Percutaneous Balloon-Expandable Aortic Valve Implantation: Transfemoral

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While surgical aortic valve replacement has been an extraordinarily effective treatment for symptomatic aortic stenosis, it has been estimated that over 40% of patients with this condition go untreated. Many of these face prohibitive operative risk, due to a number of factors such as porcelain aorta, cirrhosis, severe emphysema, and other comorbidities. Recently, transfemoral transcatheter aortic valve implantation (TAVI) has demonstrated clinical benefit in a patient population at prohibitively high risk for complications following traditional surgical valve implantation.

The initial application of this technology in human patients utilized an antegrade approach via the femoral vein, a transseptal puncture, and guidance of the prosthesis across the mitral valve and out through the left ventricular outflow tract. Although this approach avoids the complications associated with large-bore access of the iliofemoral arterial system, it proved cumbersome for most operators and was associated with a high risk of other major complications, including cardiac perforation and major structural damage to the mitral valve.

In recent years, TAVI procedures with a balloon-expandable system have been performed retrograde either through a transfemoral arterial approach (TF) or through a transapical approach involving a limited left thoracotomy and exposure of the apex of the heart. For the purposes of this article, we focus much of this discussion on our technique for total percutaneous device placement.

The preoperative steps of this procedure, other than general patient selection, include proper evaluation of iliofemoral and aortic access for retrograde device deployment and accurate annulus sizing. The critical procedural steps include the following: reassessment of annular size, vascular access, accurate valve positioning, reliable rapid ventricular pacing, valve deployment, valve assessment, and control of vascular access and closure. The procedural steps of retrograde valve positioning and deployment have been well described and we focus much of this discussion on our technique for total percutaneous device placement.

Patient Screening

The worldwide experience with TF-TAVI reveals that vascular access complications are both common and associated with significantly increased risks of morbidity and mortality. Therefore, all potential patients enrolled for TAVI undergo imaging of their aorta and iliofemoral systems. Generally this involves both invasive angiography and 3-dimensional computerized tomography (3D-CT). Ideally the 3D-CT uses IV contrast but, in some circumstances of impaired renal function, images obtained with low or no contrast administration may be used to complement the invasive angiography. In patients with impaired renal function, we use a combination of noncontrast CT and intravascular ultrasound to evaluate vessel size, calcification, and diameter.

Vessels are evaluated for cross-sectional diameter, calcification, plaque or thrombus, and tortuosity. The current iteration of the Edwards Sapien device is available in 2 sizes: 23 mm and 26 mm. At the current time, the sheath required for placement of a 23-mm Sapien valve is 22 French (25 French outer diameter, 8.5 mm), whereas the sheath required for the 26-mm valve is 24 French (28 French outer diameter, 9.3 mm). The minimal acceptable vessel diameter for the 23 mm valve is 7 mm and for the 26-mm valve is 8 mm. In the presence of marked tortuosity or calcification, we generally prefer even larger diameter vessels. Careful screening can
help to reduce the risk of vessel perforation or rupture due to an oversized sheath.

Although we have favored a percutaneous approach to femoral access, a number of situations favor surgical exposure of the common femoral artery. First, the extremes of patient size may complicate a percutaneous vessel closure. Obese patients have a higher reported incidence of complications from percutaneous vessel closure, although they also stand to gain the greatest benefit from percutaneous closure to avoid wound complications. Patients with a paucity of subcutaneous tissue may have minimal distance between the skin and the artery and be predisposed to infection of the closure device sutures. Moreover, these patients can have a very limited incision for open vessel exposure. Other groups in whom we have utilized surgical exposure are those with synthetic femoral arterial conduit or extensive vessel calcification and those with significant scar tissue. These situations may prevent proper deployment of the closure device sutures. Despite these limitations, we have been able to utilize a truly percutaneous access in the majority of our TF-TAVI patients.

**Patient Preparation and Valve Sizing**

Accurate sizing of the aortic annulus is critical to procedural success. The 23-mm Sapien valve is intended for use in native aortic annulus ranging from 18 to 21 mm, whereas the 26-mm valve is used in annulus sizes 22 to 25 mm. Some degree of oversizing is desirable, to gain a secure purchase of the valve stent on the native aortic valve tissue and to minimize risk of significant perivalvar leak. Choosing a grossly oversized valve can result in incomplete expansion and secondary prosthetic leaflet dysfunction as well as increase the risk of coronary ostial occlusion and aortic dissection. Conversely, an undersized valve can cause perivalvar leak and, in more extreme cases, lead to valve dislodgment. In the published clinical experience as well as the postmarket registry data for countries that have granted device approval, there have been no documented cases of late valve dislodgment or embolization when sized according to protocol.

The principal technique for annulus sizing has been echo-
cardiography. Typically, a parasternal long-axis view will give the most reliable annulus sizing. This view also can give information about excessive mitral annular or anterior leaflet calcification or upper septal hypertrophy, both of which can adversely affect proper valve deployment. We have found several techniques to be quite helpful in accurate annulus sizing. First, we feel it is critical for the physician implanting the valve to personally review the echocardiogram and CT rather than relying on the reports, as they will have the best understanding of the actual landing zone for the valve. Second, we and others have noted that the annulus measurement by transthoracic echocardiogram often underestimates true annulus size and have found transesophageal echocardiogram (TEE) to yield larger, and generally more accurate, annulus size measurements. In addition, given that all patients undergo a screening CT scan, the 3-dimensional reconstructions allow one to obtain a third annulus measurement. We have found that this correlates more closely with TEE rather than transthoracic echocardiogram values, although this is unproven. The TEE that is performed in nearly all TAVI patients at the time of the procedure allows a final annulus measurement before committing to a prosthetic valve size.

Procedural Steps

This procedure may be performed in a hybrid operating room with a high-quality fixed fluoroscopy system or in a catheterization laboratory that is appropriately designed for sterile surgical procedures. The patient is positioned supine on the procedural table, where anesthesia is induced. We have found that the role of the anesthesiologists in these procedures has not been extensively discussed in the literature but is of the utmost importance to procedural success. Many sites, such as ours, utilize a dedicated group of cardiac anesthesiologists highly trained in TEE and are an integral part of the TAVI team. In addition to monitoring and maintaining proper hemodynamic stability, the anesthesiologists can continuously assess and relay TEE information. In addition, having a dedicated anesthesia team allows consistent and efficient communication regarding changes in the patient’s clinical status. Some sites have utilized conscious sedation without endotracheal anesthesia to perform these procedures. The majority of centers, including ours, have chosen to use general endotracheal anesthesia during TAVI. In addition to patient comfort and airway control, this technique minimizes the risk of patient movement during critical portions of the procedure. After placement of appropriate monitoring lines including arterial line and pulmonary artery catheter, the process of femoral arterial access begins.

Vascular Access

It is important to choose the site of the large-bore access sheath carefully. One should make a preliminary choice based on the findings at cardiac catheterization and iliac angiography—and based on CT angiography—both of which will have been done before the TAVI procedure. Special attention should be paid not only to the minimum diameter of the iliac and common femoral vessels but also to the location of fluoroscopic calcium and, in particular, anterior calcified plaque right at the puncture site, which will make percutaneous closure more difficult and, in some instances, prompt the use of surgical cut-down rather than a percutaneous approach. Similarly, the most common site of access misadventure is in the external iliac artery commonly at the junction of the external and common iliacs; this site should be carefully scrutinized.

Once the potential site is chosen and the patient is suitably prepared, we characteristically use a Cook micropuncture set (Cook, Bloomington, IN) to obtain vascular access. Despite the use of general anesthesia, we infiltrate local anesthetic in hope of maintaining patient comfort following the emergence from general anesthesia. The potential insertion site is imaged fluoroscopically and marked with a metallic object (usually a hemostat). We plan to access the artery at the midpoint of the femoral head, in the common femoral artery, caudal to the inguinal ligament and proximal to the bifurcation to the superficial femoral (SFA) and profunda arteries (Fig. 2A). An anterior wall puncture is made and the 0.018-inch guidewire supplied in the kit is inserted under fluoroscopic guidance. We then insert only the inner dilator from the micropuncture sheath, which is about the same diameter as the 21-gauge access needle. Through this we make a local angiogram to confirm the site of arterial puncture and its relationship to the inguinal ligament and to the distal femoral bifurcation (Fig. 2B). If this site proves acceptable, the inner dilator is removed, and the guidewire remains in place. The inner dilator is re-mated with the micropuncture sheath, and this is placed in the vessel over the wire. The wire and inner dilator are removed and a 0.035-inch guidewire is passed through this sheath. Over this guidewire, we place an 8-French sidearm sheath. If it is thought necessary, a second angiogram can be made through this sheath to reconfirm appropriate position. Obtaining access in the optimal spot is key to a successful percutaneous approach.

At this point we enlarge the dermatotomy down to the artery so that it will receive the barrel of a 10-French Prostar closure device (Abbott Laboratories, Abbott Park, IL). Some operators prefer to use two 6-French Perclose Proglide devices (Abbott Laboratories) that are inserted at differing angles. Of note, the “preclose” method with either device for large-bore access is an off-label usage. We continue to prefer the ProStar because its sutures are not preknotted, affording more precise control. When using the ProStar device, it is critical to create an adequate dermatotomy and subcutaneous tunnel (Fig. 3A). In addition, the device must be properly placed in the artery at approximately a 45-degree angle to ensure proper suture needle deployment (Fig. 3B). Once deployed, the sutures are secured with 2 hemostats, moistened, and maintained under moist gauze off to 1 side of the puncture. Finally, we replace the guidewire and place a 10- or 12-French sheath in the artery.

At this point, access is obtained in the contralateral groin, in the common femoral artery, and vein. We generally place a 6-French sheath in each. An OmiFlush catheter is advanced to the abdominal aorta just superior to the bifurcation. The contralateral common iliac is instrumented with a 0.035-inch Terumo Glidewire, which is
manipulated distally into the common and external iliac arteries past the indwelling 10-French sheath and into the SFA. If possible, the Omni flush catheter is advanced over the guidewire and into the contralateral SFA. At this point, we replace the glide wire with a moderately supportive 0.035-inch wire such as a Rosen wire over which we pass a 7-French Balkan sheath as far distal as possible (Fig. 4A). We replace the 0.35-inch guidewire with an 0.018-inch Steelcore wire and withdraw the Balkan sheath just distal to the aortic bifurcation. This allows us to maintain access to the entire iliofemoral system on the side of large-bore access and permits the contralateral advancement of a 5- or 6-French pigtail catheter to the ascending aorta (Fig. 4B). We believe that creating wire access to the SFA from the contralateral side at the beginning of the procedure provides the greatest safety and flexibility during large-bore access sheath removal.

Next we advance an Amplatz extra stiff wire through the 10-French sheath followed by a serial dilatations. We believe that slow stepwise dilatations are preferable and thus we remove the 10-French sheath and dilate the access site with 12- and 14-French dilators before beginning dilations with the 16-French dilator in the Edwards introducer set. This process is best performed by 2 operators—the person closest to the access site will advance the dilators, while an assistant standing to his right will secure the wire. Advancement of the larger sizes is done slowly with a to-and-fro rotation. Following advancement, withdrawal can be accomplished by the assistant who will withdraw the dilator slowly using an opposite motion.

**Figure 2** Localizing the optimal site for femoral arterial access. (A) Anatomy of the femoral vessels at the inguinal ligament. Note location of arterial puncture at common femoral artery, above the bifurcation of the artery and below the inguinal ligament. (B) Femoral angiogram through a micropuncture dilator demonstrating appropriate femoral artery access site. a. = artery; lig. = ligament.
Figure 3  Use of the 10 French Perclose Prostar (Abbott Laboratories, Abbott Park, IL) used to “preclose” the access in the femoral artery. (A) Demonstrates the device in the artery, with (B) showing the sutures after deployment. Note that use of this device for preclosure of large-bore access is off-label in the United States. a. = artery.
Figure 4  Strategy for managing femoral access percutaneously. (A) A sheath crossing over from the left common femoral artery to the left iliofemoral system. (B) The sheath pulled back to the descending aorta with its 0.018-inch guidewire maintained in the contralateral femoral artery and a 0.035-inch guidewire going to the aortic arch, over which a pigtail catheter will be placed. (C) The Sapien delivery sheath placed from the left common femoral artery, alongside the previously placed 0.018-inch guidewire. (D) The Sapien delivery sheath being pulled back, with the contralateral sheath used to deliver a proximal compliant balloon to the iliac artery above the sheath.
while maintaining wire position. The operator at the groin will take care to maintain hemostasis by direct pressure once the sheath is removed. This is repeatedly performed serially with all the dilators advanced under careful fluoroscopic visualization. In many instances, it is possible to observe arterial calcifications fluoroscopically and, by considering their movements, understand how the iliac artery system is being stressed or deformed. The more resistance is felt, the more the advancement should be slow and deliberate. Occasionally it may not be possible to advance the largest dilator and this is a point at which the prudent operator may wish to abandon this approach and consider an alternate means of access such as an iliac conduit.

Once the largest dilator has been passed and removed, the previously prepared access sheath is placed in an identical fashion. It is important to watch every aspect of this advancement under fluoroscopy and advance the radiopaque tip of this sheath into the abdominal aorta. When the sheath is in place, the dilator can be removed and the sheath flushed when access has been obtained. At this point, there is the large-bore sheath on the access side and next to a 0.018-inch Steelcore wire that passes from the contralateral iliac system alongside of the sheath and ends distantly in the superficial femoral artery (Fig. 4C).

If it has not been done beforehand, access for a pacing catheter should be obtained in the femoral vein on the side opposite of the large-bore access. Of note is that we prefer a temporary screw-in lead for these cases. Once this lead is placed successfully, it is difficult to dislodge as opposed to a standard temporary bipolar pacing catheter, which can easily be moved. The loss of rapid ventricular pacing even for 1 or 2 beats during valve deployment can result in disastrous ejection of the valve cranially into the ascending aorta; we find that this pacing catheter offers the greatest stability. Pacing thresholds are tested and the wire position adjusted as necessary to achieve a reliable pacing capture. Once vascular access is secure, the patient is fully heparinized. We begin with 70 units per kilogram of unfractionated heparin and monitor activated clotting time closely to maintain it above 250 seconds.

A 5-French or 6-French angled pigtail angiographic catheter is advanced to the aortic root from the Balkan femoral sheath and used to determine the ideal fluoroscopic angle for showing the aortic annulus in a planar fashion. This is important for determining appropriate location for valve deployment. The calcium landmarks on the native valve can be misleading and it is important to correlate these with the true aortic annulus determined by aortic root angiography. Typically, we have found a nearly AP-to-AP-caudal angulation of the fluoroscopy gantry yields a planar view. Depending on the patient’s anatomy, a left anterior oblique-cranial or right anterior oblique-caudal angle may be optimal. This may sometimes be predicted by preprocedural catheterization or CT angiography studies and newer software programs may allow more accurate prediction of ideal angulation. This can reduce the need for repeated root angiograms and resultant contrast load.

**Balloon Dilation**

Once all vascular access is obtained, the stenotic valve is crossed and a catheter is placed in the left ventricle. Generally we prefer a 6-French pigtail catheter and a 0.035-inch straight wire for crossing the valve. There are however many ways in which this can be accomplished and many operators prefer an Amplatz curve or a right Judkins catheter. Nevertheless, once the valve is crossed, and the pigtail or other catheter is advanced, a transaortic gradient is measured along with the appropriate hemodynamics from indwelling pulmonary artery line. The left ventricular catheter that was advanced from the large-bore access is removed over an exchange-length Amplatz short tip extra stiff wire that has been precurved to sit in the apex of the left ventricle with a minimum of ectopy. This curve also minimizes the risk of apical perforation.

Although the initial balloon aortic valvuloplasty (BAV) may be performed with a smaller sheath (usually 10-12 French), we have opted for a practice of placing the valve delivery sheath before crossing the valve and performing BAV. The disadvantages of this approach are that the large sheath has been placed (thus exposing the patient to the peripheral vascular complication risk) before crossing the native aortic valve and performing the dilation. Theoretically, a patient could have a native valve that cannot be crossed or dilated and therefore not receive the prosthetic transcatheter valve. This scenario, however, is quite uncommon, occurring in less than 2% of registry patients. Second, keeping the large-bore sheath, with its hydrophilic coating, for a longer period of time in the artery can predispose the sheath to become more adherent and difficult to remove. Given the short time taken to cross and dilate the valve, however, we have not felt this added time to be significant. We feel that the advantages of early sheath placement to be significant. These include the ability to rapidly place the Sapien valve should the patient become hemodynamically unstable secondary to BAV. This may happen if significant aortic insufficiency is created by the BAV. Also, we minimize the risk of losing wire access to the left ventricle in the process of exchanging the smaller sheath for the delivery sheath. This becomes more important in the infrequent instance of discovering the need for surgical retroperitoneal exposure and direct iliac cannulation or conduit placement. Last, complete inability to safely place the sheath, while again infrequent, allows one to devise an alternative treatment strategy, such as high-risk surgical aortic valve replacement (AVR) and possible future transapical TAVI, before subjecting the patient to the risk of BAV.

Given the presence of a large-bore access, a wide variety of balloon dilation catheters can be chosen without regard to sheath size. We tend to use Tyshak or Z-med II catheters with diameters just slightly smaller than the echocardiographically measured annulus size. In general a 22-mm balloon is the most common size that is selected. Careful balloon preparation reduces the likelihood of air embolism in case of balloon rupture. A mixture of contrast to saline of 1:4 allows fluoroscopic visualization and rapid balloon inflation and deflation. The purpose of the BAV is to assure that the native valve is amenable to TAVI and to allow the device to cross the previously stenotic valve. Additionally, simultaneous injection of contrast into the aortic root during BAV can allow final confirmation of appropriate prosthetic valve sizing and adequate clearance between the native leaflets and coronary ostia. Finally, this is when we first test rapid ventricular pacing to find an
appropriate rate to eliminate cardiac output. Typically, this is between 180 and 210 bpm and needs to reduce the pulse pressure maximally (generally to below 40 mm Hg) to avoid ejection of the balloon. Excessive rapid pacing runs may adversely impact ventricular function and therefore should be confined to BAV and device delivery once an appropriate pacing rate has been established.

Taking care to watch the aortic pressure carefully, the balloon is advanced across the valve, rapid pacing is initiated, and a rapid inflation is performed (Fig. 5A). One or more dilatations can be performed—the concept is to provide predilatation so that the valve can be advanced and not to provide a definitive valvuloplasty result. In addition, once the balloon valvuloplasty is performed, it is possible that severe aortic regurgitation could supervene and one must be prepared to place the aortic valve very promptly once balloon dilation is initiated. Not only does this process allow one to predilate the valve to ensure relatively easy passage of the valve and balloon delivery catheter but also allows additional assessment of annulus size and will help demonstrate how rapid ventricular pacing will be tolerated and whether or not the patient has a quick or prolonged hemodynamic recovery. Once predilation is judged adequate, the balloon catheter is removed and the valve assembly can be advanced into place.

**Valve Placement and Deployment**

It has been our practice to mount the prosthetic valve before BAV, in the event of sudden hemodynamic instability requiring rapid valve deployment. The steps for mounting the valve on the delivery catheter are protocol-driven and have been well-described. They have evolved somewhat as the delivery catheters have iteratively changed. Currently, with the RetroFlex-3 catheter, the balloon is filled with a 1:4 contrast mixture and calibrated to the appropriate size. Meticulous de-airing is performed, along with flushing of the wire channel. The flexing mechanism is tested. The valve is then crimped onto the delivery balloon using a specially designed crimping device. This is done shortly before the anticipated device deployment to minimize time that the valve is in a crimped state, with its theoretical damage to leaflets. The mounted device and balloon are resized to ensure that they will traverse the sheath and then placed into a loader. The operator assures that the valve is mounted in the correct orientation. The device is now ready for use.

The valvuloplasty balloon is removed and exchanged for the device delivery catheter. Importantly, once the valve is advanced out of the tip of the sheath into the aorta, it cannot reliably be withdrawn back into the sheath. Therefore, it is critical to assure that the valve is correctly mounted and that the wire position in the left ventricle is maintained. As the catheter tip approaches the aortic arch, the flexing mechanism is maximally engaged to allow the catheter to traverse the arch with minimal trauma (Fig. 5B). The native valve is crossed; care must be taken at this juncture to avoid pushing the catheter too far into the left ventricle and risking perforation. The valve is positioned in the native annulus using a combination of calcium landmarks and root angiography (Fig. 5C). This process may need to be expedited if the patient suffers hemodynamic instability secondary to obstruction of the aortic outflow. However, one must be confident of optimal valve position before deployment and occasionally it may be appropriate to withdraw the valve to the ascending aorta if necessary to regain hemodynamic stability while assessing proper position. With the RetroFlex-3 catheter, the valve is best positioned with the midpoint of the valve at the radiographic aortic annulus. We perform additional confirmation by TEE before deployment. Respirations are suspended to minimize movement; rapid pacing is initiated, and the deployment balloon is inflated maximally (Fig. 5D). Generally, the inflation is held for several seconds to allow proper valve expansion. Rapid pacing is maintained until the balloon is fully deflated. Given the prolonged period of rapid pacing, patients may at this point experience a period of hemodynamic instability. The team must be prepared for expedient defibrillation and for hemodynamic support—generally pharmacologic.

A rapid TEE assessment is performed to assure proper valve position and function and to assess for perivalvar leak. The presence of a significant perivalvar leak may prompt a balloon re-inflation to attain better seal against the native annulus. If this is performed, it must be again done with rapid pacing and care must be taken not to oversize the stent or “flare” the distal end of the stent, which could cause leaflet malcoaptation leading to central aortic regurgitation. In the rare instance of leaflet dysfunction, another valve may be deployed within the first (“valve-in-valve”) for salvage. In cases of central aortic insufficiency, the culprit may be deformation of the prosthetic leaflets by the Amplatz wire. We prefer to remove this for formal echocardiographic evaluation after a rapid assessment of basic valve function and perivalvar leak (Fig. 5E). After echocardiographic assessment, gradients are measured and a complete aortogram performed to further demonstrate valve function.

**Access Removal and Hemostasis**

Following acceptable placement of the aortic valve prosthesis, the next serious hurdle is successful removal of the large-bore arterial access and the avoidance of complications.

At this point the team should be aware that if it was difficult to advance the large-bore sheath, removal will likely be difficult. First, the outside diameter of the sheath may be approximately equal to, or even slightly greater than, the inside diameter of the artery. Second, the sheath has been in place for a significant time and blood has been excluded from the space between the sheath and the artery, in effect “drying out” the sheath and defeating the lubricious coating of it. Thus removal can be problematic. Although it is possible to perforate the aorta or the iliac arteries on sheath advancement, the most common source of hemorrhagic complication is avulsion of the iliac artery—particularly the external iliac—at the time of sheath removal. Various techniques familiar to those skilled in peripheral intervention, such as local infusion of vasodilators through micropuncture catheters, may be useful.

At this point, arterial pressure should be monitored from the side arm of the large-bore access sheath and from the contralateral Balkan or similar sheath. Most operators replace the large-bore dilator and slowly withdraw the sheath until its end is in the
Figure 5  (A) A balloon aortic valvuloplasty performed using retrograde arterial access. (B) The Sapien valve being maneuvered along the aortic arch over the guidewire toward the aortic valve. (C) The Sapien valve positioned in the native aortic annulus. (D) Balloon inflation, deploying the prosthetic valve in the native aortic annulus. (E) The Sapien valve after deployment.
common iliac artery. Although not common, uncovering an aortic perforation can occur at this time. Should hypotension or hemodynamic compromise ensue, this is an important aspect of the differential diagnosis that can be confirmed or refuted with a local angiogram. Aortic occlusion (Coda) balloons and protocols for their use should be available.

As the large-bore sheath is removed into the common iliac artery, the contralateral Balkan, Ansell, or Arrow sheath is advanced over the 0.018 indwelling guidewire well into the contralateral common iliac. At this point, contrast injections can be made through this sheath to document the status of the iliac system on the side of large-bore access. It is important to note that the sheath withdrawal actually elongates and narrows the artery in which the sheath is placed; too rapid a withdrawal or the application of too much force can avulse the external from the common iliac artery and lead to an unsalvageable situation. Thus it is important to monitor this process with contrast injections and pressure monitoring. A standard 0.035-inch compatible 4-cm-long angioplasty balloon is used for occlusion and is advanced through the contralateral sheath to the external iliac artery on the side of the large-bore valve delivery sheath (Fig. 4D). From local angiography and from preprocedure imaging, the diameter of the external iliac should be sufficiently known to pick an occlusion balloon for the external iliac. Commonly, balloon sizes range from 7 to 12 mm, depending on the diameter of this vessel.

At this point, with gentle inflation of the balloon, the distal pressure as measured from the side arm of the Sapien delivery sheath should diminish to that of the collaterals supplying the limb. This is an indication that the balloon has virtually occluded the vessel and has “depressurized” the insertion site. The large-bore access is completely removed and the indwelling sutures from the 10-French ProStar are carefully tied. After a short waiting period, the balloon is deflated while injecting small amounts of contrast into the Balkan sheath to outline the puncture site. If there is any extravasation, the balloon can be advanced across that area and inflated gently to reduce the pressure on the wound in the vessel. We find this method is extremely effective in patients whose iliac vessels meet size criteria and have little or no anterior calcification of the vessel at the puncture site. Once hemostasis is complete, the 0.018-inch wire can be removed and occlusion devices of choice used on the contralateral access sites.

**Postoperative Care**

Postprocedure, all patients are monitored in an intensive care setting for at least 12 to 24 hours. Cardiac rhythm is continuously monitored and the presence of new ventricular conduction delay or block may prompt prolonged presence of the temporary pacing wire or even consideration, although infrequent, of permanent pacemaker implantation. As with any traditional AVR patient, careful fluid and hemodynamic monitoring are standard. In addi-
tion, access sites and peripheral perfusion are assessed frequently. Patients may be mobilized on the day following the procedure and, in general, arterial and central venous lines are removed.

Conclusions

The emergence of transcatheter valve technology holds great promise for patients with aortic stenosis who are not ideal candidates for open surgical repair. It merits emphasis that the technology in its present form is not intended to replace surgical aortic valve replacement in the average patient. As such, the patients in whom this technology will be applied will continue to be a challenging population who will in general be elderly with multiple comorbid conditions. The convergence of a technically challenging procedure in a challenging patient subset requires careful thought and preparation at each time point in the patient's hospitalization. This article is meant to outline our systematic approach to these patients and hopefully to aid others in the institution of these programs. There is great hope that the technology will continue to evolve to make this novel procedure safer and more widely available in the near future. Furthermore, the technology in this field is evolving rapidly; the next generation Edwards Sapien XT is already being used outside the United States and trials in this country are imminent. It is likely that the devices that come into clinical use in years to come will have major iterative improvements from current generations. Even in its current form, however, this technology holds promise to treat a large population of symptomatic patients for whom traditional AVR holds undue risk.

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References