

Bridging to orthotopic heart transplant: Reducing the risk of intra-operative blood loss



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KEYWORDS:

heart transplant;
mechanical support
device;
bridging to heart
transplant;
transfusion;
blood loss

BACKGROUND: Orthotopic heart transplantation remains the gold standard for patients with end-stage heart failure. Many devices exist to bridge patients with heart failure to transplant. Impella 5.5 (Abiomed, Danvers MA) is an example of a temporary mechanical assist device, which prioritizes patients as Status 2 by the 2018 UNOS policy change, increasing their likelihood of transplantation. Given the increase in device use, we sought to compare intra-operative complications, particularly blood loss, between bridging strategies to transplantation.

METHODS: We conducted a single-institution retrospective analysis between January 2019 and May 2023.

RESULTS: A transfusion requirement was defined as greater than 4 units of blood given intra- or immediately post-operatively (24%, 22/93). The transfusion group was more likely to have had a prior sternotomy (82% vs. 48% $p < 0.01$) and to be on a durable left ventricular assist device (LVAD) (45% vs. 21% $p = 0.02$). There was no difference in anticoagulation or antiplatelet use prior to the odds ratio (OR). The use of Impella 5.5 did not increase the risk of intra-operative bleeding (14% vs. 21% $p = 0.44$). In the adjusted outcomes, factors associated with intra-operative bleeding included average temperature and LVAD (OR 3.63 95% CI [1. –12.3], $p = 0.04$)

CONCLUSION: The shift to prioritize bridging devices has not been met with an increased risk of blood transfusion. We found that parameters such as a prior sternotomy, duration of temporary mechanical assist device (tMCS) use, and the presence of an LVAD were associated. This represents the first study to compare intra- and immediately post-operative transfusion data between bridging devices in the setting of transplantation. JHLT Open 2025;8:100220

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Abbreviations: OHT, Orthotopic heart transplantation; HF, End-stage heart failure; MCS, Mechanical assist device; tMCS, Temporary mechanical assist device; IABP, Intra-aortic balloon pumps; ECMO, Extracorporeal membrane oxygenation; LVAD, Left ventricular assist devices; OPTN, Organ Procurement and Transplantation Network; OR, Odds Ratio

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Orthotopic heart transplantation (OHT) is the gold standard and definitive management modality for end stage heart failure. However, there are a limited number of donor hearts available at any given time with increases in the heart transplant wait-list by up to 40% in the last 10 years.¹ Thus, many patients need to be bridged to transplant using mechanical circulatory support devices (MCS). In the bridge-to-transplant treatment paradigm, various MCS devices are employed.² MCS devices include temporary mechanical circulatory support devices (tMCS) like Impella, Tandem-Heart, intra-aortic balloon pumps (IABP), and extra-corporeal membrane oxygenation (ECMO), as well as durable devices like left ventricular assist devices (LVAD).³ MCS selection strategies rely on the severity and type of cardiac failure, method of placement (percutaneous or surgical), flow rates/mechanism, anticoagulation needs, and discharge potential.^{4,5}

In 2018, the Organ Procurement and Transplantation Network (OPTN) changed its adult heart allocation system to prioritize the more medically urgent recipients. The goal of these changes was to decrease waitlist mortality⁶ with Impella, one of the tMCS options, prioritizing patients as Status 2. Consequently, the usage of tMCS devices has risen substantially, while the use of durable MCS devices has decreased.⁷ Despite the rise in the use of tMCS devices for bridge-to-transplant, it remains to be determined how these devices impact perioperative bleeding risk and subsequent transfusion requirements during the perioperative period.⁸ Intra- and postoperative bleeding requiring blood transfusion is clinically significant as its association with adverse postoperative outcomes, such as postoperative MCS usage, acute renal failure, and 30-day mortality is well demonstrated.⁹

In this study, we aimed to evaluate the impact of temporary MCS devices and the duration of their use on perioperative bleeding risk in order to better inform clinical decision making surrounding device selection in bridge to transplant strategies.

Methods

Study design and patient cohort

This was a retrospective analysis of a tertiary care center's cardiac transplant surgical database maintained at the University of California, San Francisco (UCSF). Patients were included if they had undergone a heart transplant at UCSF between January 2019 and May 2023. The EMR of individual patients were reviewed and relevant data collected. This study was approved by the Committee on Human Research at UCSF (IRB # 24-41355 approved 2/26/2024).

Primary outcome

The primary objective of this study was to determine risk factors for intra-operative bleeding. This was assessed by

collecting data on intra-operative and post-operative transfusion requirements. A transfusion requirement was defined as the need for greater than four units of packed red blood cells either during or within 24 hours of the operation.¹⁰ We validated this definition retrospectively by looking at how many of our patients required washout for their transfusion which was 90%.

Mechanical circulatory support device (MCS)

For all patients the presence of MCS at the time of transplant was recorded. This included LVAD, ECMO, IABP, and Impella. We also recorded if patients were without MCS. While some patients had experience with multiple MCS devices, the device in place at the time of transplant was the one recorded for the purpose of this study. We further stratified our tMCS groups by duration using a similar model to Shou et al. whereby we used the interquartile ranges to create 4 groups to compare: group 1 (≤ 12 days), group 2 (13–38 days), group 3 (37–871 days), and group 4 (> 871 days).¹¹

Statistical analysis

Descriptive statistics were applied to summarize and tabulate data and logistic regression analysis was applied to adjust for significant variables. Cross-tabulations were used to investigate associations between both pre-operative and intra-operative patient characteristics and a transfusion requirement. Chi-square tests and Mann–Whitney U tests were applied to categorical and continuous variables, respectively. A multivariable logistic regression model was used to test the association between transfusion requirement and the type of mechanical circulatory support device in use, after adjustment for age, pre-operative ejection fraction, and intra-operative temperature. Results are presented in the form of odds ratios (OR) including 95% confidence intervals (CI). A 2-sided alpha of 0.05 was used to determine statistical significance for all analyses. Data analyses were performed using Stata/SE 15.1 (College Station, Texas).

Results

A total of 93 patients who met the study criteria were identified. Of these, 22 required significant blood transfusions and 71 did not. Baseline demographic and clinical characteristics are shown in Table 1. The majority of patients were male ($n = 62$, 67%), white ($n = 31$, 33%) or Hispanic ($n = 24$, 26%) and had had a prior sternotomy ($n = 78$, 84%). The majority of patients received brain death heart donations (donation after brain death) ($n = 84$, 90%) and received a heart transplant-alone ($n = 78$, 84%). Very few patients had pre operative chest radiation ($n = 1$, $< 1\%$). The most common form of MCS was the durable LVAD ($n = 25$, 27%) and Impella ($n = 18$, 20%), of which, 11 were Impella 5.5 and seven were Impella CP.

Table 1 additionally demonstrates the breakdown of baseline characteristics by transfusion requirement. There was no difference in sex, race, ethnicity, or baseline

Table 1 Pre-Operative Demographics

	RBC Transfusion > 4 (N = 22)	RBC Transfusion < 4 (N = 71)	p-value
Sex			0.86
Male	15	47	
Women	7	24	
Race/Ethnicity			0.41
Asian	3	11	
Black	4	11	
Hispanic	5	19	
Native American	1	1	
White	7	24	
Other	2	5	
Median Age in years (min-max)	56 (17–76)	50 (20–74)	0.412
Organ(s)			0.02
Transplanted Heart	15	63	
Heart/Kidney or Lung	7	8	
Donator Type			0.62
DCD	1	7	
DBD	21	63	
Prior Sternotomy			0.005
Yes	18	34	
Prior Radiation			0.58
Yes	0	1	
Ejection Fraction			0.85
< 20	4	9	
20–30	2	6	
30–40	0	2	
40–50	1	1	
> 50	7	15	
Atrial Fib			0.63
Yes	9	25	
Carotid Artery Disease			0.76
Yes	4	15	
COPD			0.07
Yes	1	0	
CVA			0.07
Yes	5	6	
Dialysis			0.95
Yes	1	3	
HLD			0.21
Yes	6	11	
HTN			0.91
Yes	9	39	
MI			0.87
Yes	4	14	
ILD			0.07
Yes	1	0	
Pulmonary HTN			0.76
Yes	4	11	
Peripheral Vascular Disease			0.58
Yes	0	1	
Renal Disease			0.86
Yes	6	18	

Table 1 (Continued)

	RBC Transfusion > 4 (N = 22)	RBC Transfusion < 4 (N = 71)	p-value
Smoker			0.29
Yes	2	2	
Aortic Valve Disease			0.07
Yes	1	2	
Mitral Valve Disease			0.21
Yes	3	4	
Tricuspid Valve Disease			0.01
Yes	5	3	
Any Anticoagulation			0.41
Yes	13	48	
Any Anti-platelet			0.76
Yes	8	13	

DBD, donation after brain death; DCD, donation after circulatory death; COPD, chronic obstructive pulmonary disease; HLD, hyperlipidemia; HTN, Hypertension; MI, myocardial infarction.

comorbidities (chronic obstructive pulmonary disease, dialysis, hypertension, prior-myocardial infarction, smoking, pulmonary hypertension, or valvular disease). The median age of patients requiring a transfusion was not significantly different but did trend towards being older than those without a transfusion requirement: 56 (range: 17–76) compared to 50 (range: 20–74) years old. There was no significant difference in bleeding risk by donor type (donation after circulatory death or donation after brain death), by prior radiation to the chest or by the use of anticoagulation pre-operatively. There was a significant difference in bleeding risk between patients who only underwent heart transplant and those who underwent dual organ transplant (Heart alone $n = 15$, 19% vs. Heart/Kidney or Heart/Lung, 47% $p = 0.02$). More patients requiring transfusion had a prior sternotomy ($n = 18$, 82% vs. $n = 34$, 48%).

The intra-operative and post-operative characteristics are provided in Table 2. When broken down by transfusion requirement, those with a transfusion requirement had a baseline lower average temperature, although this difference was not statistically significant (Mean 36 vs. 37°C, $p = 0.06$). There was no difference in cold ischemia time, the use of TransMedics Organ Care System (OCS) or post-operative presser requirements between transfusion groups. However, the group with more blood loss did trend towards longer intensive care unit (ICU) stays (13 vs. 10 days) and higher morbidity ($n = 4$, 18% vs. $n = 5$, 1%).

Tables 3 and 4 describes the differences in bleeding risk by different mechanical assist device and further stratifies that difference by the duration of tMCS use. More patients requiring transfusion had an LVAD ($n = 10$, 45% vs. $n = 15$, 21%). There was no significant difference in bleeding risk between those on ECMO, Impella, or IABP. When comparing Impella 5.5 and Impella CP there was no significant difference in bleeding risk ($p = 0.891$). Amongst the LVAD patients

Table 2 Intra-Operative and Post-Operative Demographics

	RBC Transfusion >4 (N = 22)	RBC Transfusion <4 (N = 71)	p-value
Average Temp in the OR (mean degrees Celsius)	36	37	0.06
Cold Ischemia Time (mean minutes)	276	254	0.46
Use of TransMedics OCS			0.28
Yes	1	15	
ICU Time (mean days)	13	10	0.62
Post-Operative Pressors			0.10
0	2	7	
1	8	35	
2	2	5	
3	0	14	
Dead			0.12
Yes	4	5	

ICU, intensive care unit; OCS, Organ Care System; OR, odds ratio.

Table 3 Bleeding Risk Amongst tMCS by Device Duration

	RBC Transfusion >4 (N = 22)	RBC Transfusion <4 (N = 71)	p-value
Group 1/2/3/4			0.04
ECMO	0	12	0.54
Group 1	-	8	
Group 2	-	4	
LVAD	10	14	0.02
Group 3	3	8	
Group 4	7	6	
IABP	2	13	0.30
Group 1	1	6	
Group 2	0	5	
Group 3	0	1	
Group 4	1	0	
Impella	3	15	0.44
Group 1	1	0	
Group 2	0	4	
Group 3	1	2	

ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pumps; LVAD, left ventricular assist devices; tMCS, temporary mechanical assist device.

Table 4 Adjusted Outcomes of Transfusion Requirement after OHT

Variables	Odds ratio	95% Confidence interval	p-value
LVAD	3.44	1.0–11.7	0.04
Age	1.03	0.98–1.08	0.13
Pre-op EF	1.29	0.36–4.55	0.69
Dual organ transplant	3.5	0.89–13.44	0.07
Average Body Temp in OR	0.48	0.22–1.03	0.06

LVAD, left ventricular assist devices; OHT, orthotopic heart transplantation; OR, odds ratio.

there was a notable difference in bleeding risk when we compared longer and shorter duration LVAD use (Group 3 $n = 3/11$, 27% vs. Group 4 $n = 7/13$, 54%). Amongst patients with Impella the duration of use was overall much shorter than that of LVAD and did not correlate clearly with bleeding risk (Group 1 $n = 1/1$, 100%, Group 2 $n = 0/4$, 0% vs. Group 3 $n = 1/3$, 33%). One of the 3 patients on Impella who had post-operative bleeding was also on ECMO. There were only 2 patients in the study who had dual tMCS. Three patients underwent sequential upgrade from IABP to Impella to ECMO. Only one of which had a significant transfusion requirement. This patient also had the longest cumulative duration of Impella in the study population.

In the unadjusted analysis, the risk of intra-operative blood loss was found to be three times higher in the LVAD

group (OR 3.11 95% CI [1.12–8.6], $p = 0.03$). We adjusted for possible confounding factors like age and pre-operative ejection fraction, as surrogates for overall fragility. We also included dual organ transplant as this was significantly correlated with bleeding in our univariate analysis. Additionally we included average body temperature in the OR as this is a known risk factor for bleeding. The risk of intra-operative blood loss remained associated with the presence of LVAD (OR 3.63 95% CI [1. –12.3], $p = 0.04$). Impella was initially included in this model but it did not reach significance and so was excluded. Repeat sternotomy was initially included but was found to have a confounding effect with the presence of an LVAD and so was removed from the final model. Duration of tMCS device did not confound the association with LVAD but additionally did not strengthen the model and so was also excluded from the final analysis.

Discussion

To date, this is the largest study to examine the risks associated with peri-operative bleeding during heart transplantation.¹² We found several associations with intra-operative bleeding including those who had a prior sternotomy, those with durable LVADs, and those with longer

device duration. Surprisingly, and contrary to common belief, there was no significant association with the use of tMCS such as ECMO or Impella. We also found no correlation between the use of anti-platelets or anticoagulation and transfusion requirements. Those with prior LVADs had the highest odds of requiring a blood transfusion.

The 2018 UNOS policy change prioritizing patients with tMCS as Status 2 for heart transplantation has led to an increase in device use. One study of US transplant centers found the proportion of admits with acute decompensated heart failure-related cardiogenic shock managed with tMCS almost doubled in the first year post-policy change alone.¹³ Early data from retrospective reviews of the OPTN database show that the shift to prioritizing the most medically urgent candidates has decreased the risk of death while on the waitlist, decreased median wait times, and increased transplant rates without significant adverse effects for patients transplanted off long duration assist devices.⁶

However, the use of mechanical circulatory support devices is not without risk of complications such as bleeding. Especially with the use of continuous flow devices like the Impella 5.5, studies on which have found a nearly tenfold increase in bleeding events compared to pulsatile flow devices.¹⁴ The anticoagulation requirement for the duration of device use has been associated with thrombocytopenia as well as the development of acquired Von Willebrand syndrome. The incidence of significant bleeding during treatment has been reported to be as high as 54% and Impella support has been associated with a need for multiple blood transfusions during device use.¹⁵

It is widely accepted that massive transfusion in the heart transplant population would lead to poorer outcomes related to inflammatory reactions or transfusion mediated sensitization.^{9,16–18} Subramaniam and colleagues retrospectively analyzed 197 heart transplant recipients and found a statistically significantly higher odds of post-operative mechanical circulatory support use, acute renal failure necessitating hemodialysis and a higher 30 day mortality.⁹ The risks associated with peri-operative bleeding and transfusion during cardiac surgery and specifically heart transplantation are many, including post-operative infection, kidney failure, shock, and death.

Despite the increase in tMCS use, there has been a dearth of literature on the effect of Impella use on intraoperative transfusion requirements during heart transplantation. Our study demonstrated that patients transplanted after having an Impella did not have an increased risk of intraoperative bleeding (14% vs. 21%, $p = 0.44$). In a study of 16 patients bridged to transplant with an Impella at their institution, Haddad et al. found that the median units of blood needed during transplant was four, with about 12% of patients requiring an additional 1–2 units of blood postoperatively.¹⁹ In our larger study, only 20% of patients required more than four units of blood peri-operatively providing evidence that Impella use might be safer than previously expected with regards to intraoperative transfusion requirements. Notably we found no change in this relationship when Impella was stratified by its duration of use.

We found that several factors were associated with peri-operative transfusion: those with prior sternotomy, LVADs pretransplant, and longer device duration. Of note, the association between bleeding and longer device duration was driven by LVAD bleeding a not by Impella, IABP or ECMO use. In a small retrospective review comparing patients bridged to transplant with an Impella 5.5 compared to an LVAD, Shapiro et al. found that the use of an Impella 5.5 was associated with a reduction in total intra-operative product requirement including cryoprecipitate, platelets, and autologous blood salvage. Similar to our study, they noted a trend towards fewer packed red blood cell transfusion requirement.²⁰ However, our study provides further confirmation that the shift to prioritize patients with tMCS has not been met with concomitant increase in peri-operative bleeding risk.

Given these findings centers ought to consider systemic hemostatic agents when evaluating the bleeding risk of heart transplants. One group found that recombinant Factor VII had no significant effect on decreasing bleeding in heart transplants, which included those who underwent redo sternotomy with LVAD explant with higher costs to the patient.²¹ Administering 4-factor prothrombin complex concentrates (PCC) prior to surgery for patients who will require LVAD explant and were previously anticoagulated on warfarin has been associated with an overall lower transfusion requirement.²² This is a routine practice we follow at our institution. Another practice that may mitigate bleeding peri-operatively is to look at thromboelastography (TEG) in addition to following ACTs and platelet. Redfern and colleagues retrospectively analyzed their heart transplants before and after the implementation of TEG at their institution. The results were significant and included a reduction in reoperation from seven to three percent, with a reduced odds of re-exploration by nearly three-fold.²³

Ultimately, centers should attempt to anticipate bleeding risks and implement algorithmic transfusion/hemostasis protocols to lessen the burden of peri-operative bleeding during and after OHT. Rapier and colleagues in Australia found a significant decrease in red cell transfusions for OHTs following the implementation of a blood management protocol.²⁴

Our study does have limitations. First, because it was a retrospective analysis from a single-institution, our study is subject to referral and selection bias. The number of patients requiring transfusion was small and so the sample size raises the possibility of a Type II statistical error, although a retrospective power calculation was around 90%. Additionally, our patients skew towards a higher risk population given the high proportion of redo sternotomies and therefore many of our operative teams take measures to mitigate bleeding risks. On the other hand, an important strength of our study was the ability to capture granular data regarding our patient's clinical features that may not be available in large databases, for example the shift between devices, the use of concomitant tMCS, and the duration of device use. Our study also reflects on our institutional best practices.

In conclusion, our work shows that the use of Impella as a bridge to transplant was not associated with increased

intraoperative and immediate post-operative transfusion requirements. This relationship did not change based on duration of Impella use. We showed that the use of this form of tMCS did not increase intraoperative blood loss. Our study lends greater credence to the use of the Impella as a safe bridging strategy to OHT.

CRediT authorship contribution statement

Phoebe Miller: Project administration, Conceptualization, Data curation, Formal analysis, Writing - original draft. **Andrew Akcelik:** Data curation, Writing -original draft. **Alyssa Murillo:** Data curation, Formal analysis, Investigation. **Alison Baskin:** Writing - original draft, Software, Visualization. **Alexander Merriman:** Data curation, Formal analysis, Writing - original draft. **Mohammad Arammash:** Data curation, Formal analysis, Writing - original draft. **Jason Smith:** Project administration, Writing - review and editing, Supervision, Resources. **Amy G. Fiedler:** Project administration, Conceptualization, Writing - review and editing, Supervision, Resources.

Disclosure statement

The authors have no affiliations to disclose.

Financial support

There was no funding used for the generation of this manuscript.

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