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PII: S2666-2507(23)00392-9
DOI: https://doi.org/10.1016/j.xjtc.2023.10.012
Reference: XJTC 1541

To appear in: JTCVS Techniques

Received Date: 6 May 2023
Revised Date: 5 October 2023
Accepted Date: 10 October 2023

Please cite this article as: Schumer EM, Bai YZ, Kotkar KD, Masood MF, Itoh A, Schilling JD, Ewald GA, Damiano MS, Fischer I, Kaneko T, Damiano RJ, Pawale A, Surgically implanted endovascular, micro axial left ventricular assist device: A single institution study, JTCVS Techniques (2023), doi: https://doi.org/10.1016/j.xjtc.2023.10.012.

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Surgically implanted endovascular, micro axial left ventricular assist device: A single institution study

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Meeting Presentation: This abstract was presented as an oral presentation at the 103rd annual American Association for Thoracic Surgery meeting May 6-9, 2023.

Classifications: Mechanical circulatory support, heart failure, heart transplant

Word Count: 5314

Conflict of Interest:

Dr. Itoh is a speaker for Abbott and Abiomed Inc and receives honoraria from both. Dr. Kotkar is a speaker for Abiomed Inc. and does not receive honoraria.

Funding: There was no funding for this project.

Informed Consent: Consent was not obtained as this study was exempt under a waiver of HIPAA authorization of the Privacy Rule.

IRB: This study identified as 202209179 was approved by the Washington University Institutional Review Board on 9/28/2022.

Corresponding author:
ABBREVIATIONS:  AST = aspartate aminotransferase, ALT = alanine transaminase, BiVAD = biventricular assist devices, BMI = body mass index, CABG = coronary artery bypass grafting surgery, CPR = cardiopulmonary resuscitation, CS = cardiogenic shock, CSG = cardiogenic shock group, CVD = cerebrovascular disease, FDA = Federal Drug Administration, HRCSG = high risk cardiac surgery group, IABP = intra-aortic balloon pump, LVAD = left ventricular assist device, NYHA = New York Heart Association, PCI = percutaneous coronary intervention, PVD = peripheral vascular disease, RVAD = right ventricular assist device, VA ECMO = venoarterial extracorporeal membrane oxygenation, VIS = vasoactive inotropic score, VV ECMO = venovenous extracorporeal membrane oxygenation

Central Message: Outcomes with Impella 5.5 are diverse and depend on indication for use.

Perspective Statement: The treatment of cardiogenic shock and high-risk cardiac surgery has changed with the introduction of the Impella 5.5. We present a large, single-center case series describing outcomes with this device.

Central Picture: Survival after Impella 5.5 implantation
Abstract

Objective: Impella 5.5 (Abiomed, Inc., Danvers, MA), a surgically implanted endovascular micro-axial left ventricular assist device, is increasingly used worldwide and there have been more than 10000 implants. The purpose of this study is to describe a large-volume, single center experience with the use of Impella 5.5.

Methods: Data were obtained retrospectively from patients supported with an Impella 5.5 implanted at our institution from May 1, 2020 to December 31, 2022. Demographic, operative, and post-operative outcomes for each group are described. Results are reported in median (interquartile range) or n (%). The entire cohort was divided into five main groups based upon the intention to treat at the time of Impella 5.5 implantation: 1) patients who had a planned Impella 5.5 implanted at the time of high-risk cardiac surgery (HRCS), 2) patients with cardiogenic shock (CS), 3) patients bridged to a durable LVAD, 4) patients bridged to transplant, and 5) patients with postcardiotomy shock, who received unplanned Impella 5.5.

Results: There were a total of 126 patients supported with Impella 5.5. Overall survival to device explant was 76.2% with 67.5% surviving to discharge. Mid-term survival was assessed with a median follow-up time of 318 days and demonstrated an overall survival of 60.3% and median 650 days (549, 752).

Conclusions: Outcomes after using Impella 5.5 are variable depending on the indication of use. Patient selection may be of utmost importance and requires further experience with this device to determine who will benefit from insertion.

Keywords: Ventricular assist device, cardiogenic shock, temporary mechanical circulatory support
Introduction

Prior to the introduction of the Impella 5.0 and Impella 5.5 (Abiomed, Inc., Danvers, MA), options for temporary left ventricular support were an intra-aortic balloon pump (IABP), temporary central ventricular assist device, Impella 2.5 or CP (Abiomed, Inc., Danvers, MA), TandemHeart (LivaNova, Houston, TX) or venoarterial extracorporeal membrane oxygenation (VA-ECMO). The Impella 5.5 received US Federal Drug Administration (FDA) approval in October, 2019 and its implementation in clinical practice has increased the options for treatment of heart failure and cardiogenic shock.

The Impella 5.5 is a micro-axial left ventricular assist device (LVAD) that can be implanted through a graft surgically attached to the axillary artery or aorta\(^1\)\(^2\). The inlet sits in the left ventricle and outlet in the ascending aorta, traversing the aortic valve. It is capable of up to 5.5 liters/minute of blood flow and is approved by the FDA for up to 14 days of use, although clinically has been used for much longer.

Recent data have been published regarding the safety and short-term outcomes of this device. These studies have been limited to small, single-center case series\(^3\)\(^4\) and larger multi-
institutional, industry-driven studies\textsuperscript{5,6}. Thus, we sought to describe detailed outcomes with the use of Impella 5.5 at a large heart failure center.

**Materials and Methods**

This study was a retrospective review of our institutional Society of Thoracic Surgeons (STS) database to include all patients who underwent implantation of an Impella 5.5 device from May 1, 2020 to December 31, 2022. There were no additional exclusion criteria. The design and results of the study are shown in the visual abstract (Figure 1).

The entire cohort was divided into five main groups based upon the intention to treat at the time of Impella 5.5 implantation as shown in Figure 2. 1) patients who had a planned Impella 5.5 implanted at the time of high-risk cardiac surgery (HRCS), 2) patients with cardiogenic shock (CS), 3) patients bridged to a durable LVAD, 4) patients bridged to transplant, and 5) patients with unplanned Impella 5.5 for post-cardiotomy shock.

1. Patients who had a planned Impella 5.5 implanted at the time HRCS had a preoperative echocardiogram, right and left heart catheterization, and viability studies as needed. These patients had lower ejection fraction, low cardiac output, and adequate viability in case of planned coronary bypass surgery.

2. For CS patients who received Impella 5.5, once the shock state was reversed and end organ function had improved, an attempt was made to wean the Impella with inotropic support. During the Impella 5.5 weaning period, we monitored for adequate CO with a pulmonary artery catheter and observed for signs of weaning failure such as increasing need for inotropes or pressors, flash pulmonary edema or renal impairment. Finally, a contrast echocardiogram was performed at low
Patients who did not tolerate weaning of the Impella 5.5 and met institutional criteria completed a full evaluation for heart transplant and/or durable LVAD. A final decision regarding candidacy was made by our multidisciplinary team.

3. Patients who were initially considered reasonable durable LVAD candidates but had low cardiac output, volume overload and reversible end organ dysfunction with inotropes were bridged with Impella 5.5 for optimization prior to durable LVAD.

4. Patients who were deemed appropriate heart transplant candidates by our multidisciplinary team but who were on high dose or dual inotropes and did not respond adequately to IABP or were felt unlikely to respond adequately to IABP, and patients with severe pulmonary hypertension with high pulmonary vascular resistance, were bridged to heart transplant with axillary Impella 5.5.

5. Patients who had no plans for Impella 5.5 and low expectations for postcardiotomy shock, either received Impella directly, or along with VA ECMO or after receiving post cardiotomy VA ECMO.

All Impella 5.5 implantations were performed in the operating room with portable fluoroscopy guidance under general anesthesia. The mode of access was surgical cutdown to the right or left axillary artery, hemi-sternotomy, full sternotomy, or mini right anterior thoracotomy. The graft was tunneled to a separate exit site in all cases.

For the HRCS group, a 10 mm dacron graft was anastomosed to axillary artery or more commonly to distal ascending aorta below the origin of innominate artery before initiation of cardiopulmonary bypass, and the planned cardiac surgery was then performed. The graft was
tunneled out through the supraclavicular region if placed centrally. The Impella 5.5 was inserted prior to coming off bypass with fluoroscopy or TEE guidance. After weaning Impella 5.5 post operatively over a few days as described above, it was removed in the operative room or more commonly bedside.

During the study time period, the Impella 5.5 was the only temporary LVAD used, as situations where surgical, temporary LVAD was needed due to contraindication to Impella 5.5 were not encountered. Per our institutional practice, durable LVAD is not directly implanted for acute CS as a primary therapy. We would otherwise use a surgical temporary LVAD when the LV cavity is too small or flows higher than 5 Liters/minute are desired.

Information not available in the STS database was obtained through detailed chart review. Vasoactive Inotropic Score (VIS) was calculated using the formula: dopamine dose (μg/kg/min) + dobutamine dose (μg/kg/min) + 100 × epinephrine dose (μg/kg/min) + 10 × milrinone dose (μg/kg/min) + 10,000 × vasopressin dose (unit/kg/min) + 100 × norepinephrine dose (μg/kg/min) 7. New York Heart Association (NYHA) class at 90 days post-hospital discharge was obtained from patient notes, although a significant number of patients did not have follow-up at this length of time.

All statistical analyses were completed using SPSS v. 22 (IBM, Armonk, New York) or BlueSky Statistics (Chicago, IL). Results are reported in N (%) or median (interquartile range). As this is a descriptive study, no group comparisons were made. Kaplan-Meier survival was used to examine overall survival. This study was approved by the Washington University Institutional
Review Board on September 28, 2022 (#202209179). Consent was not obtained as this study was exempt under a waiver of HIPAA authorization of the Privacy Rule.

**Results**

A total of 126 patients underwent Impella 5.5 implantation during the study time period with 130 devices implanted. Three patients had device exchange, and 1 patient required reinsertion after a failed weaning period off Impella 5.5 support. The median length of Impella 5.5 support was 9 days (7, 15), with the maximum at 65 days. One patient did not tolerate Impella 5.5 support due to acute, severe aortic insufficiency (AI), and one patient required aortic valve repair at the time of durable LVAD implant for severe AI after Impella 5.5 removal. Thirty-four patients were in the HRCS group, 65 patients were in CS, 5 patients were bridged to LVAD from Impella 5.5 (never had ECMO), 13 patients were bridged to heart transplant, and 9 patients had unplanned Impella 5.5 for post-cardiotomy shock. Demographic information and data at the time of Impella 5.5 implantation is described in Table 1. The causes of heart failure leading to CS were predominantly acute on chronic non-ischemic cardiomyopathy, acute myocardial infarction, and ischemic cardiomyopathy and are shown in Figure 3. The procedures performed for the HRCS are shown in Figure 4. Coronary artery bypass grafting was the most common operation performed in this group (n=21). In the HRCS group, median ejection fraction was 26% (19, 32), left ventricular end diastolic dimension was 5.8 cm (5.3, 6.5), and 7 (35.3%) patients had moderate or severe mitral regurgitation.

Most patients outside of the HRCS group required some type of mechanical circulatory support in addition to the Impella 5.5 with only 10 (10.9%) supported with Impella 5.5 alone. The type of additional support is summarized in Table 2 and categorized by the timing of support.
For patients who were ultimately bridged to transplant, 3 patients had VA ECMO (one before Impella, one after and one at the time of Impella 5.5 insertion), and two of the ECMO patients had ECMO decannulated prior to transplant. For patients who went on to HeartMate III implantation (Abbott Laboratories, Chicago, IL), 27.8% of patients had Impella CP and 38.9% had VA ECMO prior to Impella 5.5. A total of 38.9% patients had a temporary RVAD after HeartMate III. Two patients failed removal of Impella 5.5 that underwent additional MCS (VA ECMO, second Impella 5.5) as a bridge to durable LVAD.

Operative details related to Impella 5.5 placement and postoperative results are summarized in Table 3. Most patients had placement through a right axillary artery cutdown. Central aortic cannulation through a sternotomy was performed at the time of high-risk cardiac surgery while one patient had placement through an upper sternotomy and one through right mini anterior thoracotomy. Six patients had purge flow decrease alarms that were treated with tissue plasminogen activator and resolved. Four patients had purge site leakage. Of these, 3 were treated with purge sidearm bypass and one was observed. These complications occurred at a median of 13 days (4.5, 15.5). Reoperation for bleeding included any return to the operating room for bleeding either at the insertion site or sternotomy. The stroke rate was 10%, and nearly 28% of the entire cohort had a new dialysis requirement at any point in their hospital course. There were no brachial plexus injuries.

Overall survival to Impella 5.5 explantation was 76.2% with 67.5% surviving to discharge. Mid-term survival was assessed with a median follow-up time of 318 days and demonstrated an overall survival of 60.3% and median 650 days (549, 752) (Figure 5); however twenty patients did not have follow-up out to six months. Overall survival was 82.4% for the HRCS group (median 771 days, 95% confidence interval 582, 959 days) and 51.6% for the non-HRCS
patients (median 579 days, 95% confidence interval 464, 694 days). For patients who received
Impella 5.5 as their only support device, overall survival was 50.0% (median 350 days, 95%
confidence interval 154, 546 days). Out of the 18 patients who proceeded to HeartMate III, 72%
were able to leave the hospital with an overall survival of 60.0% (median 85 days, 95%
confidence interval 6,164 days). The causes of death for these 8 patients were diverse and
included failure to thrive, multi-system organ failure, cancer, ischemic colitis, and severe
driveline infection with sepsis. However, the most common theme amongst patients with worse
outcomes was severe right ventricular dysfunction.

Discussion

Impella 5.5 is now a widely used option for left ventricular support but less is known about the
granular details of real-life experience or outcomes outside of the acute phase. In fact, the
majority of the current literature is mostly limited to case reports or small, institutional series.
Herein, we present our experience in a high-volume heart failure center with a diverse group of
patients and several different indications for Impella 5.5 implantation.

Although it is difficult to conclude whether patients in the HRCS group benefited from planned
Impella 5.5 as there was no control group, these patients had an acceptable survival to discharge
despite having low EF and depressed cardiac output. The goals with Impella 5.5 support in these
patients was to use less pressors, optimize volume status, extubate early, and facilitate patient
mobility. Even though we have incomplete follow up data at 6 months, there was decreased
survival for the HRCS group after hospital discharge. These patients who had borderline heart
function before cardiac surgery may need more intense follow up and medical care after
discharge. A randomized trial with longer follow up may help identify who will have long term
benefit and which patients might have done better with advanced heart failure medical or surgical therapy in lieu of conventional cardiac surgery. Some of the patients in this group would probably not have been offered conventional cardiac surgery at our center without Impella 5.5.

In contrast, patients who had an unplanned Impella for post cardiotomy shock, did not necessarily have low EF or low cardiac output preoperatively. When mechanical circulatory support was needed but was unplanned, this was associated with higher hospital mortality. Hence we would argue that careful multidisciplinary consideration should be given for planning the use of concomitant mechanical support at the time of conventional cardiac surgery, as these patients may stay on longer cardiopulmonary bypass or may need VA ECMO before transitioning to Impella 5.5 support.

Patients who had Impella 5.5 implanted for CS or as a bridge to advanced heart failure therapies or recovery represent a very different subset of patients who were quite sick at the time of presentation. The Impella 5.5 was used as both a primary rescue device and as a stabilizing or bridging tool in this patient population. Some of the patients in this cohort were already on ECMO, Impella CP, or IABP with some improvement in markers of shock such as liver function tests and lactate. In the case of IABP, the decision to increase support to an Impella 5.5 was due to inadequate support. In case of Impella CP, it was typically due to inadequate support and sometimes due to vascular compromise, hemolysis. In the case of ECMO, the Impella was used as a LV vent strategy and for eventual, possible decannulation of ECMO. However, these patients had unknown probability of LV recovery and uncertain candidacy for advanced heart failure therapies and hence high mortality.
Although we were initially surprised that many of the laboratory values were near normal at the
time of device implant, this likely occurred because many of these patients were already on a
mechanical support device and inotropes. In general, these patients required multiple modes and
combinations of mechanical circulatory support for extended lengths of time, which has been
previously described\textsuperscript{9}. Although the suboptimal outcomes in this group of patients is influenced
by the fact that the majority were poor candidates for LVAD or heart transplant, these findings
indicate that some of the Impella patients may not be salvageable despite aggressive mechanical
support.

By the same token, there are a subset of patients in this group with at least partial LV recovery
who have the potential to do well over the long-term. In a large, multi-institutional study
comparing the Impella 5.0 (Abiomed, Inc., Danvers, MA) to Impella 5.5 for CS patients,
successful weaning for those not progressing to advanced therapies occurred in 50\% of patients,
which is similar to our findings\textsuperscript{10}.

Transitioning shock patients from ECMO to Impella 5.5 before durable LVAD allows for
improvement in mobility, nutrition, volume status, end organ function and the ability to assess
right ventricular function\textsuperscript{12} without continuing the inherent risks of ECMO, compared to direct
durable LVAD implant from VA ECMO\textsuperscript{13,14}. This group had multiple devices used and their
hospitalization likely incurred disproportionately high healthcare costs for relatively poor short
term survival. In contrast, direct implantation of durable LVAD without bridging with Impella
5.5 in a selective group of patients may have certain advantages\textsuperscript{15}. Determining which patients
will benefit from durable LVAD support and Impella 5.5 bridge is key. Use of a temporary
RVAD at or after durable LVAD implantation was higher earlier in the study but improved
likely with increased team experience and patient selection in the later part of the study. Patients
with advanced age, on Impella 5.5 support, who otherwise improve but remain on renal replacement therapy, and have limited options for advanced heart failure therapies are challenging. Some of these patients may end up with durable LVAD as it is extremely difficult to withdraw temporary support in an otherwise ambulatory patient.

Amongst the cohort of 20 patients implanted with an Impella 5.5 with a bridge to transplant intent the outcomes were excellent. This included both patients who arrived in CS and those listed for transplant with an Impella 5.5 implanted as a bridging strategy. These patients were carefully selected with most patients requiring either no other type of mechanical circulatory support or were upgraded from an IABP to Impella 5.5. Reasons to use Impella 5.5 for these patients were low CO, end organ dysfunction, high pulmonary artery pressure, elevated pulmonary vascular resistance, need for multiple or high inotropes and inadequate support on IABP. Our data are similar to other published series of Impella 5.5 bridged to heart transplant\textsuperscript{16}. In the case of biventricular failure, inotropic or rarely temporary RVAD plus Impella 5.5 support is a reasonable approach to employ as a bridge to transplant. Patient selection for Impella 5.5 as a bridge to transplant is crucial, with durable LVAD remaining a backup option if transplant no longer remains feasible.

Some patients who are deemed candidates for durable LVAD who were not on VA ECMO, but needed renal, nutritional, volume optimization were also bridged via Impella 5.5, but these numbers are too small to draw any firm conclusions about benefits of this approach.

Our study has several limitations as it was a single center, retrospective analysis. As all Impella 5.5 implantations were performed at a single high-volume center, this may introduce bias into our study regarding patient selection, treatment decisions, and surgical technique. Specifically...
for patients with CS, only patients who survived to reach our institution were able to undergo Impella 5.5 implantation, thus introducing further selection bias. The STS database is limited in granular detail, which was partially overcome by significant chart review.

The study represents a real-world experience of Impella 5.5 in a large, high-volume center with outcomes extending out to three years. Patient outcomes varied significantly by indication which highlights the importance of patient selection when determining who will benefit from Impella 5.5 support. As the use of the Impella 5.5 continues to increase, long-term outcomes will need to be tracked carefully as certain patients with CS will not benefit from support with this device. We feel that the decision to implant an Impella 5.5 should be made following careful consideration of risks and benefits and with a goal-directed exit strategy in mind at the time of implant. Additionally, the cost of this therapy will need to be considered when making decisions about the appropriate patients and clinical scenarios for use of the Impella 5.5. Multidisciplinary decision making involving advanced heart failure cardiologists, heart failure surgeons, and cardiac ICU physicians will be critical to direct the use of these devices to the most appropriate patients. Future research into risk prediction models for both short- and long-term outcomes will also be important to optimize the use of the Impella 5.5 for patients with CS.
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<th>Bridge to LVAD (N=5)</th>
<th>Bridge to transplant (N=13)</th>
<th>Post-cardiotomy shock (N=9)</th>
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<td>2 (5.9)</td>
<td>39 (60.0)</td>
<td>0 (0)</td>
<td>1 (7.7)</td>
<td>9 (100)</td>
</tr>
</tbody>
</table>

Table 1. Preoperative information for all patients at the time of Impella 5.5 (Abiomed, Inc., Danvers, MA) insertion. AST = aspartate aminotransferase, ALT = alanine transaminase, BiVAD = biventricular assist devices, BMI = body mass index, CVD = cerebrovascular disease,
CPR = cardiopulmonary resuscitation, LVAD = left ventricular assist device, PCI = percutaneous coronary intervention, PVD = peripheral vascular disease, VIS = vasoactive inotropic score.

<table>
<thead>
<tr>
<th></th>
<th>Total (N=92)</th>
<th>Cardiogenic shock (N=65)</th>
<th>Bridge to LVAD (N=5)</th>
<th>Bridge to transplant (N=13)</th>
<th>Post-cardiotomy shock (N=9)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mechanical support before Impella 5.5 implant</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IABP</td>
<td>42 (46.7)</td>
<td>24 (36.9)</td>
<td>4 (80.0)</td>
<td>10 (76.9)</td>
<td>6 (66.7)</td>
</tr>
<tr>
<td>Time on IABP (days)</td>
<td>5 (2, 7)</td>
<td>3 (2, 8)</td>
<td>8 (2, 13)</td>
<td>6 (5, 7)</td>
<td>3 (0, 7)</td>
</tr>
<tr>
<td>Impella CP</td>
<td>34 (37.8)</td>
<td>30 (46.2)</td>
<td>-</td>
<td>-</td>
<td>4 (44.4)</td>
</tr>
<tr>
<td>Time on Impella CP (days)</td>
<td>4 (2, 6)</td>
<td>4 (2, 6)</td>
<td>-</td>
<td>-</td>
<td>5 (4, 6)</td>
</tr>
<tr>
<td>VA ECMO</td>
<td>33 (36.7)</td>
<td>33 (50.8)</td>
<td>-</td>
<td>2 (13.4)</td>
<td>7 (77.8)</td>
</tr>
<tr>
<td>Time on VA ECMO (days)</td>
<td>5 (4, 8.5)</td>
<td>5 (4, 7)</td>
<td>-</td>
<td>3 (2, 4)</td>
<td>5 (3, 8)</td>
</tr>
<tr>
<td>VV ECMO</td>
<td>1 (1.1)</td>
<td>1 (1.5)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Time on VV ECMO (days)</td>
<td>3 (3, 3)</td>
<td>3 (3, 3)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Mechanical support during and/or after Impella 5.5 implant</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RVAD</td>
<td>16 (17.8)</td>
<td>8 (12.3)</td>
<td>3 (60.0)</td>
<td>2 (15.4)</td>
<td>4 (44.4)</td>
</tr>
<tr>
<td>Time on RVAD (days)</td>
<td>14 (6, 19)</td>
<td>10 (6, 19)</td>
<td>14 (0, 20)</td>
<td>15 (7, 22)</td>
<td>15 (12, 16)</td>
</tr>
<tr>
<td>---------------------</td>
<td>------------</td>
<td>------------</td>
<td>------------</td>
<td>------------</td>
<td>------------</td>
</tr>
<tr>
<td>VA ECMO</td>
<td>9 (9.8)</td>
<td>6 (9.2)</td>
<td>-</td>
<td>2 (15.4)</td>
<td>1 (11.1)</td>
</tr>
<tr>
<td>Time on VA ECMO (days)</td>
<td>3 (2, 5.5)</td>
<td>3 (2, 6)</td>
<td>-</td>
<td>3 (2, 4)</td>
<td>5 (5, 5)</td>
</tr>
<tr>
<td>VV ECMO</td>
<td>3 (3.3)</td>
<td>3 (4.6)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Time on VV ECMO (days)</td>
<td>4 (3, 4)</td>
<td>4 (3, 4)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Table 2. Mechanical circulatory support used other than Impella 5.5 (Abiomed, Inc., Danvers, MA) for patients with cardiogenic shock reported in N (%) and median (interquartile range). IABP = inta-aortic balloon pump, LVAD = left ventricular assist device, RVAD = right ventricular assist device, VA ECMO = venoarterial extracorporeal membrane oxygenation, VV ECMO = venovenous extracorporeal membrane oxygenation.
<table>
<thead>
<tr>
<th>Site of Insertion</th>
<th>Total (N=126)</th>
<th>High-risk cardiac surgery (N=34)</th>
<th>Cardiogenic shock (N=65)</th>
<th>Bridge to LVAD (N=5)</th>
<th>Bridge to transplant (N=13)</th>
<th>Post-cardiotomy shock (N=9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right</td>
<td>89 (70.6)</td>
<td>13 (38.2)</td>
<td>53 (81.5)</td>
<td>4 (80.0)</td>
<td>12 (92.3)</td>
<td>7 (77.8)</td>
</tr>
<tr>
<td>Left</td>
<td>10 (7.9)</td>
<td>0 (0)</td>
<td>7 (10.8)</td>
<td>1 (20.0)</td>
<td>1 (7.7)</td>
<td>1 (11.1)</td>
</tr>
<tr>
<td>Aortic</td>
<td>27 (21.4)</td>
<td>21 (61.8)</td>
<td>5 (7.7)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1 (11.1)</td>
</tr>
<tr>
<td>Reoperation for bleeding</td>
<td>17 (13.5)</td>
<td>4 (11.8)</td>
<td>7 (10.8)</td>
<td>0 (0)</td>
<td>2 (15.4)</td>
<td>4 (44.4)</td>
</tr>
<tr>
<td>Stroke</td>
<td>13 (10.3)</td>
<td>3 (8.8)</td>
<td>7 (10.7)</td>
<td>0 (0)</td>
<td>(0)</td>
<td>3 (33.3)</td>
</tr>
<tr>
<td>New dialysis</td>
<td>35 (27.8)</td>
<td>6 (17.6)</td>
<td>17 (26.2)</td>
<td>2 (40.0)</td>
<td>6 (46.2)</td>
<td>4 (44.4)</td>
</tr>
<tr>
<td>Local infection</td>
<td>4 (3.2)</td>
<td>2 (6.3)</td>
<td>1 (1.5)</td>
<td>1 (20.0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Location of removal</td>
<td>OR</td>
<td>77 (78.6)</td>
<td>15 (48.4)</td>
<td>40 (93.0)</td>
<td>12 (92.3)</td>
<td>5 (83.3)</td>
</tr>
<tr>
<td></td>
<td>21 (21.4)</td>
<td>16 (51.6)</td>
<td>3 (7.0)</td>
<td>0 (0)</td>
<td>1 (7.7)</td>
<td>1 (16.7)</td>
</tr>
</tbody>
</table>
Table 3. Outcomes after Impella 5.5 (Abiomed, Inc., Danvers, MA) implantation. LVAD = left ventricular assist device, NYHA = New York Heart Association

| Survival to Impella 5.5 explant | 96 (76.2) | 31 (91.2) | 41 (63.1) | 5 (100) | 13 (100) | 6 (66.7) |
| Survival to discharge | 85 (67.5) | 31 (91.2) | 35 (50.7) | 2 (40.0) | 13 (100) | 4 (44.4) |
| Survival at 6 months | 60 (56.6) (N=106) | 15 (75.0) (N=20) | 30 (48.2) (N=62) | 1 (20.0) | 13 (100) | 1 (16.7) (N=6) |
| NYHA class at 90 days | I | 34 (27.0) | 8 (23.5) | 13 (20.0) | 1 (20.0) | 1 (11.1) |
| II | 19 (15.1) | 7 (20.6) | 11 (16.9) | - | 1 (7.7) | - |
| III | 8 (6.3) | 2 (5.9) | 5 (7.7) | - | - | - |
| IV | 4 (3.2) | 1 (2.9) | 1 (1.5) | - | 1 (7.7) | 1 (11.1) |

**Figure legends**

**Figure 1.** Graphical abstract showing overall survival to Impella 5.5 explant was 76%, overall survival was 60.0%, and low device-related complication rate. Outcomes after Impella 5.5 vary significantly by indication but are overall encouraging.

**Figure 2.** Intentions for Impella 5.5 implantation. AI: aortic insufficiency, AS: aortic stenosis, CABG: coronary artery bypass grafting, CO: cardiac output, CVP: central venous pressure, ECMO: extracorporeal membrane oxygenator, HRCS: high risk cardiac surgery, IABP: intra-arterial balloon pump.

**Figure 3.** Etiology of heart failure for the patients who had Impella 5.5 implanted for cardiogenic shock, bridge to durable ventricular assist device, bridge to transplant, and post-cardiotomy shock (A) and survival by etiology (B).

**Figure 4.** Procedures performed during high-risk cardiac surgery. CABG = coronary artery bypass grafting surgery.

**Figure 5.** Kaplan Meier analysis demonstrating survival of the entire cohort who received an Impella 5.5 extending out to 3 years, shown with 95% confidence interval.

**References**


Survival by Etiology of Heart Failure

- POST-CARDIOTOMY
- MYOCARDITIS
- POST-PARTUM
- ACUTE MI
- ISCHEMIC
- NON-ISCHEMIC

Overall Survival (median follow-up 650 days) vs. Survival to Impella 5.5 Removal
Concomitant with HRCs
1. LVEF<25% for CABG, Severe AS, Severe AI
2. LVEF <30% in presence of severe MR
3. Right heart catheterization showing low cardiac output
4. Viable myocardium in cases of CABG
5. Long cross clamp time in addition to above
6. Preoperatively on IABP, Impella CP in addition to above

Bridge to heart transplant
Patient deemed candidate for transplant and
1. Has low CO in spite dual or high inotropes
2. Has reversible end organ dysfunction
3. Will likely have inadequate support with IABP, or on IABP with inadequate support
4. Has PASP 60+ mmHg, PVR 3-4 Woods

Conductions for Impella 5.5 insertion

Bridge to Durable LVAD
Patient deemed candidate for LVAD implantation but currently decompensated with one or more of following:
1. Volume overload, high CVP, correctable RV dysfunction
2. Pulmonary edema, high oxygen requirement
3. Recent, reversible, end organ dysfunction
4. Malnutrition, deconditioning

Cardiogenic shock
1. Predominant LV failure
2. Adequate gas exchange
3. High dose inotropes, multiple inotropes/vasopressors
4. Low cardiac output
5. Increasing lactate, worsening end organ function
6. IABP thought to be inadequate
7. Inadequate support on IABP, Impella CP
8. Impella CP with hemolysis, bleeding, vascular compromise, or prolonged need for support
9. Patient not extenuate who could need VA ECMO support
10. Stable for transport to OR and to receive general anesthesis
11. Post VA ECMO, with severe LV dysfunction, as LV vent and then as a bridge to weaning or advanced surgical heart failure therapy
12. Post inferior VSD, for stabilization before closure

Post cardiomyopathy cardiogenic shock, unplanned Impella 5.5

ETIOLOGY OF HEART FAILURE

- Post-cardiomyopathy: 42%
- Myocarditis: 5%
- Post-partum: 2%
- Acute MI: 35%
- Non-ischemic: 8%
- Ischemic: 15%

Survival by Etiology of Heart Failure

- **Post-cardiomyopathy:**
  - Overall Survival (median follow-up 650 days): 50%
  - Survival to implant: 25%
- **Myocarditis:**
  - Overall Survival: 65%
  - Survival to implant: 30%
- **Post-partum:**
  - Overall Survival: 45%
  - Survival to implant: 50%
- **Acute MI:**
  - Overall Survival: 60%
  - Survival to implant: 40%
- **Ischemic:**
  - Overall Survival: 65%
  - Survival to implant: 20%
- **Non-ischemic:**
  - Overall Survival: 55%
  - Survival to implant: 55%
Procedures performed during high-risk cardiac surgery

- CABG: 21
- Aortic: 5
- Aortic Valve: 13
- Mitral Valve: 11
- Tricuspid Valve: 5
- Atrial Fibrillation: 6
OUTCOMES WITH A SURGICALLY IMPLANTED ENDOVASCULAR, MICRO AXIAL LEFT VENTRICULAR ASSIST DEVICE

KEY QUESTIONS
What are outcomes with Impella 5.5 (Abiomed, Inc., Danvers, MA)?

KEY FINDINGS
Survival decreased significantly for all groups from time of Impella 5.5 to mid-term follow-up.

TAKE-HOME MESSAGE
Outcomes after Impella 5.5 vary significantly by indication but are overall encouraging.

HIGH RISK CARDIAC SURGERY
N=34

CARDIOGENIC SHOCK
N=65

LVAD
N=5

TRANSPLANT
N=13

POST-CARDIOTOMY SHOCK
N=9
OUTCOMES WITH A SURGICALLY IMPLANTED ENDOVASCULAR, MICRO AXIAL LEFT VENTRICULAR ASSIST DEVICE

KEY QUESTIONS
What are outcomes with Impella 5.5 (Abiomed, Inc., Danvers, MA)?

KEY FINDINGS
Survival decreased significantly for all groups from time of Impella 5.5 to mid-term follow-up.

TAKE-HOME MESSAGE
Outcomes after Impella 5.5 vary significantly by indication but are overall encouraging.
Surgically Implanted Endovascular, Micro Axial Left Ventricular Assist Device: A Single Institution Study

Erin M. Schumer, MD, MPH¹, Yun Zhu Bai, MD¹, Kunal D. Kotkar, MD¹, M. Faraz Masood, MD¹, Akinobu Itch, MD, PhD², Joel D. Schilling, MD, PhD², Gregory A. Ewald MD², Marci S. Damiano, MSN¹, Irene Fischer, MPH¹, Tsuyoshi Kaneko, MD¹, Ralph J. Damiano, MD¹, Amit Pawale, MD¹

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