Deploying Mechanical Circulatory Support Via the Axillary Artery in Cardiogenic Shock and High-Risk Percutaneous Coronary Intervention

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We sought to study the feasibility of axillary artery as alternative access for mechanical circulatory support (MCS) in cardiogenic shock and high-risk percutaneous coronary intervention (HR-PCI) patients with severe occlusive peripheral artery disease (PAD). In patients with severe PAD, the iliofemoral artery may be so diseased preventing deployment of MCS, precluding the use of lifesaving therapy. In such circumstances, the axillary artery may be a viable access site. Records of all patients presenting with cardiogenic shock or HR-PCI requiring MCS through axillary artery access at our institution from January 2016 to September 2018 were examined. Demographics, clinical, procedural, and outcomes data were collected on all patients. A total of 48 patients presented with cardiogenic shock (60%) or HR-PCI (40%) requiring MCS via axillary artery due to prohibitive PAD (mean age 66 ± 11 years). Admission diagnoses were non-ST segment elevation myocardial infarction (38%), unstable angina (23%), ST segment elevation myocardial infarction (19%), and cardiac arrest (21%). Time from axillary access to activation of Impella was 11.9 ± 4 minutes. Four patients required concomitant Impella RP for right ventricular support due to biventricular cardiogenic shock. Twenty-two 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. Axillary artery appears to be a viable alternative access for large bore devices in patients with prohibitive PAD. As experience of the field with this approach grows, it may be the default access for deployment of large bore sheaths in the future. **(Am J Cardiol 2020;128:127−133)**

The use of percutaneous mechanical circulatory support (MCS) devices has become an integral component of cardiac interventions. The 2011 American College of Cardiology/American Heart Association/Society for Cardiovascular Angiography and Interventions Guideline for Percutaneous Coronary Intervention recommend consideration of percutaneous MCS as adjunct to high-risk percutaneous coronary intervention (HR-PCI) (Class IIb) and for cardiogenic shock presenting with ST-elevation myocardial infarction (Class Ib).[1] The Impella MCS device is designed to be placed via the femoral artery, either percutaneously (2.5 and CP) or inserted surgically in the hands of an experienced surgeon (5.0). Subclavian artery and the axillary artery access sites have been described but are not routinely used.[2−5] Atherosclerosis is a systemic disease and patients with coronary artery disease can have peripheral arterial disease (PAD).[6,7] The presence of severe PAD, small vessel size, excessive tortuosity, or calcification of the iliofemoral arteries can be prohibitive for deployment of percutaneous MCS. Inserting an Impella in a patient with existing PAD increases the risk of limb ischemia. We previously published our experience with successful use of the axillary artery access as an alternative to the standard common femoral artery approach in 17 cardiogenic shock patients.[8] In this study, we examined the axillary artery as an alternative access for MCS in HR-PCI and cardiogenic shock patients with severe PAD using a larger patient population.

Methods

This is a retrospective review of a prospectively maintained database of all patients treated in the cardiac catheterization laboratory at the Detroit Medical Center Wayne State University, Detroit, Michigan, USA. Records of all patients presenting with cardiogenic shock or HR-PCI who underwent percutaneous axillary artery access from January 2016 to September 2018 were examined. Procedural, demographic, and clinical data were collected.

In this cohort, the use of the axillary artery as a conduit for deployment of MCS was not the default. At the start of a procedure, angiograms of bilateral iliofemoral arteries were obtained and assessed by the operator. If the iliofemoral system had severe PAD, small vessel size, excessive tortuosity, or calcification, this would make it unfavorable for deployment of MCS and the operator would resort to

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the use of axillary artery as the "bailout" access site (Figure 1).

The axillary access technique was previously described by our group.[8] In brief, the patient is prepared and draped in supine position with the arm abducted at 90°. After sedation, topical anesthesia is administered at the access site. The first objective is to assess if the axillary artery is adequate in size to accommodate large bore access via angiography of the subclavian and axillary arteries. This is achieved by inserting a 6-Fr sheath in the ipsilateral radial artery or a 6-Fr sheath placed in either femoral artery. A 5-Fr JR4 guide catheter is advanced over a guidewire through the femoral artery and selectively engaged in the left subclavian artery or innominate artery. After the axillary artery has been deemed safe to access, angiography is utilized to precisely define the access point that is lateral to the thoracoacromial artery and medial to the circumflex humeral and subscapular arteries.

Next, a micropuncture needle is then advanced under angiographic guidance at an angle of 45° or less from skin toward the access point. A 0.035-inch J-tip wire is then advanced into the subclavian artery and the micropuncture sheath is exchanged for a 6-Fr sheath. The 6-Fr sheath is then upsized to a 7- or 8-Fr sheath to allow for introduction of the Perclose Proglide devices. Utilizing the "preclose" technique, 2 Proglide suture-mediated closure devices (Abbott Vascular, Redwood City, CA) 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 Impella sheath over a stiff 0.035-inch wire. The Perclose Proglide device was generally considered the primary closure modality. If the Perclose fails, then the operator would traditionally move to the balloon tamponade method. If that fails, then the operator would resort to using a covered stent to finally close the arteriotomy site. There were instances in which the operator would skip the Perclose modality and go straight to balloon tamponade because they felt that the Perclose technique would not adequately provide vascular closure. This was left up to the operator's discretion. Successful closure in the results section was defined as the final closure technique used for the arteriotomy site that was able to achieve hemostasis. Unsuccessful closure was defined as the closure technique that was unable to achieve hemostasis requiring conversion to an alternative method.

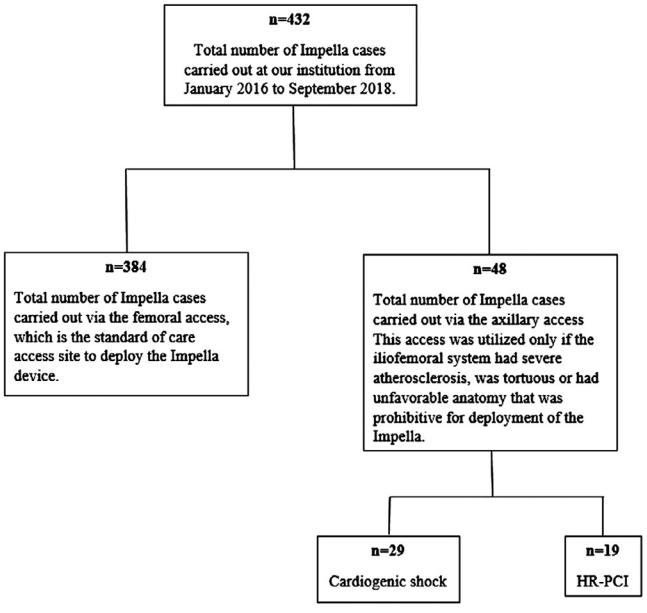

Figure 1. A consort diagram highlighting the total number of cardiogenic shock and HR-PCI cases that were carried out with Impella support deployed via the axillary or femoral access site.

The definition of HR-PCI has varied among clinical trials. In our population, a patient was considered high risk if they had unprotected left main, multivessel disease, elevated risk for bypass graft surgery, last remaining coronary artery, and compromised left ventricular function. Cardiogenic shock was defined as systolic blood pressure of <90 mm Hg for at least 30 minutes or the need for supportive measures to keep SBP ≥90 and evidence of end-organ hypoperfusion (urine output <30 ml/h and a heart rate of ≥60 beats/min with cool extremities), low cardiac index (<2.2 ml/min/m^2), and pulmonary capillary wedge pressure ≥15 mm Hg. Our institutional protocol recommends invasive hemodynamic monitoring data before inserting an Impella. A right-sided cardiac catheterization is performed for all patients as an objective determinant and a guide for hemodynamic support. This is also helpful for our cardiac team because it provides minute-by-minute hemodynamic information and allows fine-tuning the overall care of the patient.

The Society for Cardiovascular Angiography and Interventions recently published a consensus on the classification of cardiogenic shock. This staging system classifies cardiogenic shock into 5 stages and there is a dramatic incremental increase in mortality with each successive SCAI shock stage.[9,10] Bleeding events occurring during the initial hospitalization were assessed and classified according to Bleeding Academic Research Consortium (BARC) classification.[11] If a patient experienced multiple in-hospital bleeding events, the most severe was classified rather than the first event.

Results

From January 2016 to September 2018, a total of 48 patients presented with cardiogenic shock (29 patients, 60%) or HR-CPI (19 patients, 40%) requiring MCS via axillary artery due to prohibitive PAD (mean age 66 ± 11 years). Most of the patients were men and had many risk factors for heart disease. The patients had the following admission diagnoses; Non-ST segment elevation myocardial infarction (NSTEMI), unstable angina, ST-segment elevation myocardial infarction (STEMI), and cardiac arrest manifesting as pulseless electrical activity or ventricular fibrillation. The mean preoperative ejection fraction of this population was 27 ± 16%. All patients had their cardiac function assessed using an echocardiogram performed either by an ultrasound technician (elective procedure) or a cardiologist on call (emergent procedure) (Table 1).

There were differences in terms of hemodynamic parameters and laboratory parameters between our cardiogenic shock and HR-PCI populations. The HR-PCI population was an especially high-risk cohort as noted by their co-morbidities, right-sided cardiac catheterization data, and laboratory data (Table 2). The indications for MCS were cardiogenic shock and HR-PCI. Within the cardiogenic shock cohort,

Table 1
Baseline characteristics for cardiogenic shock patients who received MCS via axillary artery access (n = 48)

Variable	(n = 48)
Age (years)	
Mean ± STDV	66 ± 11.3
Range	(23-86)
Weight (kg)	
Mean ± STDV	82 ± 19.2
Range	(48-151)
Height (cm)	
Mean ± STDV	170 ± 10.2
Range	(147-185)
Men	40 (83%)
Women	8 (17%)
Black	19 (40%)
White	14 (29%)
Hispanic	1 (2%)
Other	14 (29%)
Hypertension	46 (96%)
Coronary artery disease	42 (88%)
Prior myocardial infarction	31/42 (74%)
Prior PCI	28/42 (67%)
Prior coronary bypass	9/42 (21%)
Hyperlipidemia	35 (73%)
Diabetes mellitus	21 (44%)
Chronic kidney disease	23 (42%)
Peripheral arterial disease	20 (42%)
Stroke/transient ischemic attack	9 (19%)
Tobacco user	16 (33%)
Admission diagnosis, % (n)	
Non-ST segment elevation myocardial infarction	18 (38%)*
Unstable angina	11 (23%)*
ST segment elevation myocardial infarction	9 (19%)*
Cardiac arrest (pulse less electrical activity, ventricular fibrillation)	10 (21%)*

STDV = standard deviation.
* Percentages may not add up to 100% because of rounding.

24% of the patients required PCI and the rest were treated with optimal medical therapy. Optimal medical therapy was specifically tailored to the patient's clinical condition and consisted of inotropes, vasopressors, renin angiotensin blockade, aldosterone antagonist, nitrates, digoxin, and diuretics when clinically indicated. Beta blockers were introduced once the patient approached closer to discharge.

The devices used for hemodynamic support were the Impella 2.5, Impella CP and concomitant Impella CP, and Impella RP. Four patients required deployment of Impella RP for right ventricular support due to biventricular cardiogenic shock (Table 3). Hemodynamic calculations were used to determine the severity of right ventricular failure and necessitated the use of right ventricular support. These calculations 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).

Both right and left axillary arteries were utilized to insert the Impella device. All patients underwent successful implantation of the Impella device via percutaneous axillary artery access. No surgical interventions were required. In our experience, there was no difference in deployment from either the left or right axillary artery. We also observed the Impella to be more stable in the axillary artery compared with the femoral artery and required less repositioning. The time from needle access to axillary artery to activation of Impella was 11.9 ± 4 minutes (range was 7 to 22 minutes). Over time, successful establishment of axillary access and time to device activation improved.

Successful closure of the axillary access site was obtained with Perclose closure device (62.5%), covered stent (22.9%) and balloon tamponade (14.6%). There were instances in which the initial axillary access site closure failed and required conversion to an alternative closure technique. Access site closure failure occurred with balloon tamponade (8.3%) and Perclose closure device (22.9%; Table 3).

Of the 48 patients, 21 (20 cardiogenic shock cohort, 1 HR-PCI cohort) died before device explant and 27 survived to discharge. In terms of complications, patients expired from refractory cardiogenic shock and from sepsis related to genitourinary and gastrointestinal sources. Four patients suffered device-related upper limb ischemia that was managed successfully with a percutaneous axillary-brachial bypass circuit. Fourteen patients (29%) developed severe acute kidney injury requiring renal replacement therapy, 13 of which were able to regain renal function. Of all the patients who survived, all had preserved upper extremity perfusion and 2 (4%) developed reduced motor function after sheath removal and closure in the immediate postoperative period. One patient (2%) required escalation of mechanical support to extracorporeal membrane oxygenation because the Impella was providing inadequate support. One patient experienced an ischemic stroke that was contralateral to the site of the Impella insertion. BARC ≥2 bleeding was observed in 6 patients (13%) and 4 patients (8%) developed device-related hematoma (BARC type 1). Laboratory confirmed hemolysis occurred in 4 patients (8%). In 1 patient, the Impella had to be removed because of severe hemolysis. In our case series, we had 1 patient develop axillary artery thrombus in a patient who had the Impella implanted for a relatively long period of time (4 days). No pneumothorax was observed (Table 4).

Discussion

The goal of this study is to demonstrate our experience with the axillary artery as a conduit for MCS. To our knowledge, this study is the largest collection of cases that illustrates the use of the axillary artery as an alternative access site for deployment of the Impella. The device was implanted successfully in all 48 patients. The high mortality rate in our cohort is not surprising and is attributable to their critical illness (cardiogenic shock with multisystem organ failure) and chronic co-morbidities rather than due to complications related to the axillary access. Bleeding, vascular, and thromboembolic complications were low in patients who survived to discharge. Short insertion time coupled with adequate hemodynamic support and potential for patient ambulation suggest that axillary artery access is a safe and feasible access site for patients with severe PAD, who otherwise would have been denied lifesaving therapy.

Tayal et al examined CT angiograms of 110 patients and showed that the average diameter of the right axillary artery

Table 2
Hemodynamic and laboratory characteristics

Variable	Combined cohort(n = 48)	Cardiogenic shock(n = 29)	HR-PCI(n = 19)
Cardiac output (L/min)			
Mean ± STDV	4.16 ± 1.24	3.73 ± 1.18	4.75 ± 1.08
Range	(1.61-6.59)	(1.61-6.18)	(2.93-6.59)
Cardiac index (L/min/m2)			
Mean ± STDV	2.18 ± 0.64	1.94 ± 0.59	2.51 ± 0.56
Range	(0.99-3.47)	(0.99-3.3)	(1.44-3.47)
Left ventricular end diastolic pressure (mm Hg)			
Mean ± STDV	29.43 ± 9.63	30.89 ± 10.63	26.33 ± 6.56
Range	(9-49)	(9-49)	(16-34)
Right atrial pressure (mm Hg)			
Mean ± STDV	18.70 ± 9.75	21.37 ± 8.69	14.19 ± 10.04
Range	(2-51)	(9-51)	(2-39)
Pulmonary artery systolic pressure (mm Hg)			
Mean ± STDV	49.98 ± 16.87	53.44 ± 16.39	45.05 ± 16.73
Range	(16-92)	(34-92)	(16-76)
Pulmonary artery diastolic pressure (mm Hg)			
Mean ± STDV	27.54 ± 10.72	30.85 ± 9.23	22.84 ± 11.16
Range	(9-52)	(15-51)	(9-52)
Creatinine (mg/dl)			
Mean ± STDV	2.1 ± 1.8	2.38 ± 1.79	1.59 ± 1.84
Range	(0.91-8.89)	(0.79-8.82)	(0.61-8.89)
Blood urea nitrogen (mg/dl)			
Mean ± STDV	35.7 ± 21.8	40.86 ± 20.55	27.79 ± 21.71
Range	(7-105)	(15-105)	(7-86)
Hemoglobin (g/dl)			
Mean ± STDV	11.0 ± 2.8	10.95 ± 3.23	11.12 ± 2.13
Range	(6.9-18.6)	(6.9-18.6)	(8.3-15.3)
Platelets (10^3)			
Mean ± STDV	230 ± 90	236 ± 109	220 ± 49
Range	(38-464)	(38-464)	(154-310)

STDV = standard deviation.

was 6.38 mm and 6.52 mm on the left.[12] The axillary artery is smaller than the femoral artery, yet large enough in most patients to accommodate sheaths up to 14 to 16 Fr safely. Tayal et al also found that the prevalence of axillary artery calcification compared with the femoral artery is very low, 1.04% to 2.1% versus 17.8% to 19.8%.[12] This is something that we have also seen intraoperatively and this that may be dubbed the "axillary artery paradox."

The utilization of axillary access site for deployment of MCS is an emerging field and should be utilized by operators that are familiar with this approach with carefully selected patients in specific clinical scenarios. When utilizing the axillary artery approach to deploy large bore sheaths, there are inherently patient factors, axillary artery anatomy, and limitations that must be considered. Specifically, the left axillary artery should be avoided in certain instances. If a patient is status postcoronary artery bypass graft surgery where the left internal mammary artery is grafted or if a patient has an arteriovenous fistula in 1 arm (eg, for dialysis), then the axillary artery supplying that limb should not be used. We use angiography to judge the severity of tortuosity and/or calcification of the artery that helps us to determine whether to use the right versus the left axillary artery. In terms of anatomy, there is concern for neurovascular injury because the area of the arteriotomy site is in proximity to the brachial plexus. There is also concern for bleeding complications and compromise of blood flow to the upper extremity because the axillary artery is more prone to dissection or disruption due to the lack of a muscular component of the arterial wall. In our case series, 2 patients developed reduced mobility in the immediate postoperative period. BARC ≥2 bleeding was observed in 12.5% (n = 6/48). In comparison, Burzotta et al examined outcomes of 86 HR-PCI patients supported by Impella 2.5 or CP via the femoral access. In their experience, 6 patients had BARC type 1 bleeding and 6 patients had BARC ≥2 bleeding.[13] Alushi et al examined the outcomes of 62 patients who sustained an acute myocardial infarction complicated by cardiogenic shock and were supported by Impella 2.5 or CP deployed via femoral access. Nine patients developed BARC ≥2 bleeding in this population.[14]

What complicates matters more is that there is no dedicated closure device for large bore sheaths in the axillary artery. In our case series, there were instances in which a suture-mediated closure system or balloon tamponade were unable to obtain hemostasis and a covered stent was used. Because the axillary artery lacks a muscular component, it might make it more difficult to achieve hemostasis and it explains the high rate of the Perclose suture mediated device failure. Therefore, we had to resort to balloon tamponade or covered stent closure. Although studies have shown successful outcomes in lower extremity arterial occlusive disease, there are concerns regarding its long-

Table 3
Procedural characteristics

Indications for MCS	
Total CS patients	29 (60%)
SCAI SHOCK stage A	0
SCAI SHOCK stage B	0
SCAI SHOCK stage C	11 (23%)
SCAI SHOCK stage D	4 (8%)
SCAI SHOCK stage E	14 (29%)
-CS patients who underwent PCI	7 (−24%)
-CS patients who did not undergo PCI	22 (−76%)
Total HR-PCI patients	19 (40%)
MCS device	
Impella CP	40 (83%)*
Impella 2.5	4 (8%)*
Impella CP and Impella RP	4 (8%)*
MCS device duration (hours)	
CS patients median (range)	72 (24-288)
HRPCI patients median (range)	1.25 (0.2-96)
Axillary site	
Right	27 (56%)
Left	21 (44%)
Successful closure technique, n (%)	
Closure device (Perclose)	30 (63%)*
Covered stent/Stent graft	11 (23%)*
Balloon Tamponade	7 (15%)*
Unsuccessful closure technique, n (%)	
Balloon Tamponade	4 (8%)
Closure device (Perclose)	11 (23%)

MCS = mechanical circulatory support; CS = cardiogenic shock; HR-PCI = high risk percutaneous coronary intervention.
* Percentages may not add up to 100% because of rounding.

term durability when a metallic stent is placed across mobile joint such as a shoulder. Chen et al have published a case report where they demonstrated a 10-year patency rate of a Viabahn-covered stent in a patient, who had a successful axillary pseudoaneurysm exclusion. This illustrated the durability of the covered stent, given that it has been subjected to long-term rotational movements.[15]

Table 4
Outcomes of patients with severe PAD and received MCS for hemodynamic support

Outcomes	
Technical success rate	48 (100%)
Death	22 (46%)
-21 in cardiogenic shock cohort	
-1 in HR-PCI cohort	
Severe acute kidney injury requiring renal replacement therapy	14 (29%)
Sepsis	7 (15%)
Arm ischemia related to device	4 (8%)
Axillary artery dissection	2 (4%)
Escalation of mechanical support to ECMO	1 (2%)
Ischemic stroke	1 (2%)
BARC end points, n (%)	
BARC type 0 or 1	4 (8%)
BARC type 2	5 (10%)
BARC type 3	
Type 3a	0
Type 3b	0
Type 3c	1 (2%)
BARC type 4	0
BARC type 5	0

HR-PCI = high risk percutaneous coronary intervention; ECMO = extracorporeal membrane oxygenation; BARC = Bleeding Academic Research Consortium.

Careful technique assures a very low rate of access-related complications. The axillary artery should be accessed between the second and third portion at the lateral border of the pectoralis minor muscle. This technique is associated with the lowest chance of causing brachial plexus injury. Also, this area is superficial enough to be manually compressible for the purpose of achieving hemostasis. In the event compromise of blood flow to the distal extremities occurs, this is overcome by creating an external axillary-radial bypass or axillary-brachial bypass circuits. For the axillary-radial bypass, a 6-Fr sheath is inserted in the ipsilateral radial artery. Using long extension tubing and male−to−male connector, the side arm of the large bore in the axillary artery is connected to the side arm of the radial sheath (Figure 2). For the axillary-brachial bypass, the vessel is accessed with micropuncture needle exchanged for 6-Fr sheath. Then the side arms of the large bore and the brachial sheath are connected using male−to−male connector (Figure 3).[16] In our institution, all patients with such conduits are transferred to the coronary care units and monitored hourly using vascular ultrasound Doppler to evaluate patency and function of the conduit. We aim for a target activated clotting time of 200 to 220 seconds.

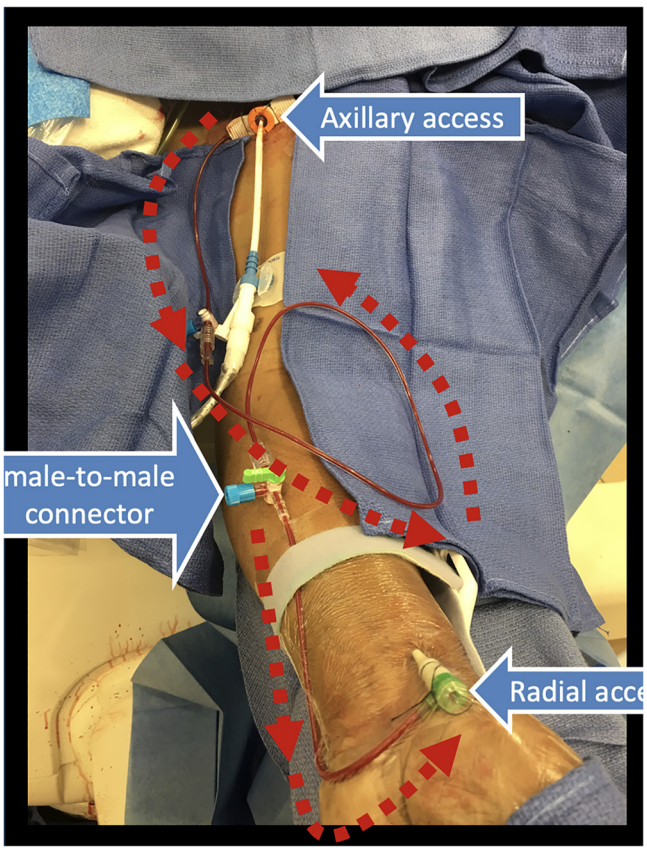

Figure 2. Axillary-radial bypass. A bypass circuit is created whereby blood flows from the ipsilateral axillary artery into the ipsilateral radial artery and providing perfusion to the arm and hand.

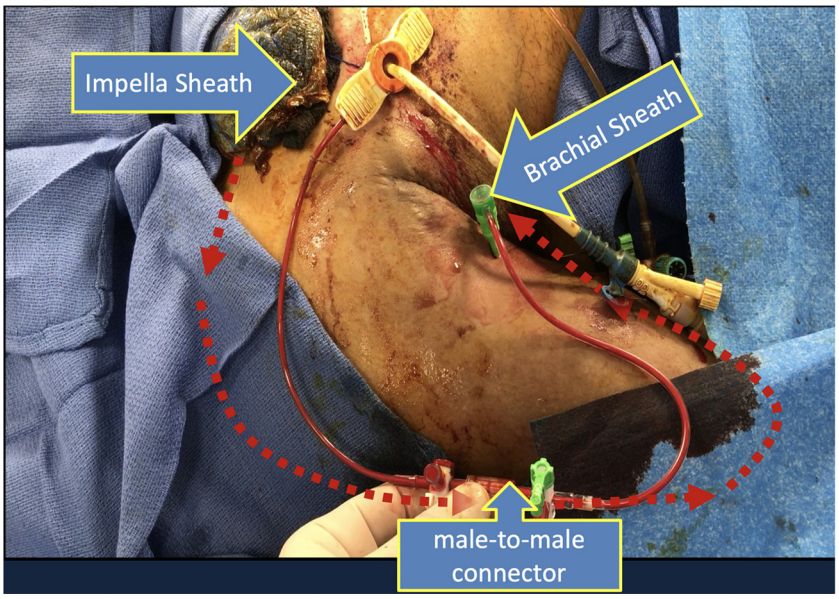

Figure 3. Axillary-brachial bypass. A bypass tract is created whereby blood flows from the ipsilateral axillary artery into the ipsilateral brachial artery to perfuse the distal extremity.

Interventionalists are increasingly referring complex patients to the catheterization laboratory with significant peripheral artery disease. In the past, these patients may have been deemed "too complex" because conditions were prohibitive from establishing large bore access that was needed to hemodynamic support. Our study suggests that axillary artery may be a safe alternative access site in such scenarios. Randomized controlled trials comparing the radial artery versus the femoral artery access have led to the radial artery being the preferred access in patients with acute coronary syndrome. In a similar fashion, studies are needed to compare the axillary artery versus the femoral artery for large bore arterial access.

Author Contribution

Marvin Kajy has contributed the most in terms of data collection, data analysis, and writing of the manuscript. All second authors have contributed equally in the drafting, writing, and proofreading of the manuscript.

Disclosures

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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