8-1-2015

Incidence and prognosis of vascular complications after percutaneous placement of left ventricular assist device

Miriam Abaunza
Henry Ford Health

Loay S. Kabbani
Henry Ford Health, lkabban1@hfhs.org

Timothy Nypaver
Henry Ford Health, tnypave1@hfhs.org

Adam Greenbaum
Henry Ford Health

Praveen Balraj
Henry Ford Health

See next page for additional authors

Recommended Citation

Abaunza M, Kabbani LS, Nypaver T, Greenbaum A, Balraj P, Qureshi S, Alqarqaz MA, Shepard AD. Incidence and prognosis of vascular complications after percutaneous placement of left ventricular assist device. J Vasc Surg. 2015 Aug;62(2):417-23.

Authors

Miriam Abaunza, Loay S. Kabbani, Timothy Nypaver, Adam Greenbaum, Praveen Balraj, Sherazuddin Qureshi, Mohammad Alqarqaz, and Alexander D. Shepard

From the Midwestern Vascular Surgical Society

Incidence and prognosis of vascular complications after percutaneous placement of left ventricular assist device

Miriam Abaunza, MD,[a] Loay S. Kabbani, MD,[a] Timothy Nypaver, MD,[a] Adam Greenbaum, MD,[b] Praveen Balraj, MD,[a] Sherazuddin Qureshi, MD,[a] Mohammed A. Alqarqaz, MD,[b] and Alexander D. Shepard, MD,[a] *Detroit, Mich*

Objective: **Mechanical assist devices have found an increasingly important role in high-risk interventional cardiac procedures. The Impella (Abiomed Inc, Danvers, Mass) is a percutaneous left ventricular assist device inserted through the femoral artery under fluoroscopic guidance and positioned in the left ventricular cavity. This study was undertaken to assess the incidence of vascular complications and associated morbidity and mortality that can occur with Impella placement.**

Methods: **We used a prospective database to review patients who underwent placement of an Impella left ventricular assist device in our tertiary referral center from July 2010 to December 2013. Patient demographics, comorbidities, interventional complications, and 30-day mortality were recorded.**

Results: **The study included 90 patients (60% male). Mean age was 66 years (range, 17-97 years). Hypertension was found in 69% of the patients, 37% were diabetic, 57% had a history of tobacco abuse, and 65% had chronic renal insufficiency. The median preprocedure cardiac ejection fraction was 30%. Most (87%) had undergone coronary artery intervention. Cardiogenic shock was documented in 67 patients (74%). The Impella was placed for an average of 1 day (range, 0-5 days). At least one vascular complication occurred in 15 patients (17%). Acute limb ischemia occurred in 12 patients; of whom four required an amputation and six required open or endovascular surgery. Other complications included groin hematomas and one pseudoaneurysm. All-patient 30-day mortality was 50%, which was not significantly associated with vascular complications. Female sex and cardiogenic shock at the time of insertion were associated with vascular complications ($P = .043$ and $P = .018$, respectfully).**

Conclusions: **Vascular complications are common with placement of the Impella percutaneous left ventricular assist device (17%) and are related to emergency procedures. Vascular complications in this high-risk patient population frequently lead to withdrawal of care. These data provide quality improvement targets for left ventricular assist device programs. (J Vasc Surg 2015;62:417-23.)**

The evolution of left ventricular (LV) assist devices (LVADs) into percutaneous devices has helped advance the boundaries of interventional cardiology in the past decade. Percutaneous LVADs (P-LVADs) have found two major applications. The first is the provision of active circulatory support for patients in cardiogenic shock (CS).[1-4] The second application pertains to elective high-risk percutaneous cardiac interventional procedures (eg, stenting a tight left main stenosis), where periprocedural P-LVAD support is thought to decrease the incidence of adverse events.[5]

From the Divisions of Vascular Surgery[a] and Cardiology,[b] Henry Ford Hospital.

Author conflict of interest: none.

Presented as an oral presentation at the Thirty-eighth Annual Meeting of the Midwestern Vascular Surgical Society, Coralville, Iowa, September 4-6, 2014.

Correspondence: Loay S. Kabbani, MD, Division of Vascular Surgery, K-8, Henry Ford Hospital, 2799 W Grand Blvd, Detroit, MI 48202 (e-mail: lkabbani1@hfhs.org).

The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

http://dx.doi.org/10.1016/j.jvs.2015.03.040

The Impella system (Abiomed Inc, Danvers, Mass) is a minimally invasive P-LVAD that is placed in a retrograde fashion across the aortic valve via the femoral artery by applying conventional catheterization techniques. A miniaturized rotary pump is used to draw blood from the LV cavity and expel it into the ascending aorta, providing 2.5 L/min to 5 L/min forward flow, depending on the device used.[6] The 2.5 L/min device is placed through a 13F sheath. The Impella has been used for cardiac support in CS patients and in patients undergoing high-risk interventional procedures.

Initial studies indicated a low incidence of vascular complications with the use of the Impella device, despite the multiple risk factors for development of vascular complications associated with the use of such a device, including large sheath size, low cardiac output state, and frequent presence of peripheral vascular disease (PAD).[6-8] The goal of this study was to analyze our experience with the Impella device, with special focus on vascular complications and their relation to morbidity and mortality.

METHODS

This study was approved by the Henry Ford Hospital Institutional Review Board and was conducted in accordance with the Health Insurance Portability and

Table I. Circumstances surrounding Impella[a] placement

Variable	*No VC (n = 75), No. (%)*	*VC (n = 15), No. (%)*	P *value*
Elective (planned)	23 (31)	0 (0)	.02
Urgent (preprocedure CS)	32 (43)	7 (21)	
Emergent (intraprocedure CS)	20 (27)	8 (40)	

CS, Cardiogenic shock.
[a]Abiomed Inc, Danvers, Mass.

Accountability Act and the prevailing ethical principles governing research.

Identification of patients. A retrospective record review was undertaken of a prospectively maintained database on all Impella implantations at a single institution. Patient informed consent was waived.

Data collection and study end points. We reviewed the outcomes of 98 Impella P-LVAD devices placed at our institution between July 2010 and December 2013. Data were obtained from a prospectively maintained catheterization laboratory database and from the electronic medical records. Collected data included demographics, comorbidities, procedure-related characteristics, vascular complications, and 30-day mortality.

Vessel size was determined by calibrating the common femoral artery (CFA) diameter on the procedural angiogram to the catheter and sheath size. CS was defined using clinical and hemodynamic criteria, as previously described in the Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock (SHOCK) trial.[9] Vascular complications were confirmed based on the interventions performed, or when medical management was undertaken, on findings documented in the medical record. The nature of the complication was determined by details contained within the operative or consultation notes.

The Impella device. The Impella is an intracardiac miniaturized rotary pump P-LVAD. This catheter-mounted continuous-flow axial pump is placed across the aortic valve under fluoroscopic guidance with inflow in the LV and outflow in the ascending aorta. The Impella provides hemodynamic support by unloading the LV and augmenting forward flow.[10] The device decreases myocardial workload while increasing cardiac output and end-organ perfusion. Placement of the device is indicated in patients with reduced LV function after coronary bypass and for support during high-risk percutaneous coronary interventions.[11,12] The size of the pump catheter can be as small as 12F, which is placed through a 13F sheath. The family of Impella catheters includes, in ascending order for size and flow: Impella 2.5 (12F, 2.5 L/min of flow), Impella Continuous Power (14F, 3.5 L/min of flow), Impella 5.0 (21F, 5 L/min of flow), and Impella Left Direct (21F, 5 L/min of flow). Although the Impella 2.5 and Continuous Power are percutaneous devices that fit through 13F and 14F sheaths, respectively, the Impella 5.0 and Left Direct catheters are usually placed after surgical exposure of the femoral artery because of their 21F catheter size. The Left Direct version has been used mainly for patients after cardiac surgery.[7] We did not place Impella 5.0 or Left Direct catheters during the study period.

Table II. Demographic and comorbidity descriptive statistics, stratified by vascular complications

	Vascular complications		
Variable[a]	*No (n = 75)*	*Yes (n = 15)*	P *value*[b]
Demographic			
Sex			
Female	26 (35)	10 (67)	**.04**
Male	49 (65)	5 (33)	
Age, years	67 ± 15	58 ± 20	.14
Height, cm	171 ± 11	167 ± 10	.22
Weight, kg	90 ± 30	81 ± 23	.23
Body mass index, kg/m^2	30 ± 8	28 ± 8	.49
Body surface area, m^2	2.0 ± 0.33	1.9 ± 0.29	.21
Comorbidity			
Hypertension	51 (68)	11 (73)	.92
CVA	14 (19)	2 (13)	.90
Hypothyroid	13 (17)	1 (6.7)	.52
CHF	29 (39)	4 (27)	.56
CAD	41 (55)	9 (60)	.92
CABG	8 (11)	2 (13)	>.99
History of MI	18 (24)	2 (13)	.57
COPD	7 (9.3)	3 (20)	.45
Atrial fibrillation	13 (17)	1 (6.6)	.51
Diabetes mellitus	31 (41)	3 (20)	.21
Hyperlipidemia	57 (76)	9 (60)	.34
History of tobacco abuse	44 (60)	7 (47)	.53
Current smoker	16 (22)	5 (33)	.52
Cardiac arrest arrhythmia	11 (15)	3 (20)	.80

CABG, Coronary artery bypass grafting; *CAD,* coronary artery disease; *CHF,* congestive heart failure; *COPD,* chronic obstructive pulmonary disease; *CVA,* cerebrovascular accident; *MI,* myocardial infarction.
[a]Categoric variables are presented as number (%) and continuous variables as mean ± standard deviation.
[b]Continuous variables were tested using a two-sample *t*-test. Categoric variables were tested with the Pearson χ^2 test, Fisher exact test, and by logistic regression. Significant *P* values are bolded.

Procedure. A transfemoral approach was used in most patients to place the Impella device. Retrograde cannulation of the CFA was achieved via the standard Seldinger technique, all placed by an interventional cardiologist. Vascular femoral access was performed under fluoroscopic guidance; subsequently, a femoral angiogram through a small-sized sheath was obtained, and if the puncture was appropriate (ie, in the common femoral artery) and the femoral artery on that side was adequate in size and free of significant disease, then that access site was used for Impella insertion. Otherwise, a contralateral femoral angiogram was performed first via a diagnostic catheter inserted from the first access site, and access was obtained on the other side under fluoroscopic guidance. Ultrasound imaging was not used here because the interventional cardiologists at our facility are more comfortable with fluoroscopic guidance.

The vessel was then sequentially predilated using 8F, 10F, and 12F dilators. Subsequently, a 13F sheath for

Table III. Outcomes of patients with vascular complications

Patient	*Vascular complication*	*Intervention*	*Hospital outcome*
1	Hematoma	Compression device	Alive at discharge
2	Hematoma	Held pressure	Hospice
3	Acute limb ischemia	Remove Impella[a]	Alive at discharge
4	Acute limb ischemia	Remove Impella	Withdrawal of care
5	Acute limb ischemia	Above-knee amputation	Withdrawal of care
6	Pseudoaneurysm	Patient unstable for open repair, placed covered stent over pseudoaneurysm	Withdrawal of care
7	Acute limb ischemia	Open repair and fasciotomy	Withdrawal of care
8	Acute limb ischemia	Fasciotomy	Withdrawal of care
9	Acute limb ischemia	Above knee amputation	Alive at discharge
10	Acute limb ischemia	Open repair	Alive at discharge
11	Acute limb ischemia	Mechanical thrombolysis	Alive at discharge
12	Acute limb ischemia	Death prior to open repair	Cardiac arrest
13	Acute limb ischemia	Mechanical thrombolysis	Cardiac arrest
14	Acute limb ischemia	Delayed amputation	Cardiac arrest
15	Acute limb ischemia	Remove Impella	Alive at discharge

[a]Abiomed Inc, Danvers, Mass.

the Impella 2.5 or a 14F sheath for the Impella Continuous Power was inserted into the artery. The device was advanced in a retrograde fashion past the aortic valve under fluoroscopic guidance. The device provides circulatory support by pumping blood at a rate of 2.5 L/min for the Impella 2.5 and 3.5 L/min for the Impella Continuous Flow. Patients were fully anticoagulated with intravenous unfractionated heparin while the device was in place. In the catheterization laboratory the goal was to maintain an activated clotting time of >250 seconds, and in the intensive care unit, using a preset heparin protocol, the goal was to maintain an activated partial thromboplastin time at twice the normal value (partial thromboplastin time of 60 to 80 seconds).

The procedure was categorized as "emergent" if the patient needed P-LVAD support due to acute deterioration during an interventional cardiac procedure, as "urgent" if the patient was in CS before the procedure, and as "elective" if the Impella was placed prophylactically before a planned high-risk procedure.

No computed tomography scans were obtained before emergent and urgent procedures. In elective cases that were performed in our facility, almost all patients had a prior diagnostic coronary angiography with femoral artery angiography and were subsequently scheduled to undergo a high-risk coronary intervention with Impella support in a separate procedure.

When a closure devise was used, two Perclose ProGlide suture-mediated closure systems (Abbott Vascular, Redwood City, Calif) were deployed in the artery after obtaining access with a 6F sheath and before placement of the Impella. The Perclose device was deployed (if the Impella was taken out) or removed at the end of the case if the Impella was left in given the risk of infection. When the duration of Impella placement was thought to be >1 day, the Perclose device was not used. Removal of the device then was preformed after the activated clotting time was <160 seconds, and hemostasis was achieved by manual compression for at least 45 to 60 minutes by operators familiar and experienced in vascular access.

Limb ischemia was determined by presence of lower extremity pain, paresthesia, or paralysis, if the patient was awake and not ventilated. The physical examination typically consisted of a cool extremity, with absent Doppler signals in the dorsalis pedis and posterior tibial arteries. With advanced ischemia, mottling of the skin was noted along with muscle tenderness. Successful medical management was achieved after the removal of the Impella device if the signals in the dorsalis pedis or the posterior tibial arteries returned along with sensation and movement to the affected leg and foot.

No clear algorithm was used to choose between intra-aortic balloon pump (IABP) support and Impella placement in patients with CS. In severely hemodynamically compromised patients, clinical experience would support the higher hemodynamic support obtained from the Impella, where even a patient with virtually no underlying cardiac activity will still have a reasonable cardiac output of 2.5 to 3 L/min.

Data analysis. All patient data were compiled in a spreadsheet. Proportions were compared with the Pearson χ^2 test, Fisher exact test, and by logistic regression. Means were compared using *t*-tests and analysis of variance. Analyses were done using SAS software (SAS Institute Inc, Cary, NC). A P value of <.05 was considered statistically significant. For survival data, Kaplan-Meier analyses and intergroup testing by log-rank testing was used.

RESULTS

Baseline and periprocedural characteristics. Between July 2010 and December 2013, 98 Impella devices were inserted in our interventional cardiology catheterization laboratory. Four patients underwent placement of 2 Impella devices and were counted only once. Another

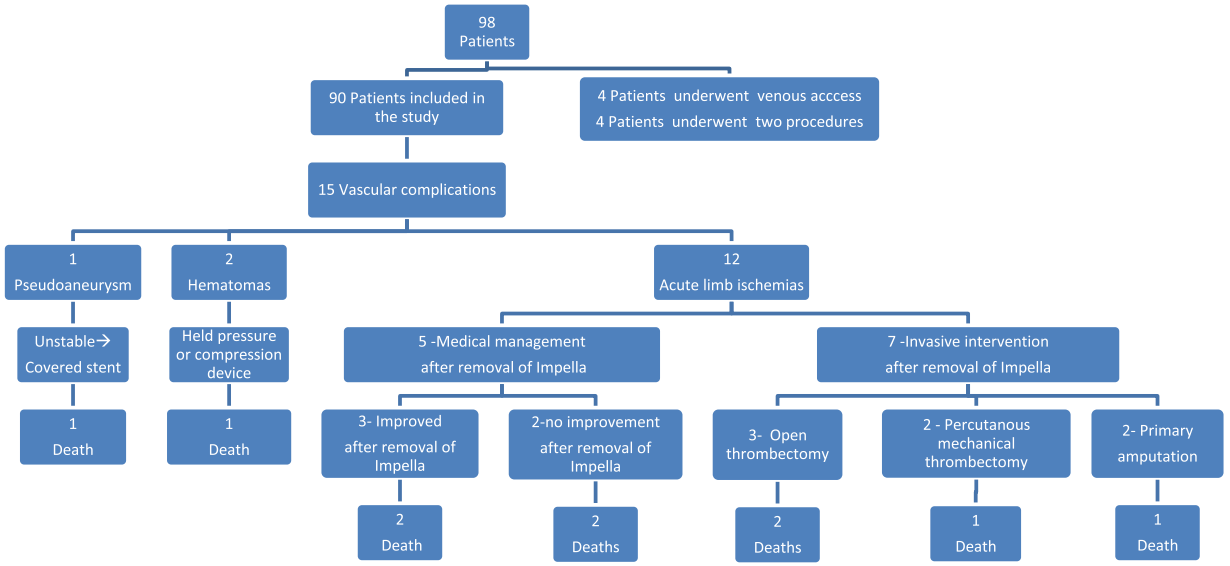

Fig 1. Outcomes of patients with vascular complications.

Table IV. Indication for Impella[a] placement

Variable	*No VC (n = 75), No. (%)*	*VC (n = 15), No. (%)*	P *value*
Primary reason for Impella placement			
Acute coronary syndrome	66 (88)	12 (80)	.68
Balloon valvuloplasty or TAVR	9 (12)	3 (20)	.09
Secondary diagnosis			
Cardiac arrest/arrhythmia	11 (15)	3 (20)	.90
CS	37 (49)	13 (87)	.02
Presence of AV and/or MV disease	11 (15)	8 (53)	.01

AV, Aortic valve; *CS*, cardiogenic shock; *MV*, mitral valve; *TAVR*, transcatheter aortic valve replacement; *VC*, vascular complication.
[a]Abiomed Inc, Danvers, Mass.

4 patients underwent placement of a venous Impella device and were excluded from our analysis. Of the 90 patients who underwent Impella device placement via an arterial access, 23 were stable patients who underwent elective placement as prophylaxis for a high-risk cardiac procedure. In the other 67 patients the Impella was placed for CS (Table I).

Patient demographics and comorbidities are noted in Table II. The mean age was 66 ± 16 years. There were 15 vascular complications: 1 pseudoaneurysm, 2 groin hematomas, and 12 acute ischemic limbs. Of the acute limb ischemia patients, five were treated medically and seven with invasive intervention (their management and outcomes are outlined in Table III and Fig 1).

Most Impella devices were removed on postprocedure day 1 (median, 1 day; range 0-5 days). The time of Impella removal was not correlated with vascular complications (P = .5). Patients with CS had a longer duration of Impella device placement (mean 0.8 ± 0.25 days vs 1.9 ± 0.24 days; P > .001). The 30-day mortality was 48% for patients without vascular complications and 57% for those with vascular complications (P = .7).

Predictors of vascular complications. On univariate analysis, female sex, CS, and a history of valve disease were significant factors associated with the development of vascular complications (Tables I, IV, and V). Race, smoking, diabetes, and pre-existing PAD were not significantly associated with vascular complications. Although CFA size was not a significant variable in the development of vascular complications, for every 1-mm decrease in vessel size, there was a 35% increase in the odds of having a vascular complication (odds ratio, 1.35; 95% confidence interval, 0.94-2.02; Fig 2). There was no significant association between the use of a closure device and the development of vascular complications. No patient who underwent an elective high-risk cardiac procedure had any vascular complications, whereas vascular complications occurred in 21% of patients undergoing an urgent procedure and in 40% of patients undergoing an emergent procedure (P = .023; Table I).

Thirty-day and long-term mortality. The occurrence of vascular complications did not significantly affect 30-day or 1-year mortality rates (Fig 3). At 30 days, mortality was 48% for patients with no vascular complications and 57% for those with vascular complications (P = .7). Patients who developed vascular complications had a longer hospital stay (10 days vs 22 days; P = .035) and a trend toward "withdrawal of care" status (29% vs 60%; P = .12).

Table V. Procedural variables during Impella[a] placement

Variable	*No VC (n = 75)*	*VC (n = 15)*	P *value*
IABP, No. (%)	26 (35)	5 (33)	.99
Inotropic support, No. (%)	36 (48)	12 (80)	.05
CPR, No. (%)	17 (23)	5 (33)	.58
Closure device, No. (%)	17 (23)	2 (14)	.73
CFA, mean ± SD mm	5.7 ± 1.5 (n = 67)	5.0 ± 1.9 (n = 15)	.18

CFA, common femoral artery; *CPR,* cardiopulmonary resuscitation; *IABP,* intra-aortic balloon support; *SD,* standard deviation; *VC,* vascular complication.
[a]Abiomed Inc, Danvers, Mass.

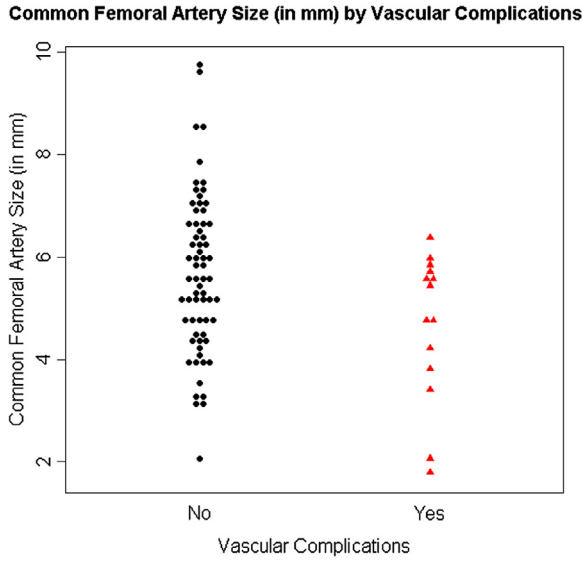

Fig 2. The effect of vessel size on vascular complications.

DISCUSSION

CS occurs in 5% to 8% of patients hospitalized with ST-elevation myocardial infarction.[13] Despite aggressive treatment and early revascularization, mortality with CS can run as high as 50% to 70%.[9] After successful revascularization, the stunned myocardium may require several days to recover. A low cardiac output state may persist during this period, leading to end-organ dysfunction and the potential for early death. Mechanical circulatory support during this time has been advocated to decrease mortality.[14] In patients undergoing a high-risk percutaneous coronary intervention, even brief episodes of myocardial ischemia may result in hypotension and decreased cardiac output, leading to a vicious cycle of coronary hypoperfusion, heart failure, and hemodynamic collapse. Accordingly, prophylactic stabilization with mechanical cardiac support is sometimes used to prevent hemodynamic instability.[5,6,15]

The IABP was, until recently, the only percutaneous device available during these high-risk procedures and for patients in CS. However, IABP support has not been shown to decrease infarct size or improve clinical outcome.[16,17] This may be due to its suboptimal improvement in cardiac support.[18] Furthermore, despite being placed through a 7F or 8F sheath, IABP catheters resulted in a 4.3% to 5.9% rate of peripheral ischemic complications requiring in-hospital intervention, with an incidence of major limb ischemia in 0.9% to 2%.[16,19-21] A study from the University of Michigan reported the need for vascular repair after IABP placement was 14%, with a 2% amputation rate.[20]

P-LVADs were developed to provide quick cardiac support in patients with CS or those undergoing high-risk interventional cardiac procedures. Currently available P-LVADs include the TandemHeart system (CardiacAssist Inc, Pittsburgh, Pa) and the Impella system. They can be inserted quickly and are less invasive than surgically implanted LVAD for unstable patients in CS.[22] In the high-risk percutaneous Coronary Intervention Study, a trend for improved outcomes was observed using Impella 2.5 support. Major adverse events were observed in 40.6% vs 49.3% in the intent-to-treat population ($P = .066$) and 40.0% vs 51.0% in the per-protocol population ($P = .023$).[23]

Our study reveals that when the Impella device was used, vascular complications occurred in 17% of patients, with acute limb ischemia developing in 12% and limb loss in 4%. Our rate of hematoma (2%) is probably under-reported. Ferreiros et al[24] reported an 11.1% vascular complications rate after Impella P-LVAD placement and a 3.7% need for vascular surgery. In the updated USpella registry, O'Neill et al[25] reported a 9.7% vascular complications rate and a 3.9 % acute limb ischemia rate. In the EUROSHOCK registry, 4.2% of patients required vascular surgery.[26] The Europella registry included 144 consecutive patients, and rates of vascular complications were 4.0% at 30 days.[8] Kovacic et al[27] reported an 8% vascular complications rate, mostly access-site hematomas. Burzotta et al[15] reported no access-site complications. O'Neill et al[24] noted that the rate of vascular operations in the Impella 2.5 arm was no different than that of the IABP arm (but they did not quote the limb ischemia rate) and concluded that there was no difference associated with the use of the larger sheath. Pershad et al[28] noted a 6% vascular complications for patients in the PROTECT II Trial (Table VI).

In our study, vascular complications were more common in women. This is probably related to the increased incidence of vascular complications in patients with smaller arteries.[29,30] None of the vascular complications in this study were attributed to thromboembolic events, and all

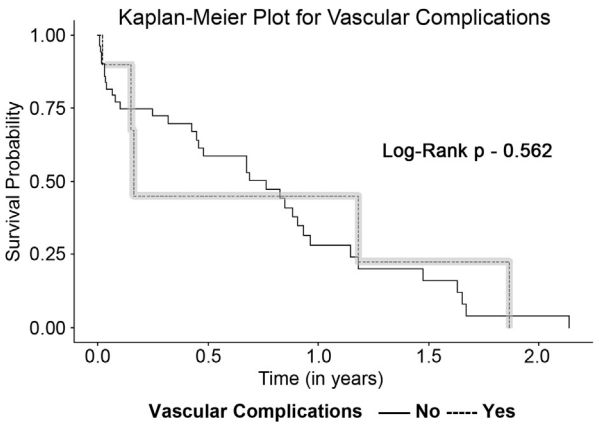

Fig 3. Kaplan-Meier survival curves stratified by vascular complication status, along with the log-rank *P* value testing for differences in strata. The *gray line* indicates where the standard error is >10%.

Table VI. Major studies listing vascular complications

First author	*Vascular complication rate, %*
Pershad[28]	6
Kovacic[26]	8
Sjauw[8]	4
O'Neill[27]	1
Ferreiro[23]	11
O'Neill[24]	10
Lauten[25]	4
Current study	17

originated from injury to the artery or occlusion from the large cannula. Patients in shock and on inotropic support also showed a significantly higher incidence of limb ischemia, probably because they were hypoperfused to begin with, and as may be expected, the Impella device was placed for a longer time. In addition, the urgent insertion of the Impella may predispose to vascular complications.

There is a high prevalence of PAD in the elderly patients who constitute most of the patients with coronary artery disease.[31] The incidence of hospital and long-term mortality after percutaneous coronary procedures is known to be significantly greater in patients with PAD.[32,33] PAD was noted in up to 32% of patients who presented with CS and needed P-LVAD support.[25] The documentation of PAD is important in evaluating the safety of large-sheath arterial access. The documented rate of PAD in our study was only 7%. A much higher rate of anatomic PAD probably existed in our patients.

Adequacy of vascular access was not routinely assessed with computed tomography. Obviously, it is not practical or even possible in emergent cases. For elective procedures, there were no vascular complications, implying that studying the patient's femoral arteries with prior angiography before the placement of the Impella was adequate.

In this study, as expected, patients with vascular complications had a longer hospital stay. There was also a trend in patients with vascular complications to accept hospice care and withdrawal of cardiopulmonary support. It seems that the addition of vascular complications may prompt a critical reassessment of the advisability of extreme measures for these profoundly ill patients by family members and may promote the acceptance of end-of-life care. We found, however, that vascular complications did not significantly affect the 30-day mortality in this very sick patient population. However, one cannot assume that vascular complications would not be linked to poorer survival in a lower-risk population. Three patients (25%) in the group with acute limb ischemia survived with a viable extremity, and patients who developed acute limb ischemia had a 66% mortality rate. This suggests that heroic limb salvage measures may not be an appropriate path in this very sick group of patients with very limited survival.

Reducing CFA cannulation complications in P-LVAD placements should be an objective in heart failure centers. In 2014 Abiomed introduced a "peel-away" sheath that is removed after the device is inserted and may allow for better distal perfusion and fewer vascular complications. Ultrasound-guided femoral artery access may help in optimizing femoral access and should be used in difficult cases.

CONCLUSIONS

Potentially devastating vascular complications occur in this very sick population in association with the Impella device. Vascular complications were more frequent in women (likely due to smaller vessel size) and in emergent procedures (likely due to the presence of shock and inotropes predisposing to limb ischemia). Patients who developed acute limb ischemia had a 66% in-hospital mortality rate.

Although vascular complications after P-LVAD placement will continue to occur, we believe that decreasing sheath sizes, better screening for PAD and small vessel size, appropriate access site selection, and increased operator experience will lower complication rates in the future. The interventional cardiologist must be able to recognize factors that may lead to potential vascular complications. In addition, specific access-site complications (eg, bleeding and acute limb ischemia) should be accurately reported so that interested parties can understand which issues have improved and which remain problems as technology advances. Heroic limb salvage measures may not be an appropriate path in this very sick group of patients with very limited survival.

AUTHOR CONTRIBUTIONS

Conception and design: MA, AS, LK
Analysis and interpretation: MA, LK, AG, TN, AS
Data collection: MA, LK MA, PB
Writing the article: LK, MA, AS
Critical revision of the article: AS, LK, AG, TN, SQ
Final approval of the article: LK, AS, TN
Statistical analysis: LK
Obtained funding: Not applicable
Overall responsibility: LK

REFERENCES

1. Hochman JS, Buller CE, Sleeper LA, Boland J, Dzavik V, Sanborn TA, et al. Cardiogenic shock complicating acute myocardial infarction—etiologies, management and outcome: a report from the SHOCK Trial Registry. SHould we emergently revascularize Occluded Coronaries for cardiogenic shocK? J Am Coll Cardiol 2000;36:1063-70.
2. Thiele H, Lauer B, Hambrecht R, Boudriot E, Cohen HA, Schuler G. Reversal of cardiogenic shock by percutaneous left atrial-to-femoral arterial bypass assistance. Circulation 2001;104:2917-22.
3. Thiele H, Sick P, Boudriot E, Diederich KW, Hambrecht R, Niebauer J, et al. Randomized comparison of intra-aortic balloon support with a percutaneous left ventricular assist device in patients with revascularized acute myocardial infarction complicated by cardiogenic shock. Eur Heart J 2005;26:1276-83.
4. Perera D, Stables R, Clayton T, De Silva K, Lumley M, Clack L, et al. Long-term mortality data from the balloon pump-assisted coronary intervention study (BCIS-1): a randomized, controlled trial of elective balloon counterpulsation during high-risk percutaneous coronary intervention. Circulation 2013;127:207-12.
5. Briguori C, Sarais C, Pagnotta P, Airoldi F, Liistro F, Sgura F, et al. Elective versus provisional intra-aortic balloon pumping in high-risk percutaneous transluminal coronary angioplasty. Am Heart J 2003;145:700-7.
6. Dixon SR, Henriques JP, Mauri L, Sjauw K, Civitello A, Kar B, et al. A prospective feasibility trial investigating the use of the Impella 2.5 system in patients undergoing high-risk percutaneous coronary intervention (The PROTECT I Trial): initial U.S. experience. JACC Cardiovasc Interv 2009;2:91-6.
7. Henriques JP, Remmelink M, Baan J Jr, van der Schaaf RJ, Vis MM, Koch KT, et al. Safety and feasibility of elective high-risk percutaneous coronary intervention procedures with left ventricular support of the Impella Recover LP 2.5. Am J Cardiol 2006;97:990-2.
8. Sjauw KD, Konorza T, Erbel R, Danna PL, Viecca M, Minden HH, et al. Supported high-risk percutaneous coronary intervention with the Impella 2.5 device the Europella registry. J Am Coll Cardiol 2009;54:2430-4.
9. Hochman JS, Sleeper LA, Webb JG, Sanborn TA, White HD, Talley JD, et al. Early revascularization in acute myocardial infarction complicated by cardiogenic shock. SHOCK Investigators. Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock. N Engl J Med 1999;341:625-34.
10. Takayama H, Takeda K, Doshi D, Jorde UP. Short-term continuous-flow ventricular assist devices. Curr Opin Cardiol 2014;29:266-74.
11. Valgimigli M, Steendijk P, Sianos G, Onderwater E, Serruys PW. Left ventricular unloading and concomitant total cardiac output increase by the use of percutaneous Impella Recover LP 2.5 assist device during high-risk coronary intervention. Catheter Cardiovasc Interv 2005;65:263-7.
12. Remmelink M, Sjauw KD, Henriques JP, de Winter RJ, Koch KT, van der Schaaf RJ, et al. Effects of left ventricular unloading by Impella recover LP2.5 on coronary hemodynamics. Catheter Cardiovasc Interv 2007;70:532-7.
13. Reynolds HR, Hochman JS. Cardiogenic shock: current concepts and improving outcomes. Circulation 2008;117:686-97.
14. Thiele H, Smalling RW, Schuler GC. Percutaneous left ventricular assist devices in acute myocardial infarction complicated by cardiogenic shock. Eur Heart J 2007;28:2057-63.
15. Burzotta F, Paloscia L, Trani C, Mascellanti M, Mongiardo R, Materazzo G, et al. Feasibility and long-term safety of elective Impella-assisted high-risk percutaneous coronary intervention: a pilot two-centre study. J Cardiovasc Med (Hagerstown) 2008;9:1004-10.
16. Thiele H, Zeymer U, Neumann FJ, Ferenc M, Olbrich HG, Hausleiter J, et al. Intraaortic balloon support for myocardial infarction with cardiogenic shock. N Engl J Med 2012;367:1287-96.
17. Thiele H, Zeymer U, Neumann FJ, Ferenc M, Olbrich HG, Hausleiter J, et al. Intra-aortic balloon counterpulsation in acute myocardial infarction complicated by cardiogenic shock (IABP-SHOCK II): final 12 month results of a randomised, open-label trial. Lancet 2013;382:1638-45.
18. Sauren LD, Accord RE, Hamzeh K, de Jong M, van der Nagel T, van der Veen FH, et al. Combined Impella and intra-aortic balloon pump support to improve both ventricular unloading and coronary blood flow for myocardial recovery: an experimental study. Artif Organs 2007;31:839-42.
19. Hatch J, Baklanov D. Percutaneous hemodynamic support in PCI. Curr Treat Options Cardiovasc Med 2014;16:1-13.
20. Messina LM, Brothers TE, Wakefield TW, Zelenock GB, Lindenauer SM, Greenfield LJ, et al. Clinical characteristics and surgical management of vascular complications in patients undergoing cardiac catheterization: interventional versus diagnostic procedures. J Vasc Surg 1991;13:593-600.
21. Syed AI, Kakkar A, Torguson R, Li Y, Ben-Dor I, Collins SD, et al. Prophylactic use of intra-aortic balloon pump for high-risk percutaneous coronary intervention: will the Impella LP 2.5 device show superiority in a clinical randomized study? Cardiovasc Revasc Med 2010;11:91-7.
22. Webb JG, Sleeper LA, Buller CE, Boland J, Palazzo A, Buller E, et al. Implications of the timing of onset of cardiogenic shock after acute myocardial infarction: a report from the SHOCK Trial Registry. J Am Coll Cardiol 2000;36:1084-90.
23. O'Neill WW, Kleiman NS, Moses J, Henriques JP, Dixon S, Massaro J, et al. A prospective, randomized clinical trial of hemodynamic support with Impella 2.5 versus intra-aortic balloon pump in patients undergoing high-risk percutaneous coronary intervention: the PROTECT II study. Circulation 2012;126:1717-27.
24. Ferreiro JL, Gomez-Hospital JA, Cequier AR, Angiolillo DJ, Roura G, Teruel L, et al. Use of Impella Recover LP 2.5 in elective high risk percutaneous coronary intervention. Int J Cardiol 2010;145:235-7.
25. O'Neill WW, Schreiber T, Wohns DH, Rihal C, Naidu SS, Civitello AB, et al. The current use of Impella 2.5 in acute myocardial infarction complicated by cardiogenic shock: results from the USpella Registry. J Interv Cardiol 2014;27:1-11.
26. Lauten A, Engstrom AE, Jung C, Empen K, Erne P, Cook S, et al. Percutaneous left-ventricular support with the Impella-2.5-assist device in acute cardiogenic shock: results of the Impella-EUROSHOCK-registry. Circ Heart Fail 2013;6:23-30.
27. Kovacic JC, Nguyen HT, Karajgikar R, Sharma SK, Kini AS. The Impella Recover 2.5 and TandemHeart ventricular assist devices are safe and associated with equivalent clinical outcomes in patients undergoing high-risk percutaneous coronary intervention. Catheter Cardiovasc Interv 2013;82:E28-37.
28. Pershad A, Fraij G, Massaro JM, David SW, Kleiman NS, Denktas AE, et al. Comparison of the use of hemodynamic support in patients ≥80 years versus patients <80 years during high-risk percutaneous coronary interventions (from the Multicenter PROTECT II Randomized Study). Am J Cardiol 2014;114:657-64.
29. Zhao ZG, Liao YB, Peng Y, Chai H, Liu W, Li Q, et al. Sex-related differences in outcomes after transcatheter aortic valve implantation: a systematic review and meta-analysis. Circ Cardiovasc Interv 2013;6:543-51.
30. Stangl V, Baldenhofer G, Laule M, Baumann G, Stangl K. Influence of sex on outcome following transcatheter aortic valve implantation (TAVI): systematic review and meta-analysis. J Interv Cardiol 2014;27:531-9.
31. Saw J, Bhatt DL, Moliterno DJ, Brener SJ, Steinhubl SR, Lincoff AM, et al. The influence of peripheral arterial disease on outcomes: a pooled analysis of mortality in eight large randomized percutaneous coronary intervention trials. J Am Coll Cardiol 2006;48:1567-72.
32. Guerrero M, Harjai K, Stone GW, Brodie B, Cox D, Boura J, et al. Usefulness of the presence of peripheral vascular disease in predicting mortality in acute myocardial infarction patients treated with primary angioplasty (from the Primary Angioplasty in Myocardial Infarction Database). Am J Cardiol 2005;96:649-54.
33. Jeremias A, Gruberg L, Patel J, Connors G, Brown DL. Effect of peripheral arterial disease on in-hospital outcomes after primary percutaneous coronary intervention for acute myocardial infarction. Am J Cardiol 2010;105:1268-71.

Submitted Dec 9, 2014; accepted Mar 18, 2015.