

Chapter 14: Step-by-Step Guide for Percutaneous Transaxillary (PTAX) Transcatheter Aortic Valve Replacement (TAVR) with a Balloon Expandable Valve (Sapien S3[®] valve, Edwards Inc., Irvine CA)

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Introduction

Interventional cardiology is a rapidly evolving field with an ever-expanding array of new coronary, peripheral, and structural heart procedures being performed. Accordingly, today's interventional cardiologist must be adept at totally percutaneous arterial access and closure using large-bore catheters. Arterial access via the common femoral artery (CFA) remains the default vascular access site of choice in the United States for transcatheter aortic valve replacement procedures (TAVR).(1,2) However, advanced peripheral artery disease (PAD) may preclude the CFA as a suitable access site.(3) In this regard, the transapical(4), direct aortic(5), transcarotid(6), transcaval(7), and transaxillary (TAX)(8) implantation routes currently serve as alternative access options. These strategies typically involve open surgical exposure. Nevertheless, there are no convincing data on the superiority of surgical exposure.(9,10)

Among the alternative access options, transaxillary and transcaval access are the only ones that may still be accessed percutaneously. Thus some centers have developed a level of comfort utilizing the axillary artery (AA), most typically in the setting of hostile aorto-iliofemoral segments due to extensive calcification and atherosclerotic disease.(11) Prior work has demonstrated that the AA can accommodate sheaths with an outer diameter of up to 18 Fr with a mean vessel diameter of 6.38 mm (right) and 6.52 mm (left).(12) Moreover, these vessels appear to be less frequently affected by the atherosclerotic disease than the CFA even in the setting of advanced PAD, with 2.1% of AAs displaying computed tomographic evidence of atherosclerotic disease vs 19.8% in CFAs.(12)

Anatomy

The most crucial portion of a percutaneous TAX (PTAX) TAVR is the procedural planning phase. Ideally, this requires a high-resolution computed tomography (CT) scan be obtained as part of the initial work-up. If alternative access is planned, the reconstructed CT window should be wide enough to include both axillary arteries.

Figure 1 illustrates pertinent axillary artery anatomy. The axillary artery begins proximally as the subclavian artery which runs above the first rib and subsequently becomes the axillary artery when it courses infra-clavicular. It then runs posterior to the pectoralis minor muscle and becomes the brachial artery at the inferior border of the teres minor muscle. The ideal access site of the axillary artery is in its first segment just proximal to the thoracoacromial branch due to the absence of overlying nerves or veins. For PTAX TAVR with the Edwards LifeSciences' balloon expandable Sapien 3 prosthesis (Edwards Inc., Irvine CA), the topic of this chapter, the left axillary artery is preferred, because it allows for coaxial orientation of the valve prosthesis within the aortic annulus. Further, patients are more likely to be right-

hand dominant so left-sided access may carry less risk and make recovery easier, and there is less of a chance of carotid compromise from the left relative to traversing the right innominate artery. When determining access side, two other angles need to be considered based on the reformatted CT analysis: the aortic annular angle and the angulation of the takeoff of the subclavian / innominate from the aortic arch. An angle $>30^\circ$ between the aortic annular plane and the horizontal axis (i.e., a horizontal orientation of the annulus) should be considered as a significant limitation for the right sided access as co-axiality of the prosthesis prior to deployment can be very challenging. In regards to vessel orientation, a type 1 aortic arch maybe more challenging for right-sided access if the innominate originates high and distal on the arch, while a left subclavian takeoff that is retroflexed towards the descending aorta maybe more inhospitable for left-sided access. In general, without significant prior experience, we would suggest the left axillary artery should chosen preferentially as it more closely mimics transfemoral access.

Room Set-Up, Left Transaxillary Access

A sterile table should be placed at the patient's left shoulder extending perpendicular to the bed with the fluoroscopic camera on the opposite side of the patient as depicted in Figure 2. Radpads should be placed around the left shoulder area to block radiographic scatter. A plethysmography probe should be placed on the patient's left index finger as well and the waveform should be visible to the operators throughout the case. Ideally, the fluoroscopic monitors should be positioned at the patient's left shoulder facing towards the feet just cranial to the table extending perpendicularly outward. This allows the operators to stand side-by-side at this table as they would in a femoral access case but in this instance, they will be facing towards the patient's head where the monitors are positioned.

Access and Baseline Angiography

Femoral access is obtained per standard and a six French (6F) sheath is inserted into the common femoral artery. In the absence of femoral access, ipsilateral radial access can be obtained though is not preferred as retrograde angiograms are less revealing and bailout strategies are restricted. Through the femoral access site, a 6F Judkins Right 4.0 (JR4) diagnostic catheter is used to engage the left subclavian artery. A confirmatory angiogram is performed if renal function allows and a 260 or 300 cm 0.018" wire (Platinum Plus or equivalent) is left down the arm for protection and to fluoroscopically identify the artery (Video 1). Half or full dose heparin should be provided at this juncture. The JR4 catheter is withdrawn while carefully maintaining wire position. A metallic instrument on the skin can then be used to outline the course of the artery relative to the 0.018" wire by fluoroscopy (Figure 3). Ultrasound guidance is then used to confirm access location paying particular attention to the relationship between the axillary artery and vein. One may need to move slightly medial or lateral if the vein is over-riding the artery at the desired location.

With fluoroscopy and ultrasound guidance, the left axillary artery is punctured percutaneously with a micropuncture system using the modified Seldinger technique (Video 2). Generally, access is obtained just medial and inferior to the shoulder prominence in the deltopectoral groove.

A small, 5-6 mm incision should be made at the access site and the subcutaneous tract should be dilated with hemostats and then a 6F dilator; vessel closure can safely be performed using a vascular

preclosure technique. For this purpose two ProGlide devices (Abbott Vascular, Abbott Park, IL, USA) are typically used to “preclose” the vessel (Video 3). Of note when deploying the Proglide devices, care should be taken when pulling back on the Proglide devices after deployment of the foot plates as the axillary arteries tends to have a less robust medial layer and will feel less elastic than the CFA. Following pre-closure, an 8Fr sidearm sheath is then placed in the arteriotomy through which a standard catheter (AL1, JR4, etc) is used to cross the aortic valve.

Commander Sheath Introduction

We prefer to cross the valve through the 8F sheath as the Edwards Commander sheath is relatively long for the purposes of axillary access and will hang outside the body such that all preceding steps require close cooperation between multiple operators. After crossing the aortic valve, pre-procedure hemodynamics and gradients should be measured in standard fashion and then a stiff wire (either pre-shaped or operator-shaped)—we prefer an 1cm straight-tipped Amplatz super stiff with a U shaped curve or a Confida wire—should be left in the left ventricle.

The axillary arteriotomy site should then be serially dilated with the Edwards dilator and then the Commander Delivery Sheath should be placed under careful fluoroscopic guidance. In this case, the Edwards logo is face down (sheath seam towards the head). The primary operator should pay close attention that the system does not traumatize the greater curvature of the subclavian artery. The sheath should be delivered into in the ascending aorta (Video 4). The dilator may be removed while carefully leaving the wire in place. Kinking of the sheath at the subclavian curvature following dilator removal is possible though not at all common and can be easily overcome during valve delivery using a “push-pull” technique. Additional heparin for full therapeutic anticoagulation should be provided at this point if not previously done.

During dilation and sheath delivery, a peripheral over-the-wire balloon sized 1:1 with the artery with a shaft length of at least 130 cm can be loaded over the 0.018” wire from the groin and left in the proximal or mid portion of the left subclavian artery. This balloon can then be inflated between device exchanges to minimize blood loss by inflating to 1-2 atmospheres as equipment is removed from the arteriotomy. Operators should watch the oxygen saturation probe on the left hand for waveform obliteration to ensure an adequate seal when inflating the angioplasty balloon. With growing experience, we have moved away from mandating this step as we have come to understand that the axillary artery is easily manually compressible against the second rib (even in patients with high body mass indices). Nevertheless, for those with limited experience using the axillary artery for access, we would encourage utilization of a “blocking balloon” while developing comfort with this access technique. The balloon will need to be moved in and out of the subclavian artery at various points to allow the Commander sheath to pass comfortably into the ascending aorta. The long 0.018” wire from the femoral artery should be left along the access vessel throughout the case as this allows for rapid endovascular hemostasis with a balloon, or delivery of a stent graft should one be needed and we would strongly encourage removing it only as the last step in the procedure.

As mentioned, the Commander sheath is long and much of it will be outside of the patient’s body after insertion (Figure 4). It is vital that the primary operator maintain a vigilant watch on the sheath from

this point forward to ensure that it does not inadvertently migrate. Though it is a theoretic concern that bleeding could occur along the expanded seam of the Commander eSheath in this position, we have never found this to be true.

Device Deployment

Device deployment is essentially unchanged relative to transfemoral access with the exception of loading the valve on the balloon, which must be performed in the ascending aorta. At the point at which the valve is seen to exit the tip of the sheath under fluoroscopy, the nose cone of the delivery system will likely already be across the native aortic valve (Video 5). This does not appear to cause significant problems and loading of the balloon into the valve will draw the nose cone back into the ascending aorta. To create more room for valve loading, the eSheath can be drawn back into the proximal subclavian but only after the valve has been advanced into the ascending Aorta. Valve deployment proceeds in usual fashion from this point forward (Figure 5 and Video 6).

Closure

Once the valve has been deployed and results appear satisfactory, the delivery system is unflexed and removed through the sheath; the peripheral angioplasty balloon may be inflated as the sheath is being removed to decrease access site bleeding (Video 7). The sheath should be removed over the dilator and the Proglide sutures should be cinched into place. As aforementioned, the 0.018” wire is maintained across the access site and the original peripheral angioplasty balloon is brought to the mid subclavian artery to allow for a ‘dry field’ closure if desired. We prefer to use an over-the-wire peripheral angioplasty balloon with a 0.035” lumen so that cineangiography of the vessel can be performed through the balloon with the wire still in place by adding a Co-Pilot to the end of the balloon and injecting through it (Figure 6 and Video 8). Thus, if extravasation or vascular injury is noted, wire position is not lost and the balloon can be rapidly advanced if needed. If hemostasis has been achieved, the wire and angioplasty balloon can be safely removed.

If hemostasis is not achieved, as with femoral access, options include another Proglide deployed in a different orientation, endovascular hemostasis with the angioplasty balloon across the arteriotomy site for 3-5 minutes, or manual pressure in combination with protamine. If none of these solutions are effective, stent grafting can be an option (we prefer the 0.018” lumen Viabhan system, which typically requires the femoral sheath be upsized to 7Fr) or surgical repair with a cut down can be pursued as needed.

Post-operatively, plethysmography should be monitored on the subtended hand while the patient is in the hospital to ensure vascular patency. The patient should be instructed to avoid pushing/pulling with the access arm for repositioning himself or herself in bed (use a sling as a reminder as needed). The nurse caring for the patient should also be instructed to perform frequent pulse and neuro checks of the upper extremity. We also advise patient to avoid lifting his or her arm above shoulder height during the immediate post-operative period (ideally one week) and to not lift anything over 10 pounds using that arm (though there is no data we are aware of to support these activity limitations we feel that these precautions should be taken out of an abundance of caution).

Video Legend

Video 1. Initial left axillary artery angiography through a 6F JR4 catheter from the CFA sheath.

Video 2. Using a combination of fluoroscopic and ultrasound guidance (ultrasound not shown), the left axillary artery is accessed via micropuncture needle.

Video 3. Proglide insertion example for “pre-close” technique.

Video 4. Edwards Commander sheath insertion from the left axillary artery.

Video 5. Edwards Sapien S3 balloon mounting.

Video 6. Edwards Sapien S3 valve deployment from the left axillary artery percutaneous approach.

Video 7. Edwards Commander sheath removal from the left axillary artery with blocking balloon technique.

Video 8. Post-Edwards Commander sheath removal digital subtraction angiography of the left axillary artery through the lumen of an over the wire peripheral balloon located in the proximal left subclavian artery.

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Figure 1: Cadaveric model illustrating pertinent axillary artery anatomy.

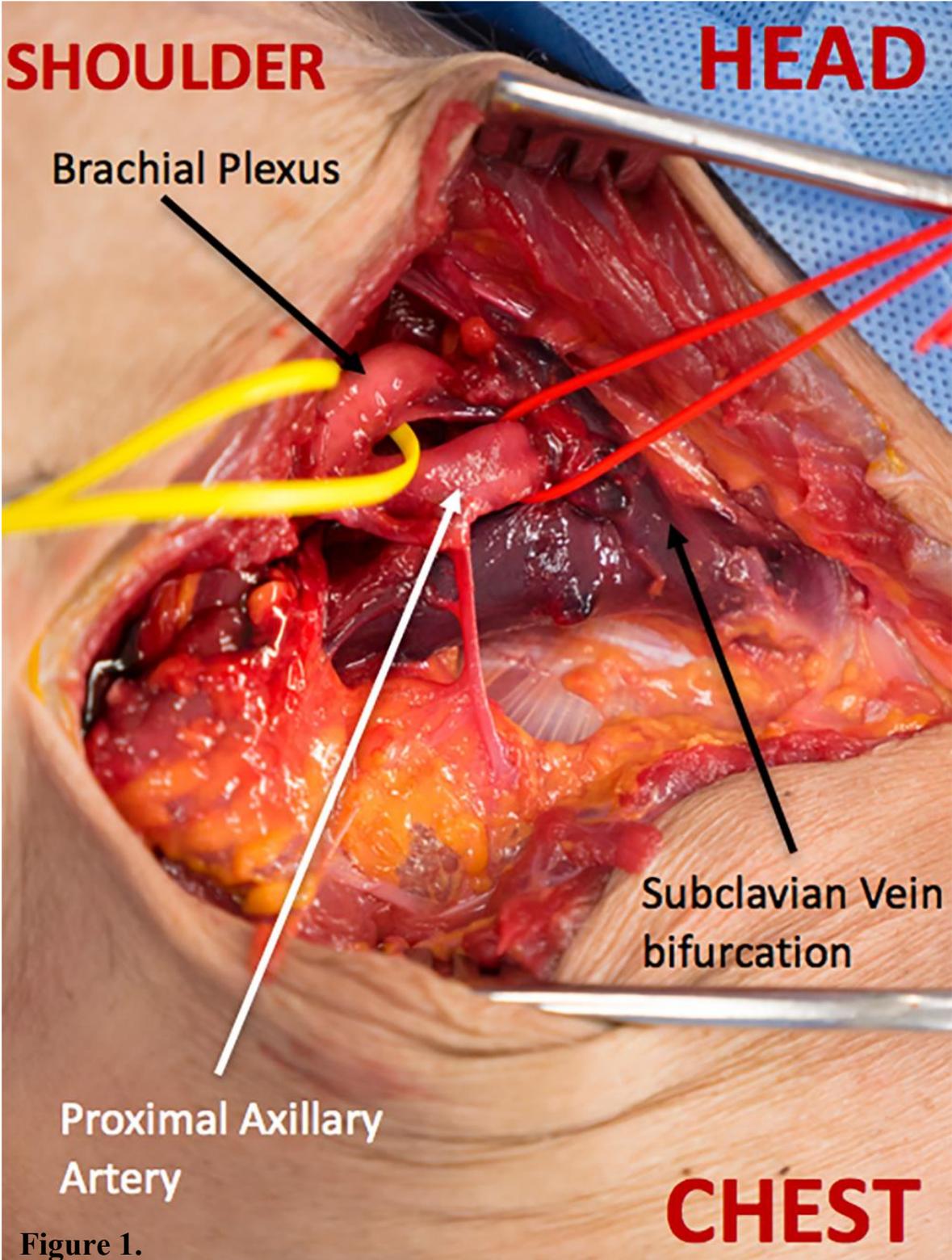


Figure 1.

Figure 2. Stylized room arrangement for PTAX TAVR.

**Members of the Heart Team Present
in the Procedure**

IC: Interventional Cardiologist

CTS: Cardiothoracic Surgeon

A: Anesthesiologist

E: Echocardiographer

P: Perfusionist

DPL: Device Prep Lead

OR / CCL Staff: OR/Cath Lab Staff

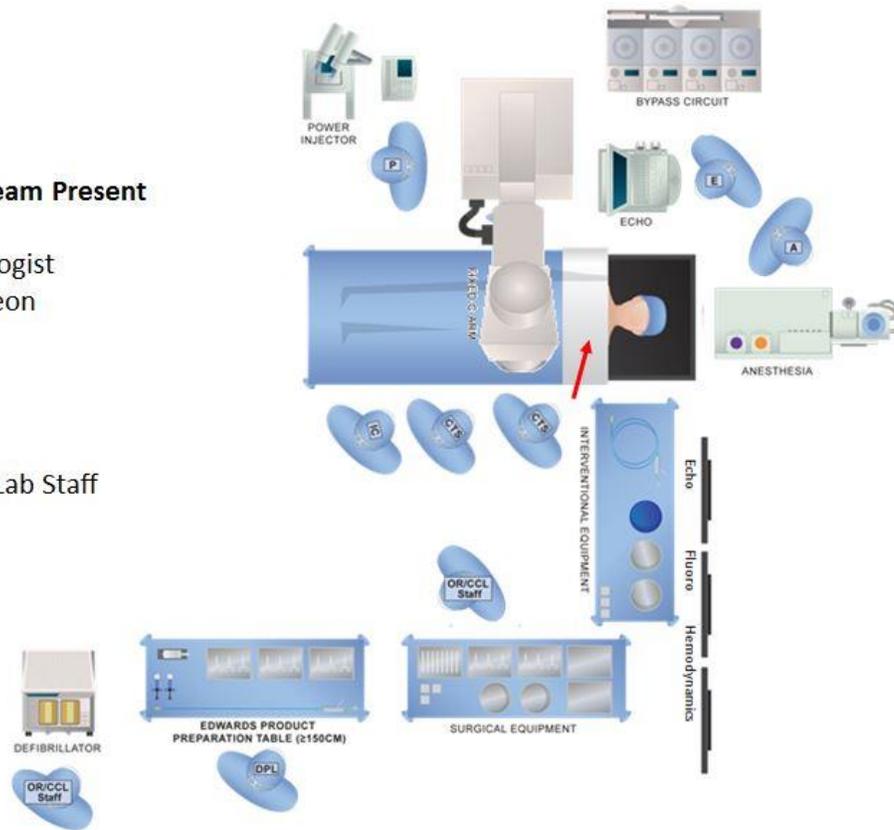


Figure 2.

Figure 3: A metallic instrument on the skin can then be used to outline the course of the artery relative to the 0.018" wire by fluoroscopy. A marker may be used to identify the course of the artery relative to the skin once this is done.

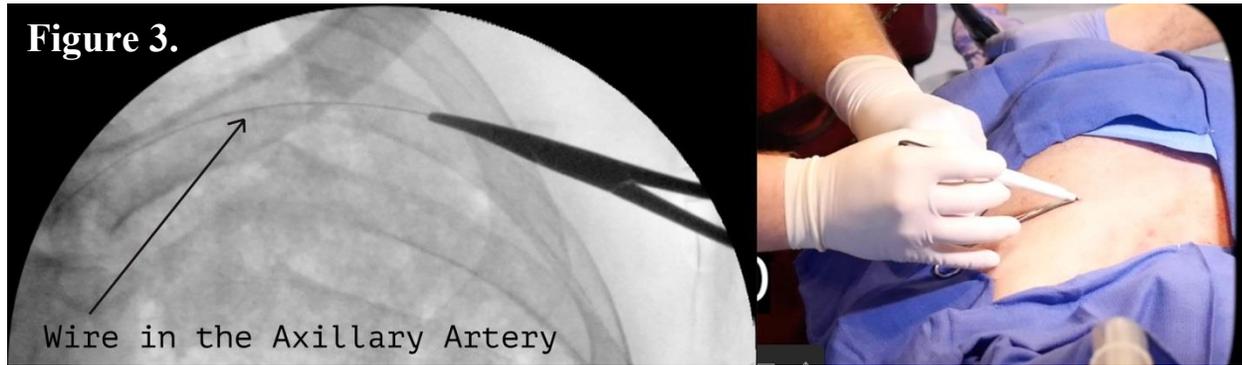


Figure 4: Much of the Edwards Commander delivery system sheath will likely be extruding from the patient's shoulder once it is in place.



Figure 5. Edwards Sapien S3 valve deployment.

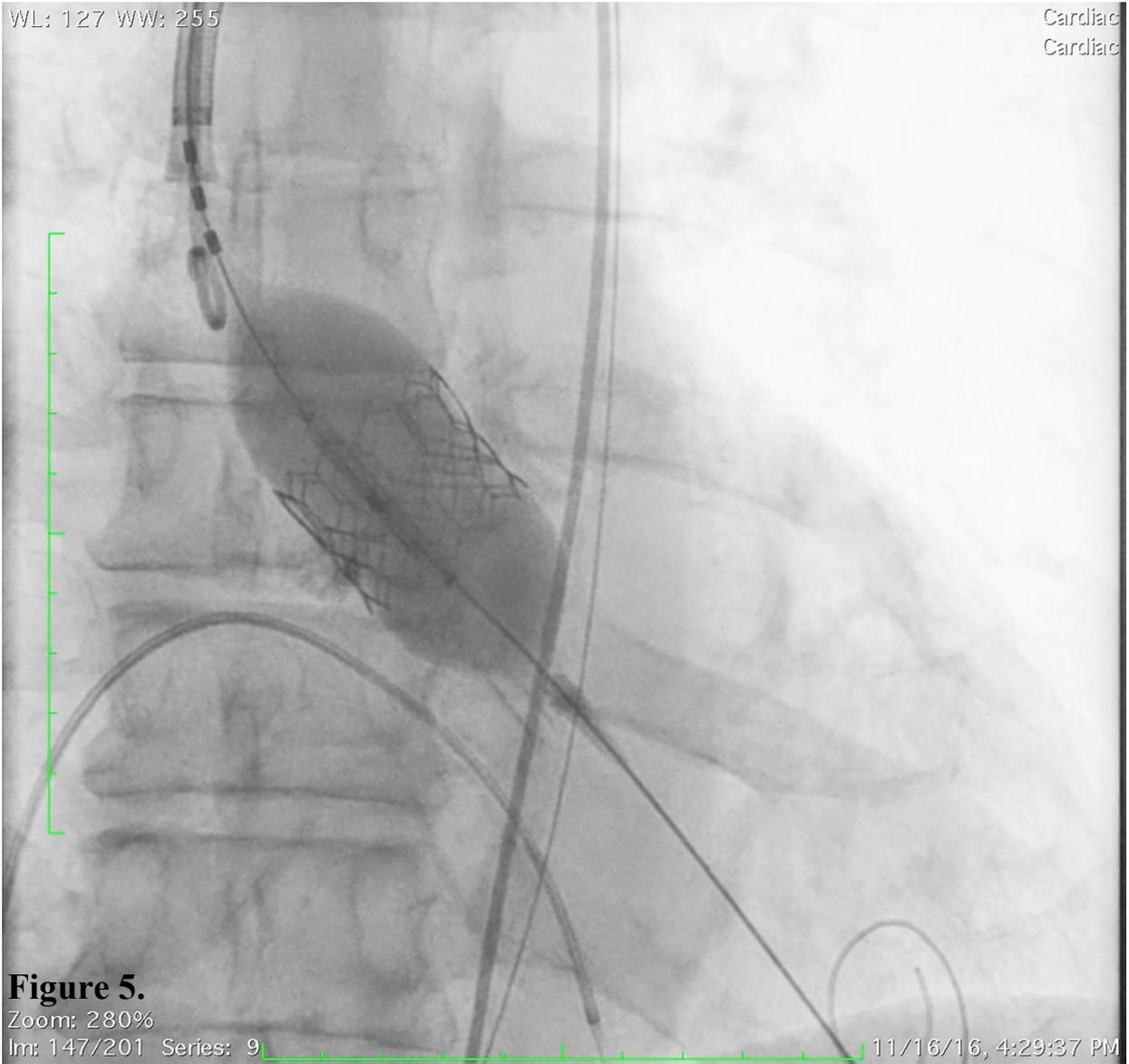


Figure 6: An over-the-wire peripheral angioplasty balloon with a 0.035" lumen in the proximal portion of the left subclavian artery so cineangiography of the vessel can be performed through the balloon with the wire still in place by using a Co-Pilot at the end of the balloon and injecting through it.

