Axillary Artery Access for Mechanical Circulatory Support Devices in Patients With Prohibitive Peripheral Arterial Disease Presenting With Cardiogenic Shock

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In patients with severe peripheral vascular disease, the common femoral artery may be so diseased as to not allow for deployment of mechanical circulatory support (MCS) such as in the setting of cardiogenic shock (CS). We sought to study the feasibility of axillary artery as alternative access for MCS in CS patients with severe occlusive peripheral artery disease (PAD). Records of all patients who presented with CS requiring MCS through axillary artery access from January 2016 to October 2017 were examined. Demographics, clinical, procedural, and outcomes data were collected on all patients. A total of 17 patients (mean age 68 ± 14 years, 95% men) were identified. This was due to severe PAD in the iliac and/or common femoral arteries prohibiting large bore sheath access in all cases. Of the 17 patients, 9 required percutaneous coronary intervention. Time from axillary access to activation of Impella was 14.8 ± 4 minutes. Three patients required concomitant Impella RP for right ventricular support due to biventricular CS. Twelve patients died before Impella was explanted due to multiorgan failure, stroke, and infection. None of the patients who died had vascular complications related to axillary access. All 5 patients who survived to Impella explant were discharged from the hospital without major complication. Axillary artery is a safe and feasible alternative access for large bore devices in patients with prohibitive PAD. The meticulous technique described assures a very low rate of access related complications. **(Am J Cardiol 2019;123:1715−1721)**

The common femoral artery remains the vascular access site of choice in the United States for advanced interventional procedures that utilize equipment for complex coronary interventions, mechanical circulatory support (MCS), endovascular aortic aneurysm repairs, and transcatheter aortic valve replacement (TAVR).[1,2] Both peripheral vascular disease and coronary artery disease have similar risk factors, and it is common to encounter the challenge of treating structural or complex coronary patients with significant concomitant peripheral artery disease (PAD).[3−5] Small caliber common femoral and iliac arteries with severe PAD significantly increase the risk for vascular complications. That risk increases greatly as the larger bore sheaths are used.[6−9] Therefore, patients presenting with cardiogenic shock (CS) requiring MCS may be deprived of advanced therapies due to prohibitive PAD. The axillary artery has been shown to be an acceptable alternative access site for MCS in the presence of severe PAD.[10,11] Both the left and right axillary arteries have been used for TAVR, intra-aortic balloon pump, and Impella insertion.[12−16] Previously published reports described the technique in patients presenting for high risk coronary interventions with stable hemodynamics.[15,17] We studied the use of the axillary artery as alternative access for MCS in CS patients with severe PAD.

Methods

Population

This is a retrospective review of a prospectively maintained database of all patients treated in the cardiac catheterization laboratory at the Detroit Medical Center of Wayne State University, Detroit, Michigan. Records of all patients presenting with CS who underwent percutaneous axillary artery access from January 2016 to October 2017 were examined. Procedural, demographic, and clinical data were collected.

Axillary Artery Anatomy

The axillary artery originates from the subclavian artery (SCA) as it passes out of the rib cage at the lateral margin of the first rib, where it becomes extrathoracic. The axillary artery is divided into 3 segments based on its relation to the pectoralis minor muscle (Figure 1). During angiography, those segments can be identified by the origin of the arterial branches: the superior thoracic artery emerges from the first

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segment, the thoracoacromial, and lateral thoracic arteries from the second segment and the subscapular artery from the third segment. The caliber of the axillary artery ranges from 6 to 7 mm which makes it suitable to accommodate sheaths with an outer diameter of up to 18Fr. Furthermore, the axillary artery is rarely affected by atherosclerotic disease, with 2.1% displaying evidence of atherosclerosis on computed tomographic compared with 19.8% in common femoral arteries.[10] However, although the axillary artery is not frequently diseased, it is more prone to dissection or disruption due to the lack of a muscular component of the arterial wall.

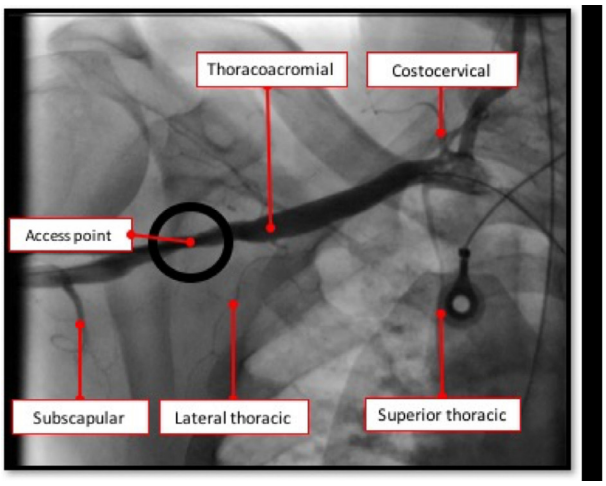
Axillary Access Procedure Technique

The patient is prepared and draped in supine position with the arm abducted at 90° away from the body. Conscious sedation and topical anesthesia are administered at the access sites in the usual fashion. A 6Fr sheath is placed in the ipsilateral radial artery or a 6Fr sheath placed in either femoral artery. A 5Fr JR4 guide catheter is advanced over a guidewire through the femoral artery and selectively engaged in the left SCA or innominate artery. Angiography of the subclavian and axillary arteries is performed for to ensure adequate size, tortuosity, and degree of atherosclerosis. A diameter cutoff of ≥6.0 mm ensures enough room for the 14Fr sheath and adequate distal perfusion. Angiographic assessment and identification of the axillary artery branches is important to precisely define the access point that is lateral to the thoracoacromial artery and medial to the circumflex humeral and subscapular arteries "sweet spot" (Figure 1).

Once the appropriate axillary artery site is identified, local anesthesia is administered 2 to 3 cm lateral to the sweet spot. There are 3 ways to target the sweet spot with access needle: 1 JR4 or MP catheter is used to engage the left SCA or the innominate artery to perform contrast angiography to identify the axillary artery anatomy and identify the sweet spot (Figure 2) in cases when there is contrast limit, wire-guided access is often used. In this technique, a 0.038 wire is advanced in the axillary artery and into the brachial artery. After one contrast injection, the sweet spot is identified and the operator target the wire over the sweet spot using live fluoroscopy (Figure 3) Similar to the guidewire technique, the operator can use pigtail catheter as target to the sweet spot.

A micropuncture needle is then advanced under angiographic guidance at an angulation of 45° or less from skin toward the access point that is lateral to the thoracoacromial artery (between the second and third segment of the axillary artery), immediately medial to the shoulder (Figure 3). A 0.035-inch J-tip wire is then advanced into the SCA and the micropuncture sheath is exchanged for a 6 Fr sheath. We dilate the tract previous with 7 or 8-Fr sheath to introducing the Perclose Proglide devices to prepare the access. Utilizing the "preclose" technique, 2 Proglide suture-mediated closure devices (Abbott Vascular, Redwood City, California) are deployed at the 10 o'clock and 2 o'clock positions and left uncinched. The arteriotomy is then sequentially dilated, before introduction of the 14Fr Impella CP sheath over a stiff 0.035-inch wire of choice (Lunderquist, Amplatz Super Stiff, Supra Core) (Figure 3).

A 5 or 6Fr multipurpose catheter is then used to cross from the aortic valve to the left ventricle using standard crossing techniques. A 0.018-inch (Platinum Plus guidewire, Boston Scientific) is then advanced through the MP catheter into the left ventricle. The catheter then removed and Impella CP device is then inserted over the wire and advanced under fluoroscopic guidance into the left



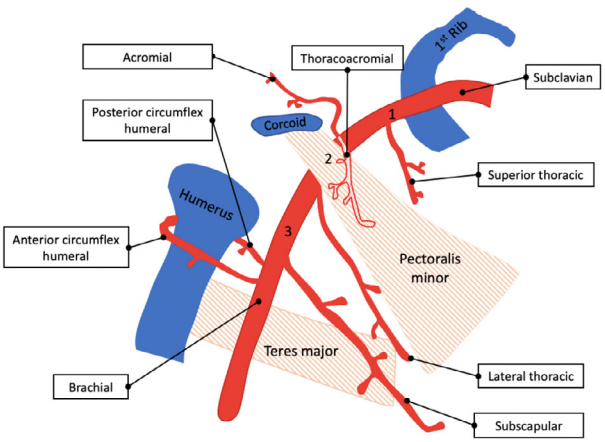


Figure 1. (***Right***) Illustration of the right axillary artery. The subclavian artery becomes the axillary artery immediately after passing beyond the first. The axillary artery has three segments based on its location relative to the pectoralis minor muscle. The first segment is medial to the pectoralis minor, second segment is posterior to the pectoralis minor and third part is lateral to the pectoralis minor. Once the axillary artery passes the inferior border of teres minor muscle it becomes the brachial artery. Branches of axillary artery are important landmarks for axillary artery access and are found in different axillary artery segments. • First segment: Superior thoracic artery. • Second segment: thoracoacromial and lateral thoracic artery. • Third segment: subscapular, anterior humeral circumflex and posterior humeral circumflex arteries. (***Left***) Axillary artery segments and branches: "Roadmap angiogram" to define access point landmarks.

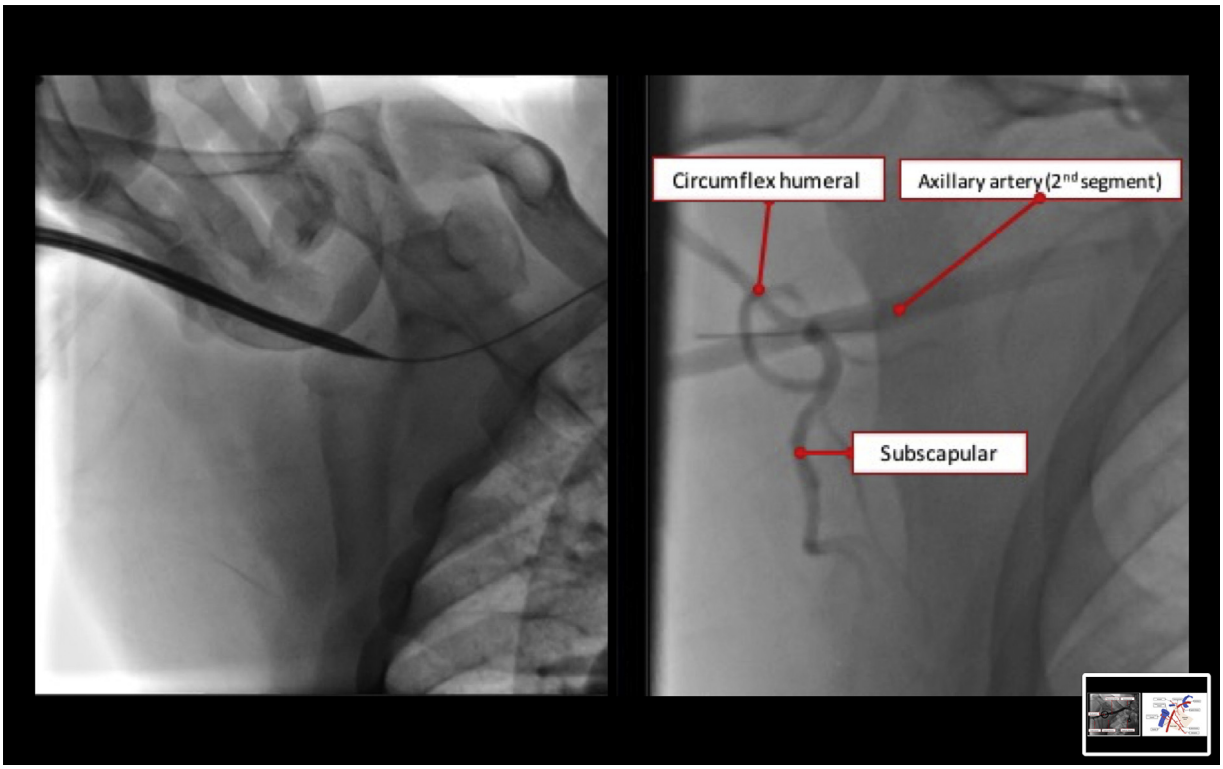


Figure 2. (***Right***). A micropuncture needle is advanced to gain axillary arterial access. Puncture site should be lateral to the thoracoaromial artery and medial to the circumflex humeral or subscapular arteries. (***Left***). Impella 14Fr sheath is advanced into the mid SCA under fluoroscopy to prevent traumatic injury to the proximal subclavian curvature. SCA = subclavian artery.

ventricle. Angiography of the proximal SCA is required to assure adequate perfusion distal to the large-bore sheath to prevent from limb ischemia. Hemodynamic support is then initiated. Coronary angiography and subsequent percutaneous coronary intervention may then be performed from the femoral access site.

If prolonged hemodynamic support is needed after completion of the procedure, the Impella sheath should be sutured and secured before the patients leaves the cath lab. We recommend clamping the Perclose sutures with a hemostat and wrapping them with a sterile towel covered with a sterile Tegaderm.[18]

When the patient is deemed ready for explant, the Impella device is removed from the peel-away sheath and 0.035-inch wire is passed from the large-bore arteriotomy sheath into the descending aorta. The subclavian or innominate artery is engaged again with JR4 guide catheter (or catheter of choice) from the femoral sheath. An exchange-length 0.035-inch wire (our preference is the Glidewire Advantage, Terumo Medical Corporation, Japan) is advanced through the SCA past the large bore axillary sheath into the brachial artery. A 7−10 × 40 mm peripheral balloon that is sized in a 1:1 ratio to the parent artery diameter is used for "dry closure" of the axillary access (Figure 3). The balloon is advanced over the 0.035-inch wire from the femoral sheath and inflated at low pressure (2 to 4 atmosphere) under fluoroscopy to prevent traumatic injury to the vessel wall. To ensure adequate hemostasis without traumatic vessel injury, the balloon should be inflated while observing the arterial pressure tracing transduced from the axillary artery sheath side arm. The balloon should be inflated until the tracing is observed to completely dampened or until the plethysmographic signal measured on the ipsilateral index finger is lost.[18] Once endovascular hemostasis is achieved, the Impella sheath is then completely removed over the 0.035-inch wire and the preclosure is completed by cinching and locking the previously deployed Perclose Proglide sutures. The balloon in the distal SCA is then deflated and digital subtraction angiography is performed to evaluate for extravasation from the arteriotomy site. If no leak is noted, then the 0.035-inch wire and JR4 guide catheter are removed. If extravasation at the access site is observed, another prolong balloon inflation can be done for 15 to 20 minutes. If balloon and manual compression fails, then a covered stent (Viabahn [Gore] or iCast [Atrium]) may be deployed as final bail-out strategy.

In case of emergency when there is no time for Perclose insertion, our strategy for axillary access closure is the following: the sheath is removed and an 8 to 10 mm diameter balloon (based on the vessel size) from an alternative access (radial or femoral artery) is delivered to the arteriotomy site. Then, the sheath is removed and balloon is inflated at the arteriotomy site at 2 to 4 ATM (depending on the size of the vessel) until oozing stops. The balloon will stay inflated in place for 15 to 30 minutes over the arteriotomy site to achieve hemostasis. If final angiogram reveals extravasation at the access site, another prolong balloon inflation is used. If balloon and manual compression fails, then a covered stent can be deployed as a final bail-out strategy.

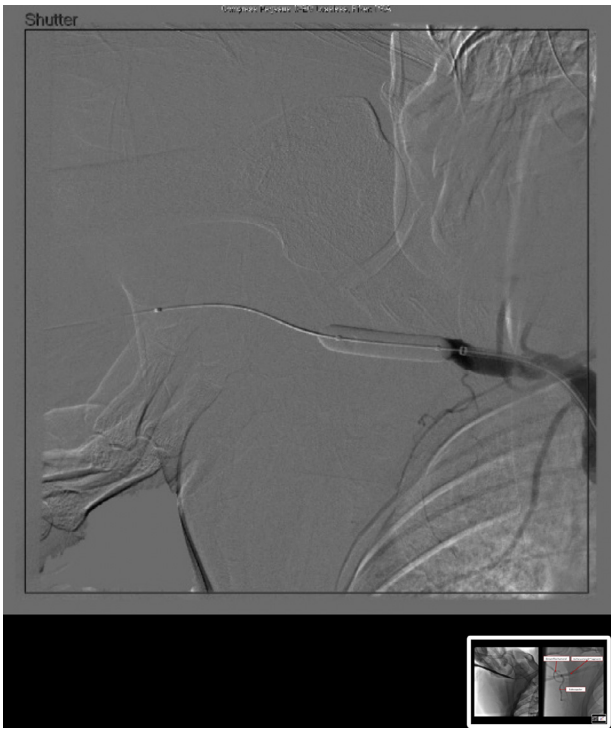


Figure 3. Dry closure technique. Appropriately-sized (1:1) 7−10 × 40 mm peripheral balloon is advanced over the 0.035-inch wire from the femoral sheath and inflated at low pressure (2−4 atmosphere). Once endovascular hemostasis is achieved, the Impella sheath is then completely removed and the preclosure is completed by cinching and locking the previously deployed Perclose Proglide sutures.

Results

From January 2016 to October 2017, a total of 17 patients presented with CS requiring MCS through axillary artery due to prohibitive PAD (mean age 68 ± 14 years). Associated co-morbidities were diabetes (47%), hypertension (95%), hyperlipidemia (100%), chronic kidney disease (88%), coronary artery disease (65%), and history of coronary artery bypass graft surgery (30%). The mean ejection fraction was 20% ± 7.2%. Nine patients presented with CS requiring percutaneous coronary intervention whereas 8 patients required MCS due to nonacute myocardial infarction (AMI) CS only.

The axillary artery was used for access due to severe PAD that involves bilateral iliac and common femoral arteries in patients presenting with CS. The right axillary artery was used in 14 (82%) patients, while 3 patients received MCS through the left axillary artery. This was mainly driven by the acuity of presentation requiring expedited mechanical support and leaving no time to prepare and drape the patient for left axillary artery. All patients underwent successful implantation of the Impella device through percutaneous axillary artery access. No surgical interventions were required. The time from needle access to axillary artery to activation of Impella was 14.8 ± 4 minutes (ranging from 8 to 21 minutes). Axillary access and device insertion improved over time.

Three patients required Impella RP for right ventricular support due to biventricular CS. In these 3 cases, hemodynamic calculations were used to determine the severity of right ventricular failure and therefore the necessity of right ventricular support. These were the cardiac power output [CPO = (mean arterial pressure × cardiac output)/451] <0.6] and the pulmonary artery pulsatility index [PAPI = (systolic pulmonary arterial pressure − diastolic pulmonary arterial pressure)/RA <0.9]. Hemodynamic and laboratory characteristics are described in (Table 1).

The mean duration of Impella CP use was 3.8 ± 1.4 days. Of the 17 patients, 12 (70%) died before device explant and 5 survived to discharge. The device was removed after an average of 2.8 days (range 1 to 7 days) in the 5 surviving patients. Out of 5 survived patients, 1 patient received preclosure with 2 Perclose Proglide device, 2 achieved hemostasis with balloon tamponade alone and 2 failed balloon tamponade and required 1 Viabahn covered stent. All survived patients had preserved upper extremity perfusion and full range of motion with no neurological defect after sheath removal and closure.

In terms of outcomes and complications, 11 patients (65%) expired from refractory CS and 1 patient (5%) from a massive intracranial hemorrhage. Seven patients (41%) required renal replacement therapy for acute kidney injury, all of whom eventually expired. Four (24%) patients suffered from sepsis related to genitourinary and gastrointestinal sources. These were unrelated to the Impella access site. One patient suffered device related upper limb ischemia that was managed successfully with a percutaneous axial-brachial bypass circuit. Significant bleeding that required blood transfusion occurred in 1 patient, which required 2 units of packed red blood cells. One patient developed an upper extremity deep vein thrombosis. No neurovascular complications were noted in the upper extremity. There were no access-related hematomas in any of the cases. We found device position to be quite stable, with little evidence of migration, even in patients who required prolonged support.

Discussion

Impella CP devices were implanted successfully through the axillary artery in all 17 patients. The duration of support ranged from 1 to 10 days. The high mortality rate of our study group is not surprising and is attributable to their critical illness (CS with multisystem organ failure) rather than due to complications related to the axillary access. Bleeding, vascular, and thromboembolic complications were low in patients who survived to discharge. The short insertion time, adequate hemodynamic support, low complication rate and patient ambulation, suggest that axillary artery access for MCS sheath is a safe and feasible alternative access for patients presenting with CS with prohibitive PAD.

For elective and nonurgent high-risk intervention procedures, it is recommended to assess alternative access sites using computed tomography (CT). When severe PAD is detected, it is possible to stage the patient for peripheral intervention first that will make it possible to use those vessels to support large bore sheath introducers and devices in the future.

Table 1
Baseline characteristics for cardiogenic shock patients who received MCS through axillary artery access (n = 17) with hemodynamic and laboratory characteristics

Gender	Age (years)	Device implanted	Indication MCS	CO (L/min)	CI (L/min/m^2)	LVEDP (mm Hg)	RAP/CVP (mm Hg)	PASP (mm Hg)	PADP (mm Hg)	Platelet (10^3)	Hgb (g/dl)	BUN (mg/dl)	Cr (mg/dl)
Male	23	Impella CP	Non-ischemic cardiogenic shock	2.72	1.37	n/a	18	46	33	328	12.7	28	1.47
Male	50	Impella CP	Cardiogenic shock w/ PCI	2.93	1.44	n/a	33	75	33	225	9.8	80	8.89
Male	55	Impella CP	Non-ischemic cardiogenic shock	1.81	1.04	18	51	39	15	155	13.6	105	2.75
Male	57	Impella CP	Cardiogenic shock w/ PCI	4.84	2.53	34	n/a	38	25	38	7.4	56	2.08
Male	57	Impella CP + RP*	Ischemic shock w/o PCI	n/a	n/a	49	29	39	31	n/a	n/a	n/a	n/a
Male	57	Impella CP	Cardiogenic shock w/ PCI	3.45	1.9	27	2	27	13	177	14.1	21	1.22
Male	60	Impella CP	Cardiogenic shock w/ PCI	3.25	1.97	30	17	51	30	218	8.9	47	1.11
Male	60	Impella CP	Ischemic shock w/o PCI	4.46	2.62	17	26	57	31	302	9.1	15	2.12
Male	63	Impella CP	Cardiogenic shock w/ PCI	6.04	2.91	17	19	76	43	147	6.8	105	4.12
Male	70	Impella CP	Ischemic shock w/o PCI	3.3	1.68	n/a	24	92	51	425	7.4	23	1.13
Male	71	Impella CP	Cardiogenic shock w/ PCI	4.57	2.7	29	10	33	20	302	11.4	21	1.08
Male	71	Impella CP	Ischemic shock w/o PCI	n/a	n/a	n/a	15	59	25	119	11	26	1.5
Male	74	Impella CP	Cardiogenic shock w/ PCI	5.02	2.28	34	20	61	32	146	10.9	68	3.27
Female	75	Impella CP + RP*	Ischemic shock w/o PCI	4.1	1.8	n/a	29	58	46	315	11.5	54	1.42
Male	76	Impella CP	Cardiogenic shock w/ PCI	2.43	1.31	n/a	12	51	31	141	11.7	57	2.18
Male	81	Impella CP	Ischemic shock w/o PCI	4.73	2.32	26	17	56	20	186	7.9	60	2.85
Male	85	Impella CP	Cardiogenic shock w/ PCI	3.88	2.16	41	18	39	23	353	10	25	1.36

MCS = mechanical circulatory support; PCI =percutaneous coronary intervention; CI = cardiac index; CO = cardiac output; LVEDP = left ventricular end-diastolic pressure; RAP = right atrial pressure; CVP = central venous pressure; PASP = pulmonary artery systolic pressure; PADP = pulmonary artery diastolic pressure; Hgb = hemoglobin; BUN = blood urea nitrogen; Cr = creatinine.

* Biventricular MCS for left and right ventricular failure.

There are several characteristics of the axillary artery that make it a favorable large bore sheath access site. The artery size makes it suitable to accommodate sheaths with an outer diameter of up to 18Fr. In a retrospective analysis of 110 CT scans done at a single institution, the mean diameter of the right axillary artery was 6.38 mm and 6.52 mm on the left. The axillary arteries demonstrated substantially lower rates of stenosis and of calcification compared with the iliofemoral arteries.[10] In 208 patients who underwent routine CT scan for TAVR procedure, minimal luminal diameters for the axillary arteries and iliofemoral arteries were 6.0 ± 1.1 mm and 6.6 ± 1.8 mm, respectively.[11]

Surgical cut down of the axillary artery is another approach that requires collaboration with a cardiothoracic surgeon, and it is done most often in hybrid laboratories designed to support both procedures. The major vessel is exposed and isolated, and a Gore graft is sutured end to side to permit large bore device insertion through the vessel.[19] This approach is limited by the requirement of coordination between anesthesia, surgery, and a hybrid operating room with fluoroscopic capabilities.[20] The time needed to perform the procedure can be prohibitive in emergency cases. In contrast, a fully percutaneous upper extremity approach in a standard catheterization laboratory with only local anesthesia facilitates the rapid insertion time required to support these critically ill patients.

Previous studies suggested that percutaneous access of axillary artery is feasible and safe for procedures requiring large bore sheath such as TAVR, intra-aortic balloon pump and Impella insertion in patients with prohibitive PAD.[12–16] Similarly, previously published reports described the use of Impella MCS devices in patients presenting for high-risk coronary interventions with stable hemodynamics, and also advanced heart failure patients who require prolonged hemodynamic support as a bridge to destination therapy.[15,17,21] This makes axillary access a favorable alternative for patients presenting acutely to the cath lab with CS with severe PAD that would otherwise preclude MCS device insertion. The findings of our case series demonstrate that percutaneous axillary artery access can be used in emergent cases without increased risk of access site or procedural complication. The technique, anatomical landmarks, and equipment we used differ from previous descriptions of this technique.[15,17,21] This gives operators more options of how to access the axillary artery in emergency cases while minimizing the risk of neurovascular injury and facilitating safe and uncomplicated access site closure. Further evaluation of percutaneous axillary access is ongoing. The ARMS registry was developed as a conjoint effort of 16 medical centers throughout the United States.[22] Preliminary data suggest that axillary approach for Impella 2.5 and CP is feasible and does not carry higher levels of complications compared with the femoral approach.

Conclusion

The axillary artery approach is an emerging alternative access for large bore mechanical circulatory support devices in patients with PAD that precludes femoral access. Utilizing our totally percutaneous technique, we have safely introduced Impella CP device sheath from the axillary artery without the need for a surgical cut-down. Axillary artery access seems to be a feasible and safe approach in CS patients who would otherwise be deemed too high risk for this device using the standard common femoral artery approach.

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Disclosure

Amir Kaki, MD − ABIOMED speaker and proctor. The rest of the authors have no conflicts of interest to declare.

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