Transapical transcatheter aortic valve replacement (TA-TAVR) has primarily been utilized in the treatment of severe aortic stenosis in patients who are poor candidates for open aortic valve replacement and who have inadequate iliofemoral access for transfemoral TAVR. In 2008, CE Mark approval was granted for TA-TAVR with the Edwards Sapien valve and the Ascendra delivery system (Edwards Lifesciences, Irvine, CA), and in 2010, the Sapien XT prostheses with the Ascendra II delivery system was approved. Most recently, the Sapien system with Ascendra was approved for TA-TAVR by the US Food and Drug Administration in October 2012, and the Engager valve with transapical delivery catheter (Medtronic, Inc., Minneapolis, MN) received CE Mark approval in February 2013.

Other devices from several companies, including the Portico valve (St. Jude Medical, Inc., Minneapolis, MN), JenaClip valve (JenaValve, Munich, Germany), and Acurate valve (Symetis, Ecublens, Switzerland), have already passed first-in-man trials and will undergo pivotal trials in the near future. It is important to view TA-TAVR as playing a complementary role to transfemoral (TF)-TAVR in the care of patients with severe aortic stenosis and high comorbid burden, rather than a supplementary role. In up to 30% to 40% of patients being evaluated for TF-TAVR, there is inadequate iliofemoral access, thus requiring consideration of a transapical approach. In terms of endovascular maneuverability, the TA approach via the left ventricle (LV) provides direct and easy access to the aortic valve. However, it is also the LV apex complications that are the Achilles’ heel of this operation.

HISTORY

The first TA-TAVR in an animal model was performed in 2000 by utilizing a self-expandable valve. The first in-human TF-TAVR was performed by Cribier et al in 2002, and the first TA-TAVR was performed by Walther et al in Leipzig in 2006. This TA-TAVR procedure was performed via a median sternotomy approach, and paravalvular regurgitation required conversion to open surgery. That same year, the Vancouver group reported successful off-pump implantation of a Sapien prosthesis using the left thoracotomy intercostal access. Initially, the Retroflex delivery system (Edwards Lifesciences) was used, but this was replaced by the Ascendra delivery system, which was specifically designed for the TA approach.

The Ascendra delivery system has since been replaced by the Ascendra II system, which is lower profile, can accommodate the Sapien XT valve, and is easy to manipulate and de-air. The Edwards Sapien valve with the Ascendra delivery system received CE Mark approval in 2008, followed by approval for the Sapien XT prosthesis with the Ascendra II system in 2010. The Sapien XT 29-mm valve was granted CE Mark approval in 2011. Valve sizes range from 20 to 29 mm, thus enabling TAVR for aortic annular diameters ranging from 17 to 27 mm. The CoreValve system (Medtronic, Inc.) is not well...
designed for the transapical approach, although several new devices by various companies are in development, including the Engager, JenaValve, Acurate, and Portico valves. In addition, LV apical closure devices that enable totally percutaneous TA-TAVR are also being actively investigated.

PATIENT EVALUATION AND OPERATING ROOM SET-UP

Given the complexity of most TA-TAVR cases, a multidisciplinary team to evaluate these patients should include the cardiac surgeon, interventional cardiologist, radiologist, echocardiographer, anesthesiologist, neurologist, and other medical consultants based on the patients’ comorbid burden. Preoperative assessment should include a “safety net” that includes a detailed plan for emergency access options for cardiopulmonary bypass, treatment options for vascular ventricular apex complications, and for potential coronary and aortic root complications. TAVR cases should be discussed at multidisciplinary meetings involving the previously mentioned medical staff. Given the presence of peripheral vascular disease that precludes these patients from the TF approach, TA-TAVR patients in general constitute a cohort with even higher comorbid burden than TF-TAVR patients.

For optimal safety and results, a hybrid operating room with sophisticated fixed imaging is essential. This hybrid operating room includes having the facilities to perform angiographic imaging, provide cardiac anesthesia with transesophageal echocardiography (TEE), access to all preoperative diagnostic imaging, and the ability to efficiently convert to an open operation with cardiopulmonary bypass. This multidisciplinary effort requires the participation of the cardiovascular surgery, anesthesiology, interventional cardiology, nursing, and perfusion teams. The patient is induced under general anesthesia, a central line with a pulmonary artery catheter is placed. TEE is performed to confirm valve sizing and to evaluate the aortic root, annulus, and LV. The patient is positioned in a supine manner, with slight elevation of the left chest and both arms tucked in. The primary surgeon performing the procedure and the surgical assistant/cosurgeon both stand on the left side of the patient. The perfusion team and the bypass machine should also be set up on this side.

TA-TAVR PROCEDURE

Percutaneous femoral venous access is achieved, and a transvenous pacing wire is advanced into the right ventricle over a 7-F sheath. Femoral artery access with a 6-F sheath is also achieved percutaneously, and a diagnostic pigtail is advanced to the level of the aortic root. Angiography is then performed to determine optimal C-arm positioning for valve deployment. At this point, the planned safety net must be discussed, and plans for emergent bypass with defined roles for the team members must be established.
The most critical factor for a successful TA-TAVR procedure is achieving access to the LV apex in a manner that results in coaxial orientation of the delivery system to the aortic valve annulus, therefore avoiding parallax. Doing so allows for precise control and deployment of the valve while minimizing movement and potential embolization of the valve during deployment. To achieve proper valve deployment, the first critical step is proper location of the incision to enable direct and coaxial access to the left ventricular apex. Using a radiopaque instrument such as a hemostat, the location of the incision in relation to the LV apex can be visualized by fluoroscopy prior to the incision. Both the location and orientation of the instrument are important factors (Figure 1).

Similar to TF-TAVR, achieving the ideal C-arm position for valve deployment is essential for precise positioning and deployment of the valve. However, in contrast to TF-TAVR, the position of the C-arm in relation to the incision is essential in providing the primary operator with working space over the thorax. Therefore, achieving the ideal C-arm angle must be balanced with placing the C-arm in a position that is not prohibitive to the working operating field over the incision. If possible, a right lateral C-arm approach is more ideal than a left lateral approach.

Once optimal C-arm positioning has been determined, a small left anterior minithoracotomy (4–5 cm) is made in the 5th or 6th intercostal space to achieve access to the cardiac apex. The incision is typically made in the midclavicular line, in the submammary fold. Initially, a small opening into the left pleural space enables finger palpation of the LV apex, which should then guide further extension of the appropriate intercostal space. The heart is then exposed with a small retractor, and the pericardium is opened longitudinally, with lateral and medial stay sutures placed to the expose the LV apex. In reoperative cases, minimal dissection of the pericardial adhesions from the LV muscle is recommended. In fact, the adhered pericardium in reoperative cases serves as an excellent buttress for the apical sutures when tying down on the LV apex.

At times, if exposure is not optimal, packing the posterolateral aspect or an extra deep pericardial stitch can help bring the LV apex into the operative field. The access site is typically not at the true apex but a few centimeters anterior and lateral to the distal-most aspect of the left anterior descending artery. This area of the heart generally has robust tissue that will allow secure placement of the sutures without tearing. Care is used to avoid placement of sutures in fatty portions of the apex. Prior to puncturing the LV apex, it is our recommendation to again confirm the ideal location and orientation of the anticipated access puncture site. This confirmation can be performed by a quick fluoroscopy view of the needle in the proposed access site before committing to actual puncturing of the apex. The key is avoiding a puncture site that is too anterior, thereby resulting in an orientation of the delivery system that is not coaxial (Figure 2).

Securing the access site with surgical sutures is the second most important component of the procedure. Adequate hemostasis of the LV apex at the completion of the procedure depends on meticulous technique. A variety of approaches have been described, and in general, two suture techniques have been noted (Figure 3). One method is two concentric purse-string sutures with multiple pledgets. A second method is the two perpendicular horizontal mattress pledget sutures technique. For both techniques, it is strongly recommended that either near or full thickness bites of the apex be performed for optimal secure suture placement. Once the sutures are placed, the following steps of the operation must be conducted efficiently to minimize the time the LV access site remains open.

The patient is heparinized at 70 to 100 units/kg (goal activated clotting time, 300 seconds), the apex is punctured with a needle, and a soft guidewire is placed into
the LV cavity and advanced through the aortic valve into the ascending aorta under fluoroscopic guidance. Upon confirming this position, a long 7-F sheath is advanced over the guidewire into the LV and out into the ascending aorta.

Using a wire exchange technique under fluoroscopic guidance, a stiff guidewire (extra-stiff Amplatz, Cook Medical, Bloomington, IN) is positioned into the descending thoracic aorta with the aid of a JR4 guide catheter (Boston Scientific Corporation, Natick, MA). The Ascendra sheath is introduced up to the midventricular cavity over the stiff guidewire using fluoroscopy. The sheath is de-aired and typically fixed 4 to 5 cm into the LV cavity. It is critical to make sure that the mitral valve subannular apparatus is not involved during the apex dilatation and in the positioning of the valve deployment system. Fluoroscopy and echocardiography can play an important role in confirming proper placement of the valve sheath system.

Once the sheath is positioned, one physician takes on the sole responsibility of securing it in place in the LV cavity. The Edwards balloon is then advanced into the aortic annulus over the stiff guidewire, and under rapid ventricular pacing (RVP), the aortic annulus is rapidly ballooned and then deflated. The balloon is then retrieved with the stiff guidewire in place. It is critical that the patient’s hemodynamics be adequately restored in preparation for valve deployment. The mounted Sapien valve or the Sapien XT on a balloon catheter in the Ascendra system is introduced over the stiff guidewire and connected to the loader. The Ascendra system is then passively de-aired, and the valve is advanced into the proper position, as previously stated, if the coaxial position is not achieved, sometimes manipulation of the stiff wire can help center the valve in relation to the annular plane.

During a period of ceased ventilation with RVP, the valve is deployed by expanding the balloon in a step-wise manner to enable some fine-tuning adjustments. In contrast to the TF platform, the TA approach is associated with more precise control, and any manipulation of the delivery system is associated with a one-to-one translation of force to the valve deployment. Therefore, only very fine adjustments are required to seat the valve in the proper position. Full inflation lasts for 5 seconds with RVP. The balloon is then retrieved into the sheath, and valve position and function are then assessed by angiography and TEE.

At this point, if there is significant paravalvular leak (typically greater than mild) and the valve is not fully deployed, it can be ballooned again. If paravalvular leak is not significant and the patient is stable, the wire can be retrieved into the LV cavity to assess for central aortic insufficiency. Evaluation for aortic insufficiency is performed with transesophageal echocardiography and aortic angiography. The wire is then removed, and with RVP, the sheath is removed and the prolene stitches tied down to achieve hemostasis. After securing the first two to three knots, RVP can be stopped. The second stitch is also tied under a short RVP burst. If the LV access site is intact, protamine is administered, and if possible, the pericardium is opposed to provide natural pressure over the puncture site. Residual bleeding may require more stitches that are tied down under RVP. The thoracotomy incision is then closed in a standard fashion over a soft chest tube drain placed in the left pleural space.
POSTOPERATIVE MANAGEMENT

In TA-TAVR patients, tighter control of systolic blood pressure is critical to maintain the integrity of the LV access site. The first 24 hours are critical, and patients should be watched carefully for postoperative bleeding. LV rupture can be catastrophic in this patient population because their physiologic and functional reserve is already so poor given their age and comorbid burden. If a patient needs to be emergently treated for LV rupture, it is critical to have the ability to initiate emergent cardiopulmonary bypass. If the LV apical tear is extensive, repair may require LV decompression on cardiopulmonary bypass. Heroic attempts at quick repair without hemodynamic stability and hemorrhagic control on an 80- or 90-year-old LV is ill-advised and can lead to catastrophic outcomes.

FUTURE DEVELOPMENTS

As the TF approach has rapidly evolved to a totally percutaneous platform with lower-profile device systems being introduced, the TA approach is also undergoing a similar evolution. In addition to newer valves being introduced for the TA approach, percutaneous LV apical closure devices are being developed and have been successfully tested in animal models, and some devices are in ongoing first-in-man clinical trials in Europe. Currently, three devices are either in, or are preparing to be in, human clinical trials in Europe. The Apica closure device (Apica Cardiovascular Limited, Galway, Ireland) consists of a coil design that provides a working port on the LV apex after it is deployed. The CardioClose (Entourage Medical Technology, Menlo Park, CA) is a suture-based percutaneous LV apex closure device (B). The Permaseal device involves placement of anchors into the LV apex that can be sealed after valve deployment (C).

Figure 4. LV apical closure devices that would enable percutaneous TA-TAVR are shown. The Apica (A), CardioClose (B), and Permaseal (C) apical closure devices provide a platform for minimally invasive closure of the LV apex after completion of TA-TAVR. All three systems are established such that they are deployed after achieving TA wire access to the aortic annulus, with built-in access for prosthesis delivery. Upon completion of TA-TAVR, the device port is withdrawn, and the closure system is employed to achieve hemostasis. The Apica provides a potentially reusable port into the LV apex that can be closed with a sealing cap (A). The CardioClose is a suture-based percutaneous LV apex closure device (B). The Permaseal device involves placement of anchors into the LV apex that can be sealed after valve deployment (C).
Once deployed, the CardioClose device provides an access site for the delivery system. When the procedure is completed, the delivery system is withdrawn, and the CardioClose system is deployed by pulling and approximating suture-locking buttons on the system, thereby achieving hemostasis.

The third platform is the Permaseal device (Micro Interventional Devices, Bethlehem, PA) (Figure 4C). The concept involves the placement of anchors over the access site that approximate the LV apical tissue at the completion of the procedure, thereby achieving hemostasis. No additional sutures are needed. After placement of the wire in the access site, the Permaseal device is guided over the wire into position, and the anchors are then deployed. Leaving the wire in place, the Permaseal device is withdrawn, and the transapical delivery system is placed over the wire and through the anchors for valve deployment.

Other percutaneous apical closure devices are also now being investigated. The reliability of hemostasis and the ability of a completely percutaneous platform would enable rapid evolution and acceptance of the TA-TAVR technique, similar to that seen with TF-TAVR.

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