mm vascular stapler below the clamp. The residual graft is allowed to retract and is tucked within the wound, which is then closed in multiple layers.

Patient selection and analysis

This is a retrospective cohort study of all consecutive patients supported with the Impella 5.5 at our center as an adjunct for open cardiac surgery from October 2020 through June 2023. All identified patients were included in this series. The usage of this device was at surgeon discretion due to concern for need for further MCS. Charts were reviewed for demographic, procedural, echocardiographic and outcomes data. Attention was paid to preoperative Society of Thoracic Surgeons predicted risk of mortality (STS-PROM) scores, Impella placement timing and location, duration of device use, postoperative morbidities and mortalities.

Statistical analysis

Normality of continuous variables was assessed; normal continuous variables are presented as a mean ± standard deviation, whereas non-normal continuous variables are presented as a median [interquartile range (IQR)]. Categorical variables are reported as a counts with percentages. Any missing data was excluded from analysis.

Ethical statement

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved on July 13, 2023 by the institutional ethics board of Baylor Scott and White The Heart Hospital Plano (approval No. 014-209) and individual consent for this retrospective analysis was waived.

Table 1 Baseline patient characteristics

Characteristic	Value
Age (years)	56.5 [52–63.8]
Male gender	5 [50]
BMI (kg/m^2)	25.19 [24.67–31.79]
STS-PROM (%)	4.32 [1.73–11.06]
Median EF (%)	25 [21.25–32.5]
NYHA class	3 [3–3]
Cardiac operation	
Isolated revascularization	3 [30]
Single valve	3 [30]
Valve and revascularization	3 [30]
Multi-valve	1 [10]
Co-morbidities	
Diabetes mellitus	2 [20]
Chronic obstructive pulmonary disease	1 [10]
Hypertension	5 [50]
Pulmonary hypertension	4 [40]
End stage renal disease on hemodialysis	0
Chronic kidney disease	5 [50]
Coronary artery disease	5 [50]
Prior cerebrovascular accident	1 [10]
Atrial fibrillation	1 [10]
Prior cardiac surgery	2 [20]
Current smoker	3 [30]
Heart failure	5 [50]

Data are presented as median [interquartile range] and counts with percentages as appropriate. BMI, body mass index; STS-PROM, Society of Thoracic Surgeons Predicted Risk of Mortality; EF, ejection fraction; NYHA, New York Heart Association.

Results

Baseline characteristics

From October 2020 through June 2023, 10 patients who underwent cardiac surgery with Impella 5.5 device support at our center were identified. All patients had complete demographic, operative, and follow-up data available. The median age of the patients was 56.5 years [interquartile range (IQR), 52–63.8 years], 5 patients (50%) were male, and the median body mass index was 25.19 (IQR, 24.67–31.79 kg/m^2). Complete baseline characteristics and co-morbidities are presented in *Table 1*. Three patients (30%) presented for isolated revascularization, 3 patients (30%) presented for single valve intervention, three patients (30%) presented for combined revascularization and valve intervention and one (10%) presented for multivalve intervention. The median preoperative EF, measured by echocardiogram, was 25% (IQR, 21.25–32.5%) and the median STS-PROM was 4.32% (IQR, 1.73–11.06%). Four patients (40%) underwent axillary device placement while six patients (60%) underwent central placement. The median length of device usage was 5.5 days (IQR, 4.0–6.8 days). One patient underwent preoperative placement, seven patients underwent perioperative placement, and two underwent postoperative placement.

Patient outcomes

Median follow up for our cohort was 262.5 days (IQR, 39.5–798.3 days). Survival to discharge was 90% (9/10) and there were no intraoperative mortalities. The 30-day survival was 80% (8/10) and 90-day survival was 70% (7/10). All three mortalities occurred in patients who underwent central Impella placement (*Figure 1*). Eight devices were removed in the operating room, one was removed at bedside, and one device was in place at the time of in hospital mortality. Eight patients (80%) experienced other complications during the hospital stay. Mortality and postoperative complications are presented in *Table 2*. Postoperative details are present in *Table 2*. In patients who were successfully discharged disposition was: inpatient rehabilitation 2, long-term acute care facility 2, home 3, and transfer to sending hospital 2 (*Figure 2*). Three patients were re-admitted to the hospital within 90-day postoperatively.

Discussion

Here we demonstrate the perioperative usage of surgical Impella 5.5 support in a high-risk surgical population. Overall intra-operative survival was 100% for this population, survival to discharge was 90%, 30-day survival was 80%, and 90-day survival was 70%. These results are promising and similar to early reports of Impella 5.5 in the non-surgical realm which Bernhardt and colleagues showed 90-day survival of 72%, while others reported survival rates of 70.4% in post cardiotomy shock patients (10,12). Our early term survival is similar to these reports and lends support the use of surgical Impella 5.5 device support in

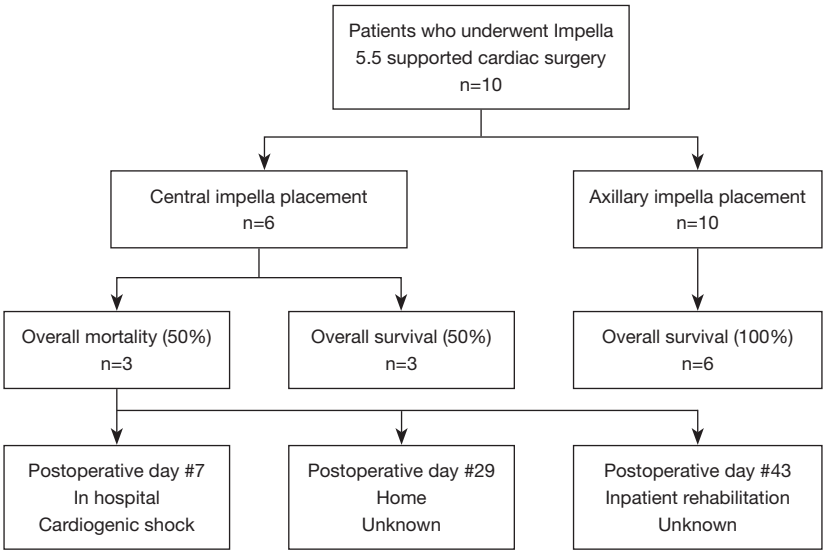

Figure 1 Flow chart with patient outcomes and cause of mortality if known.

Table 2 Operative and post-operative details

Category	Value
Impella placement timing to index operation	
Preoperative	1 [10]
Perioperative	7 [70]
Postoperative	2 [20]
Cannulation site	
Central	6 [60]
Axillary	4 [40]
Length of Impella use, days	5.5 (4.0–6.8)
Length of stay, days	23 (16–29.5)
Patients transitioned to durable mechanical circulatory support	0
Postoperative complications	
Hemorrhage	5 [50]
Acute kidney injury	4 [40]
Acute renal failure requiring renal replacement therapy	3 [30]
Atrial fibrillation	2 [20]
Cardiac arrest	2 [20]
Survival to discharge	9 [90]
30-day survival	8 [80]
90-day survival	7 [70]
90-day readmissions in patients discharged	3 [33]
Follow-up interval, days	262.5 (39.5–798.3)

Data are presented as median [interquartile range] and counts with percentages as appropriate.

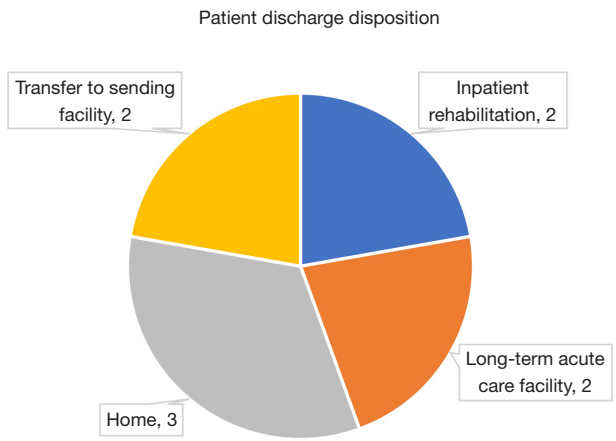

Figure 2 Discharge disposition in patients successfully discharged from the hospital following surgically placed Impella 5.5 supported cardiac surgery.

high-risk surgical patients.

Survival

Although few experiences are published regarding Impella 5.5 supported cardiac surgery, previous reports of the Impella 5.0 as a prophylactic measure in high-risk coronary revascularization had demonstrated no perioperative deaths (15). However, 30 days and longer-term outcomes are not discussed. In our study, all patients survived

perioperatively and 9/10 patients were discharged from the hospital successfully. While our in-hospital results are similar to this report, our demonstration of longer-term survival is important to the future use of Impella supported cardiac surgery in high-risk patients. These early results suggest surgical Impella support can possibly help mitigate the perioperative risk in the high-risk population.

Consideration of durable MCS

Among our patients, half (5/10) carried a diagnosis of heart failure with many patients in acute heart failure episodes. Low EF is known to be a predictor of poor outcomes in regard to cardiac surgery, with a particularly high risk for patients with an EF of ≤25% (16). In this population Thalji *et al.* proposed an algorithm which considers durable MCS support opposed to surgical intervention (16). In this study, we see the successful results of perioperative Impella support in a series of patients with a median EF of 25%. While we agree the use of durable MCS to be an important consideration preoperatively, our successes with tMCS may suggest an alternative approach in this cohort.

Timing of placement, length of use, and placement location

Seventy percent of our cohort underwent perioperative Impella placement, while the remainder were placed pre- or postoperatively. As our sample size is small the best timing strategy remains for future studies, however, the importance early identification of patients who may benefit from Impella 5.5 supported cardiac surgery could improve results.

The length of Impella usage in this series was quite reasonable, with a median length of usage of 5.5 days, which mirrors previous experiences with the Impella 5.0. The short time of use suggests the ability of surgical Impella placement to decrease the risk of post cardiotomy shock in this high-risk group. There is little consensus regarding axillary versus central placement, however we demonstrated successful results of both central and axillary placement (6 central, 4 axillary). Although all mortalities were in patients who received central placement of surgical Impella, our study is limited by a small size and future research could help delineate if there is a preferred placement site.

Limitations

Limitations of this study are a small sample size and the retrospective design. Compared to previous experiences this study does have specific advantages; the distribution of gender was equal (5 male) and patients underwent multiple types of cardiac interventions suggesting this treatment to be applicable to both revascularization and structural heart disease. Prospective trials with greater numbers of patients, such as the IMPACT trial, will be important in better identifying patients or surgeries where surgical Impella 5.5 placement would be of greatest benefit (17). Despite these limitations, we believe our experiences with early use of the Impella 5.5 for perioperative support to be promising and may benefit high risk surgical patients.

Conclusions

In our analysis, perioperative Impella 5.5 is associated with acceptable mortality in patients undergoing high risk cardiac surgery. Notably, we demonstrated excellent perioperative survival within this group of patients with zero intraoperative deaths and 90% of patients being discharged successfully. We believe the use of the Impella 5.5 as an adjunct for high-risk surgical patients may help to decrease the intraoperative surgical risk. However, further investigation is needed to identify the patient sub group most likely to benefit from this adjunct and to understand the generalizability of this adjunct.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://jtd.amegroups.com/article/view/10.21037/jtd-24-194/rc

Data Sharing Statement: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-24-194/dss

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jtd.amegroups.com/article/view/10.21037/jtd-24-194/coif). The authors

have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the institutional ethics board of Baylor Scott and White The Heart Hospital Plano (approval No. 014-209) and individual consent for this retrospective analysis was waived.

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