From the Midwestern Vascular Surgical Society

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

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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]

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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