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

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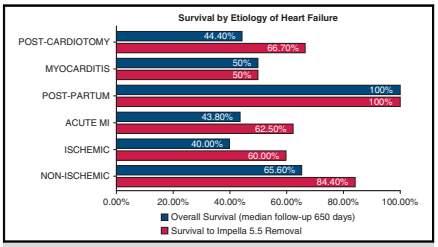
ABSTRACT

Objective: The Impella 5.5 (Abiomed, Inc), a surgically implanted endovascular microaxial left ventricular assist device, is increasingly used worldwide and there have been more than 10,000 implants. The purpose of this study is to describe a large-volume, single-center experience with the use of the Impella 5.5.

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

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

Conclusions: Outcomes after using the 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. (JTCVS Techniques 2024;23:63-71)



Survival after implantation of the Impella 5.5.

CENTRAL MESSAGE

Outcomes with the Impella 5.5 are diverse and depend on indication for use.

PERSPECTIVE

The treatment of CS and HRCS has changed with the introduction of the Impella 5.5. We present a large, single-center case series describing outcomes with this device.

See Discussion on page 72.

To view the AATS Annual Meeting Webcast, see the URL next to the webcast thumbnail.

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

The Impella 5.5 is a microaxial 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 sits in the ascending aorta, traversing the aortic valve. It is capable of up to 5.5 L/min of blood flow and is approved by the Food and Drug

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Informed Consent: Consent was not obtained because this study was exempt under a waiver of Health Insurance Portability and Accountability Act authorization of the Privacy Rule.

This study identified as 202209179 was approved by the Washington University Institutional Review Board on September 28, 2022.

Read at the 103rd Annual Meeting of The American Association for Thoracic Surgery, Los Angeles, California, May 6-9, 2023.

Received for publication May 6, 2023; revisions received Oct 5, 2023; accepted for publication Oct 10, 2023; available ahead of print Oct 20, 2023.

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2666-2507

https://doi.org/10.1016/j.xjtc.2023.10.012

Abbreviations and Acronyms

CS	= cardiogenic shock
HRCS	= high-risk cardiac surgery
IABP	= intra-aortic balloon pump
LVAD	= left ventricular assist device
RVAD	= right ventricular assist device
STS	= Society of Thoracic Surgeons
VA ECMO	= venoarterial extracorporeal membrane oxygenation

Administration for up to 14 days of use, although clinically has been used for 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.[5,6] Thus, we sought to describe detailed outcomes with the use of the 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 the 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 Graphical Abstract (Figure 1).

The entire cohort was divided into 5 main groups based on 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 CS; (3) patients bridged to a durable LVAD; (4) patients bridged to transplant; and (5) patients with unplanned Impella 5.5 for postcardiotomy shock.

1. Patients who had a planned Impella 5.5 implanted during 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 patients in CS who received the 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 cardiac output with a pulmonary artery catheter and observed for signs of weaning failure, such as increasing need for inotropes or pressors, flash pulmonary

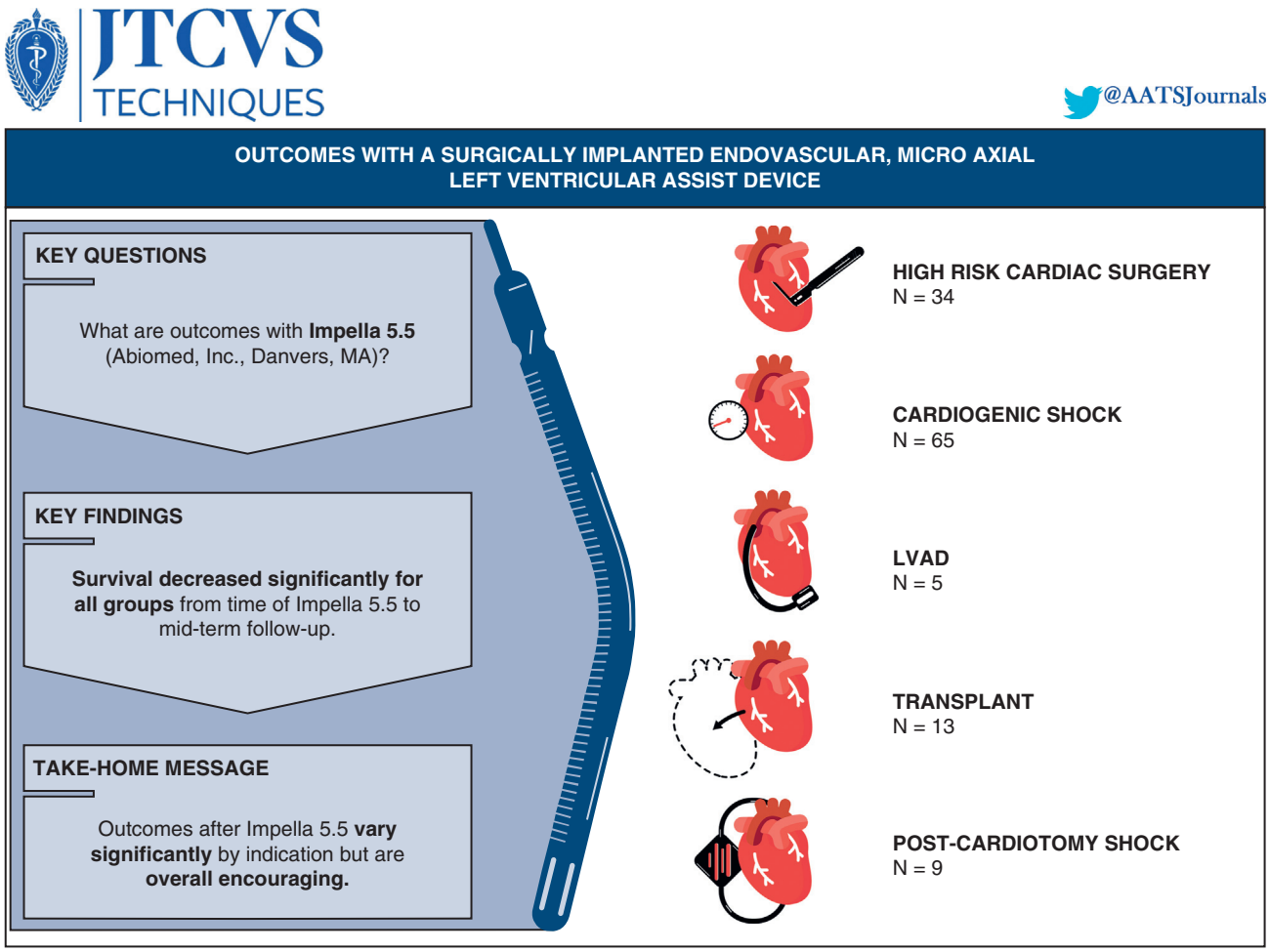

FIGURE 1. Graphical abstract showing overall survival to Impella 5.5 explant was 76%, overall survival was 60.0%, and device-related complication rate was low. Outcomes after Impella 5.5 vary significantly by indication but are overall encouraging.

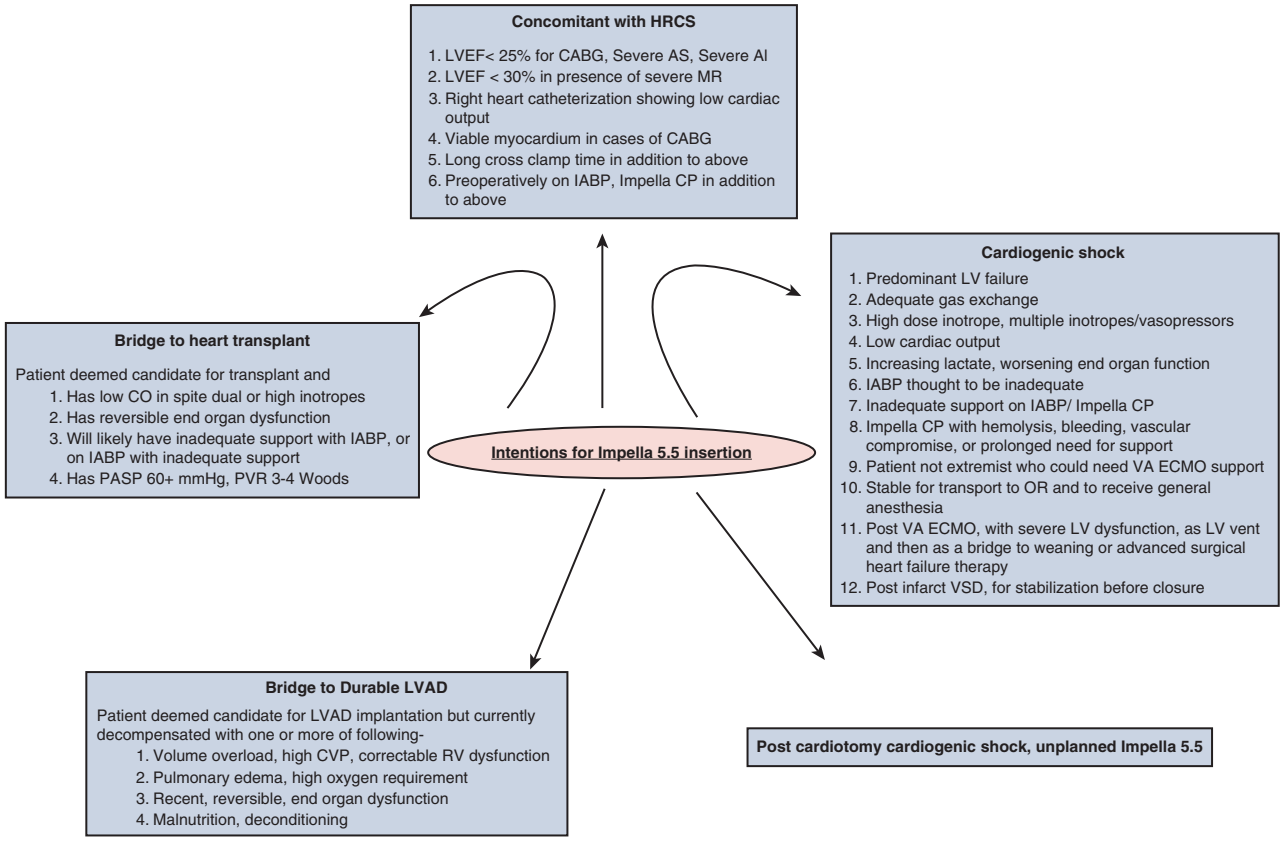

FIGURE 2. Intentions for Impella 5.5 implantation. *HRCS*, High-risk cardiac surgery; *LVEF*, left ventricular ejection fraction; *CABG*, coronary artery bypass grafting; *AS*, aortic stenosis; *AI*, aortic insufficiency; *MR*, mitral regurgitation; *IABP*, intra-aortic balloon pump; *LV*, left ventricle; *CO*, cardiac output; *VA*, venoarterial; *ECMO*, extracorporeal membrane oxygenator; *OR*, operating room; *PASP*, pulmonary artery systolic pressure; *PVR*, pulmonary vascular resistance; *VSD*, ventricular septal defect; *CVP*, central venous pressure; *RV*, right ventricle.

edema, or renal impairment. Finally, contrast echocardiography was performed at low-level Impella 5.5 support. Patients who did not tolerate weaning of the Impella 5.5 and met institutional criteria completed a full evaluation for heart transplant 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 the Impella 5.5 for optimization before 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 thought unlikely to respond adequately to IABP, and patients with severe pulmonary hypertension with high pulmonary vascular resistance, were bridged to heart transplant with an axillary Impella 5.5.
5. Patients with no plans for the Impella 5.5 and low expectations for post-cardiotomy shock received the Impella directly, along with VA ECMO, or after receiving postcardiotomy 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, hemisternotomy, 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 the axillary artery or more commonly to the 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 before coming off bypass with fluoroscopy or transesophageal echocardiography guidance. After weaning the Impella 5.5 postoperatively over a few days as described, it was removed in the operating room or more commonly bedside.

During the study time period, the Impella 5.5 was the only temporary LVAD used, because 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 left ventricular cavity is too small or flows higher than 5 L/min are desired.

Information not available in the STS database was obtained through detailed chart review. Vasoactive inotropic score was calculated using the following formula: dopamine dose (μg/kg/min) + dobutamine dose (μg/kg/min) + 100 $\times$ epinephrine dose (μg/kg/min) + 10 $\times$ milrinone dose (μg/kg/min) + 10,000 $\times$ vasopressin dose (unit/kg/min) + 100 $\times$ norepinephrine dose (μg/kg/min).[7] New York Heart Association class at 90 days posthospital 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) or BlueSky Statistics. Results are reported in N (%) or median (interquartile range). Because 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

because this study was exempt under a waiver of Health Insurance Portability and Accountability Act 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 a maximum of 65 days. One patient did not tolerate Impella 5.5 support due to acute, severe aortic insufficiency, and 1 patient required aortic valve repair at the time of durable LVAD implant for severe aortic insufficiency 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 the Impella 5.5 (never had ECMO), 13 patients were bridged to heart transplant, and 9 patients had an unplanned Impella 5.5 implant for postcardiotomy shock. Demographic information and data at the time of Impella 5.5 implantation are described in Table 1. The causes of heart failure leading to CS were predominantly acute on chronic nonischemic cardiomyopathy, acute myocardial infarction, and ischemic cardiomyopathy (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 patients (35.3%) 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 the 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 (1 before Impella, 1 after Impella, and 1 at the time of Impella 5.5 insertion), and 2 of the patients on ECMO had ECMO decannulated before transplant. For patients who went on to HeartMate III implantation (Abbott Laboratories), 27.8% of patients had Impella CP and 38.9% had VA ECMO before Impella 5.5. A total of 38.9% patients had a temporary right ventricular assist device (RVAD) after the HeartMate III. Two patients failed removal

TABLE 1. Preoperative information for all patients at the time of Impella 5.5 (Abiomed, Inc) insertion

	Total (N = 126)	HRCS (N = 34)	CS (N = 65)	Bridge to LVAD (N = 5)	Bridge to transplant (N = 13)	Postcardiotomy shock (N = 9)
Age (y)	62.0 (49.0-68.0)	63.5 (55.8-69.3)	61.0 (47.0-68.0)	65.0 (58.0-70.0)	49.0 (40.0-54.0)	72.0 (67.0-73.0)
Sex (% male)	97 (77.0)	26 (76.5)	49 (75.4)	3 (60)	12 (92.3)	7 (77.8)
BMI (kg/m^2)	28.5 (24.4-33.9)	28.4 (23.8-31.4)	29.4 (24.3-34.4)	27.8 (25.8-34.4)	28.6 (26.2-34.0)	27.0 (24.3-32.9)
Previous myocardial infarction	76 (60.3)	19 (55.9)	48 (73.8)	2 (40.0)	2 (15.4)	5 (55.6)
Diabetes	60 (47.6)	18 (52.9)	31 (47.7)	3 (60.0)	7 (53.8)	1 (11.1)
PCI	46 (36.5)	2 (5.9)	38 (58.5)	2 (40.0)	2 (15.4)	2 (22.2)
CVD	24 (19.0)	9 (26.5)	8 (12.3)	2 (40.0)	2 (15.4)	3 (33.3)
PVD	17 (13.5)	5 (14.7)	6 (9.2)	0 (0)	2 (15.4)	4 (44.4)
Hypertension	85 (67.5)	27 (79.4)	38 (58.5)	4 (80.0)	10 (76.9)	6 (66.7)
Arrhythmia	72 (57.1)	12 (35.3)	46 (70.8)	4 (80.0)	6 (46.2)	4 (44.4)
Previous cardiac intervention	83 (65.9)	7 (20.6)	54 (83.1)	5 (100)	12 (92.3)	5 (55.6)
Lactate	1.5 (1.0-2.1)	1.1 (0.8-1.3)	1.7 (1.3-2.8)	1.3 (1.0-1.6)	1.6 (1.2-1.7)	1.6 (1.2-2.1)
AST	65 (33-236)	30.0 (26-42)	160 (54-423)	46 (37-57)	34 (33-67)	215 (134-239)
ALT	58 (28-133)	30 (21-57)	99 (48-388)	59 (29-80)	31 (24-86)	69 (32-77)
Bilirubin	1.1 (0.5-1.8)	0.6 (0.4-0.8)	1.3 (0.7-2.0)	1.1 (0.6-2.1)	1.5 (0.6-2.0)	1.4 (0.9-2.8)
Creatinine (mg/dL)	1.5 (1.2-2.1)	1.2 (1.0-1.7)	1.7 (1.2-2.7)	1.4 (1.2-1.5)	1.7 (1.5-1.9)	1.5 (1.3-1.9)
VIS score	7.8 (3.0-15.5)	0 (0-5)	10.5 (7.0-19.8)	4.4 (2.5-6.3)	3.8 (2.5-12.8)	14.6 (12.2-25.8)
Dialysis	24 (19.0)	2 (5.9)	18 (27.7)	0 (0)	2 (15.4)	2 (22.2)
Received CPR	32 (25.4)	3 (8.8)	26 (40.0)	0 (0)	1 (7.7)	2 (22.2)
Intubated	51 (40.5)	2 (5.9)	39 (60.0)	0 (0)	1 (7.7)	9 (100)

HRCS, High-risk cardiac surgery; *CS*, cardiogenic shock; *LVAD*, left ventricular assist device; *BMI*, body mass index; *PCI*, percutaneous coronary intervention; *CVD*, cerebrovascular disease; *PVD*, peripheral vascular disease; *AST*, aspartate aminotransferase; *ALT*, alanine transaminase; *VIS*, vasoactive inotropic score; *CPR*, cardiopulmonary resuscitation.

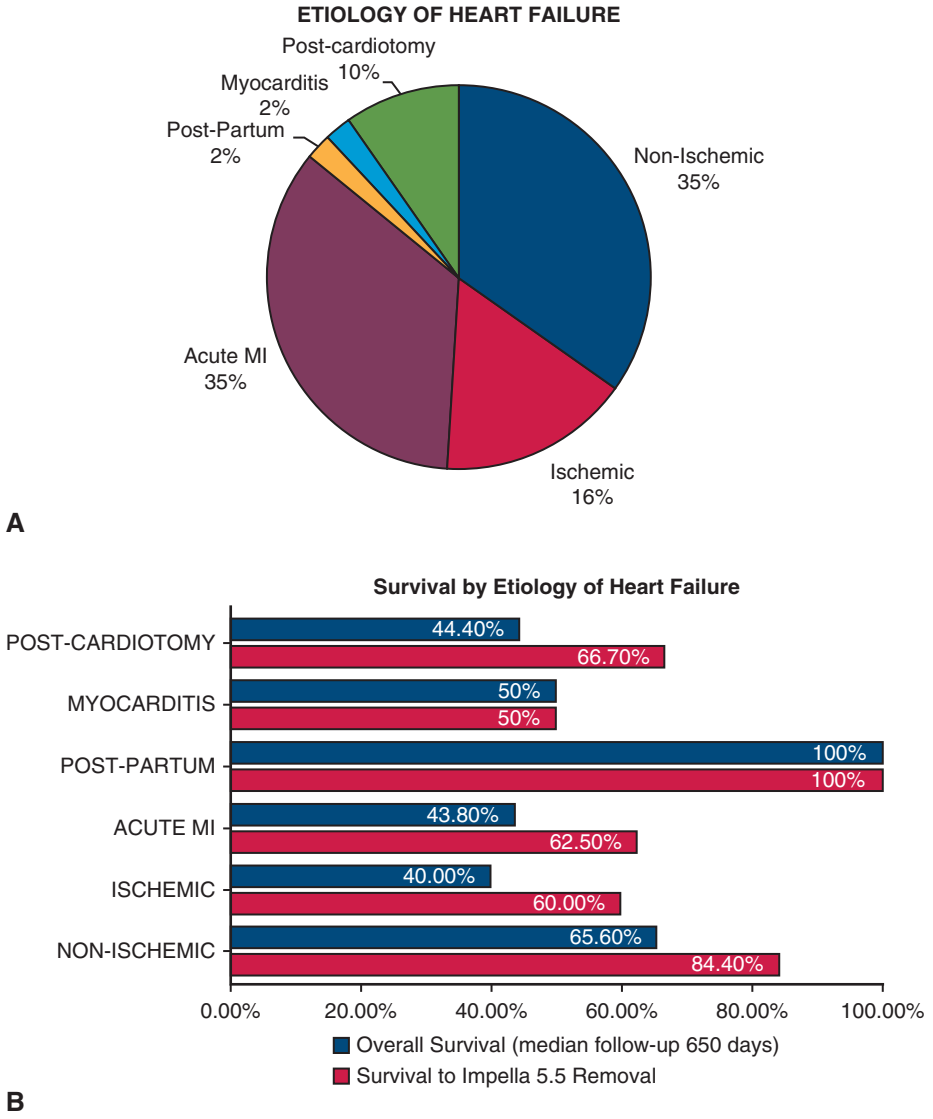

FIGURE 3. Etiology of heart failure for the patients who had the Impella 5.5 implanted for CS, bridge to durable ventricular assist device, bridge to transplant, and postcardiotomy shock (A) and survival by etiology (B). *MI*, Myocardial infarction.

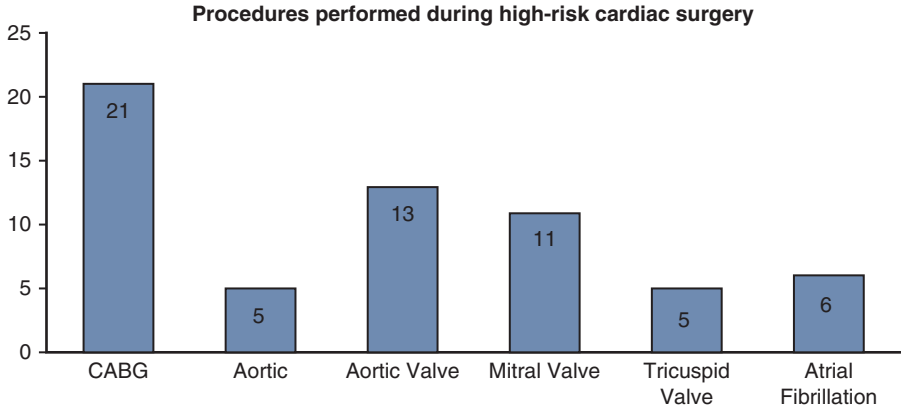

FIGURE 4. Procedures performed during HRCS. *CABG*, Coronary artery bypass grafting surgery.

TABLE 2. Mechanical circulatory support used other than Impella 5.5 (Abiomed, Inc) for patients with cardiogenic shock reported in N (%) and median (interquartile range)

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

CS, Cardiogenic shock; *LVAD*, left ventricular assist device; *IABP*, intra-aortic balloon pump; *VA ECMO*, venoarterial extracorporeal membrane oxygenation; *VV ECMO*, venovenous extracorporeal membrane oxygenation; *RVAD*, right ventricular assist device.

of the Impella 5.5 and underwent additional mechanical circulatory support (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 HRCS, whereas 1 patient had placement through an upper sternotomy and 1 through right mini anterior thoracotomy. Six patients had purge flow

TABLE 3. Outcomes after Impella 5.5 (Abiomed, Inc) implantation

	Total (N = 126)	HRCS (N = 34)	CS (N = 65)	Bridge to LVAD (N = 5)	Bridge to transplant (N = 13)	Postcardiotomy shock (N = 9)
Site of insertion						
Right	89 (70.6)	13 (38.2)	53 (81.5)	4 (80.0)	12 (92.3)	7 (77.8)
Left	10 (7.9)	0 (0)	7 (10.8)	1 (20.0)	1 (7.7)	1 (11.1)
Aortic	27 (21.4)	21 (61.8)	5 (7.7)	0 (0)	0 (0)	1 (11.1)
Reoperation for bleeding	17 (13.5)	4 (11.8)	7 (10.8)	0 (0)	2 (15.4)	4 (44.4)
Stroke	13 (10.3)	3 (8.8)	7 (10.7)	0 (0)	(0)	3 (33.3)
New dialysis	35 (27.8)	6 (17.6)	17 (26.2)	2 (40.0)	6 (46.2)	4 (44.4)
Local infection	4 (3.2)	2 (6.3)	1 (1.5)	1 (20.0)	0 (0)	0 (0)
Location of removal						
OR	77 (78.6)	15 (48.4)	40 (93.0)	5 (100)	12 (92.3)	5 (83.3)
Bedside	21 (21.4)	16 (51.6)	3 (7.0)	0 (0)	1 (7.7)	1 (16.7)
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 mo	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 d						
I	34 (27.0)	8 (23.5)	13 (20.0)	1 (20.0)	11 (84.6)	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)	-	-	1 (11.1)
IV	4 (3.2)	1 (2.9)	1 (1.5)	-	1 (7.7)	1 (11.1)

HRCS, High-risk cardiac surgery; *CS*, cardiogenic shock; *LVAD*, left ventricular assist device; *NYHA*, New York Heart Association.

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 1 was observed.[8] 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 at the insertion site or sternotomy. The stroke rate was 10%, and approximately 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. Midterm survival was assessed with a median follow-up time of 318 days and demonstrated an overall survival of 60.3% and median of 650 days (549-752) (Figure 5); however, 20 patients did not have follow-up to 6 months. Overall survival was 82.4% for the HRCS group (median 771 days, 95% CI, 582-959 days) and 51.6% for the non-HRCS patients (median 579 days, 95% CI, 464-694 days). For patients who received the Impella 5.5 as their only support device, overall survival was 50.0% (median 350 days, 95% CI, 154-546 days). 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% CI, 6-164 days). The causes of death for these 8 patients were diverse and included failure to thrive, multisystem organ failure, cancer, ischemic colitis, and severe driveline infection with sepsis. However, the most common theme among patients with worse outcomes was severe right ventricular dysfunction.

DISCUSSION

The 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. 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 because there was no control group, these patients had an acceptable survival to discharge despite having low ejection fraction 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. Although 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

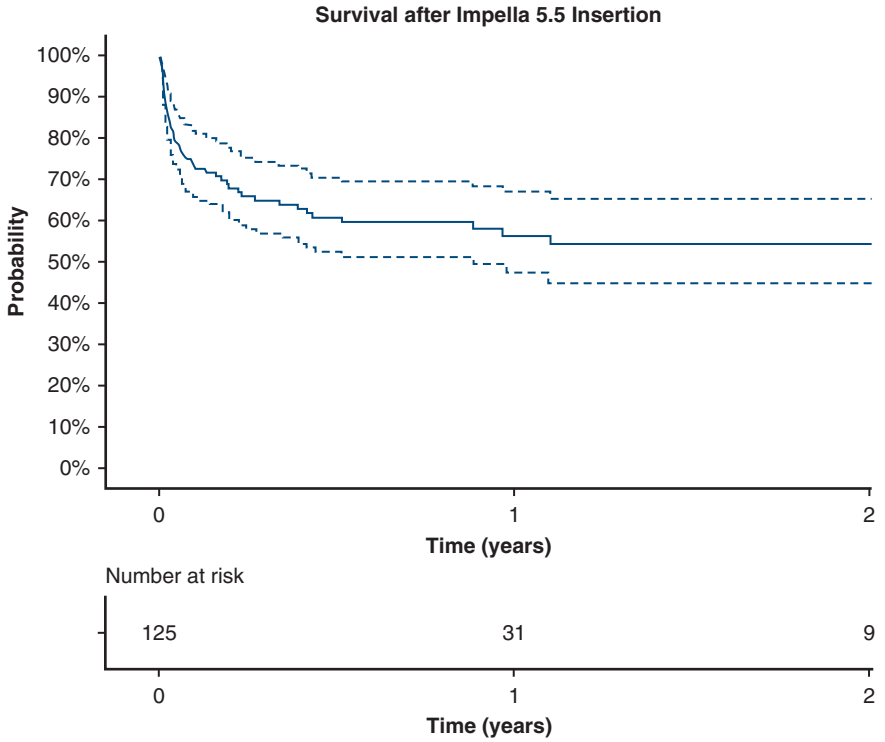

FIGURE 5. Kaplan–Meier analysis demonstrating survival of the entire cohort who received an Impella 5.5 extending to 3 years, shown with 95% CI.

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 postcardiotomy shock did not necessarily have low ejection fraction or low cardiac output preoperatively. When mechanical circulatory support was needed but unplanned, this was associated with higher hospital mortality. Thus, 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, because these patients may stay on longer cardiopulmonary bypass or may need VA ECMO before transitioning to Impella 5.5 support.

Patients who had the 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 the case of the 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 left ventricle vent strategy and for eventual, possible decannulation of ECMO. However, these patients had unknown probability of left ventricle recovery and uncertain candidacy for advanced heart failure therapies and thus 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.[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 left ventricle 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) with the Impella 5.5 for patients in CS, successful weaning for those not progressing to advanced therapies occurred in 50% of patients, which is similar to our findings.[10]

Transitioning patients in shock from ECMO to the 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,[11,12] without continuing the inherent risks of ECMO, compared with direct durable LVAD implant from VA ECMO.[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 the Impella 5.5 in a selective group of patients may have certain advantages.[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 who have limited options for advanced heart failure therapies are challenging. Some of these patients may end up with a durable LVAD because it is extremely difficult to withdraw temporary support in an otherwise ambulatory patient.

Among the cohort of 20 patients who received the 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 the Impella 5.5. Reasons to use the Impella 5.5 for these patients were low cardiac output, 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.[16] In the case of biventricular failure, inotropic or rarely temporary RVAD plus Impella 5.5 support is a reasonable approach to use 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 the Impella 5.5, but these numbers are too small to draw any firm conclusions about the benefits of this approach.

Study Limitations

Our study has several limitations because it was a single-center, retrospective analysis. Because 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 in 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.

CONCLUSIONS

The study represents a real-world experience of the Impella 5.5 in a large, high-volume center with outcomes extending to 3 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 because certain patients in CS will not benefit from support with this device. We believe the decision to implant an Impella 5.5 should be made after careful consideration of the 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 intensive care unit 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 be important to optimize the use of the Impella 5.5 for patients in CS.

Webcast

You can watch a Webcast of this AATS meeting presentation by going to: https://www.aats.org/resources/surgically-implanted-endovascular-microaxial-left-ventricular-assist-device-a-single-institution-study.

Conflict of Interest Statement

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. All other authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

The authors would like to thank Carter Scott for providing Figure 1.

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Key Words: cardiogenic shock, temporary mechanical circulatory support, ventricular assist device