Transapical Transcatheter Aortic Valve Implantation

Early results reveal successful implantation rates in patients with aortic stenosis.

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Medical progress is iterative: advances are built on lessons learned from older therapies. Surgery and interventional cardiology are very clearly built on a progression of trial and error and previous experience. Surgical and interventional therapy depend on the physical rearrangement of anatomy, in one way or another, to achieve an improved anatomic or physiologic result. Improvements of this type depend on a very clear understanding of anatomy and physiology. Transcatheter aortic valve implantation (TAVI) is an example of therapy that exhibits the iterative nature of improving medical therapy.

The pathology of aortic stenosis is multifactorial. The majority of the patients currently treated with TAVI have calcific aortic stenosis. They have tricuspid aortic valve leaflets that progressively become calcified and fixed over time. The primary symptoms in these patients are related to low cardiac output, congestive heart failure, and occasionally angina. The patients' symptoms are insidious and relentlessly progressive. There is no known nonsurgical therapy that can treat the primary problem in these patients. There are a variety of secondary problems that compound these patients' illness. They develop diastolic ventricular dysfunction and secondary mitral regurgitation, both of which exacerbate their congestive heart failure.

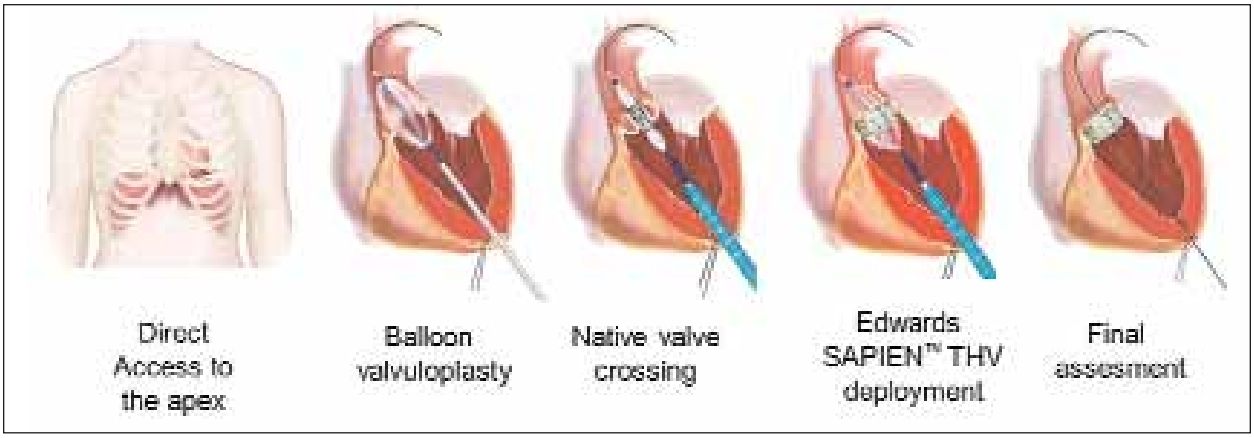
Aortic valve implantation has excellent clinical results and is widely accepted as an effective therapy for aortic stenosis. Worldwide, more than 200,000 aortic valve implantations are performed each year. Observed mortality was 2.6%, and the stroke rate was 1.3% for all comers in the Society of Thoracic Surgeons database, despite the fact that there has been a gradual increase in expected mortality as older patients with more comorbidities are referred.[1] This mortality expectation is not representative, however, of the patient population—who are much sicker and would have a higher mortality expectation—being offered balloon aortic valvuloplasty or TAVI. The Achilles' heel of aortic valve implantation is the price paid in terms of surgical morbidity and occasional mortality associated with surgical valve implantation.

The transcatheter approach for aortic valve implantation represents the progressive iteration of aortic valve implantation. Its main objective is to achieve the hemodynamic and clinical benefits of traditional aortic valve implantation while avoiding the morbidity and mortality associated with major open heart surgery.

The purpose of this article is to review the elements of the transapical approach to TAVI using the Edwards Sapien valve system (Edwards Lifesciences Corporation, Irvine, CA). The secondary objective is to demonstrate how dependent this therapy is on the lessons we have learned from the past.

PATIENT SELECTION

Currently, the patients who have had TAVI are high-risk patients with congestive heart failure and severe aortic stenosis. Patients who are being offered TAVI in the PARTNER trial (sponsored by Edwards Lifesciences) trial



(Courtesy of Edwards Lifesciences Corporation.)

Figure 1. TAVI: a step-by-step diagram of the critical steps involved in the procedure.

have a Society of Thoracic Surgeons database calculated score > 10, a predicted operative mortality of > 15%, and frequently have additional comorbid conditions, which add to the expected risk that are not reflected in the current risk calculations. At this time, although they have been performed in other trials, bicuspid aortic valves are excluded in the PARTNER trial due to concerns about the efficacy of adequate balloon dilation of the fused valve leaflets to be able to seat the valve without unacceptable paravalvular leak. The applicability of this technique to a broader group of aortic stenosis patients will be dependent upon the results of these early trials.

PROCEDURE

The hybrid procedure room is both an operating room (OR) and an angiography suite with imaging capabilities. The operating procedures of the OR team and the catheterization lab team are different, and planning, coordination, and cooperation are critical. Angiography is important to identify the aortic annulus, aortic sinuses, and their relationship to the coronary ostia. Transesophageal echography is used to measure the annulus and assess the seating of the valve for paravalvular leak. The perfusion team is present, with cardiopulmonary bypass immediately available.

TECHNICAL ASPECTS

TAVI is accomplished under general anesthesia by exposing the apex of the heart through a limited left anterolateral thoracotomy without cardiopulmonary bypass.[2-10] The incision is usually through the 5th or 6th interspace in the anterior axillary line and exposes the apex of the heart (Figure 1). The pericardium is opened and suspended, bringing the apex of the heart into the operative field. The site of left ventricular puncture is chosen to the left of the interventricular septum and 1 to 2 cm up off of the true apex. This site is selected to avoid the septum and the true apex of the heart, which is relatively thin.

Pacing wires are placed on the left ventricle and are used to rapidly pace the ventricle. This maneuver reduces left ventricular filling time and thus reduces ejection, which reduces the blood pressure to below 50 mm Hg before balloon aortic valvuloplasty and valve deployment. This maneuver prevents ejection of the dilation balloon and valve-bearing catheter during balloon aortic valvuloplasty and valve deployment. The ability to pace and reduce the blood pressure adequately is established before left ventricular puncture. A rate of 150 to 200 bpm is usually required.

A double purse-string suture is placed around the puncture site with Teflon felt pledgets that have relatively deep bites. The techniques for control of the puncture site vary but are done in order to control bleeding around the sheath and close the puncture site once the sheath is removed. Low-dose heparin is then administered.

Puncture is accomplished with a needle, a soft wire is passed across the aortic valve, a small-caliber exchange catheter is positioned, and a firmer wire is passed across the aortic valve into the descending aorta to provide a stable working wire for the valve placement. Care is taken to avoid the mitral chordal structures. Rapid ventricular pacing is begun, and a balloon aortic valvuloplasty is done. The objective of the balloon valvuloplasty is to "crack" the valve, which facilitates crossing the valve with the prosthesis, stent expansion, and coaxial placement of the valve. The balloon valvuloplasty improves, at least theoretically, the hemodynamics of the aortic valve, and hopefully affords the patient increased stability during the time the valve is being positioned and deployed.

After valvuloplasty, a large sheath is positioned through the left ventricle wall to deliver the prosthesis. Controlling bleeding around the sheath is critical. The

current sheath is relatively large to accommodate the large size of the prosthesis itself. Once the sheath is in place, the delivery catheter with the stainless steel stent and valve prosthesis mounted on a balloon is positioned over the working wire, and the native valve is crossed. Crossing of the valve from beneath the aortic valve is in general easier than crossing it retrograde. The transapical approach enables the device to be positioned through the aortic valve antegrade as opposed to the retrograde femoral artery approach, which necessitates crossing the aortic valve "the wrong way." Retrograde crossing has been facilitated by a nose cone that has been added to the device; however, the operating distance, as well as the natural tendency of the aortic valve to stay closed when approached from above as opposed to open when approached from below, will undoubtedly make the transapical approach an easier way to cross the valve. The stent valve is positioned in the orifice of the native aortic valve. The selection of the position of the valve is critically important. The valve should be positioned so that when it is deployed, the displaced native leaflets, as well as the valve itself, do not cover the coronary ostia. The prosthesis is positioned such that approximately half of the stent containing the valve is below the hinge point of the native valve, and half is above it. Great care is necessary to achieve proper position. There is a very small margin for error; once the valve is deployed, the ability to reposition the valve is limited.

When the correct position is selected, the valve is ready to be deployed. In order to deploy the valve, the ejection of the heart has to be reduced or nearly stopped. Pacing wires are used to rapidly pace the ventricle. The use of rapid ventricular pacing reduces filling of the ventricle and subsequent ejection. If the ventricle is ejecting normally when the valve is deployed, there is great risk that the valve itself will be ejected through the native aortic valve and improperly positioned. The predetermined pacing rate is chosen to reduce the blood pressure is diminished to below 50 mm Hg. Once the pressure and left ventricle ejection are reduced with rapid ventricular pacing, the valve is deployed by rapidly expanding the stent in the aortic valve annulus. The stent holds the native aortic leaflets open and anchors the valve. The valve is mounted within the stent and is deployed once the stent is expanded.

The stent anchors itself to the calcium of the patient's native aortic valve, which holds the stent in place after it is expanded. If there is not much calcium in the annulus, proper anchoring of the stent is questionable. The current valve used in the Edwards prosthesis is a biologic valve of bovine pericardium. Sizes currently available include only a larger (26 mm) and a smaller (23 mm) valve. The choice of valve is based on measurements of the annulus obtained before the procedure. Many have recommended an oversizing technique to choose a valve size 2 to 3 mm larger than the annulus size to reduce the risk of leak. The valve is chosen and crimped properly onto the delivery balloon in the OR just before use. Once the valve has been deployed, it begins to function as a one-way valve. Initially, until the leaflets are fully unrolled and softened, there is occasional transvalvular insufficiency. Interestingly, the amount of paravalvular insufficiency after the procedure has been less of a problem than was initially expected.

When this operation is successful, there is a substantial improvement in the hemodynamics of the patient. After the valve is deployed, the wires and sheath are removed from the left ventricle. Control of left ventricular bleeding is achieved through the use of previously placed purse-string pledgeted sutures and additional sutures, if necessary. Importantly, after successful implantation, left ventricular pressure has been reduced by relieving the outflow obstruction associated with the patient's native valvular disease. The operative procedure is completed by the placement of a left pleural chest tube and closure of the wound.

There are a variety of untoward events that can complicate the procedure, such as ventricular fibrillation. External defibrillation pads should be in place before the procedure. Bleeding can lead to hypotension and blood should be immediately available. Circulatory collapse can occur, and cardiopulmonary bypass may be lifesaving. Valve embolization, coronary occlusion, acute malposition and dysfunction of the implanted prosthesis, and severe aortic insufficiency after TAVI have occurred. Recovery strategies for each must be planned before they occur, because these patients deteriorate very quickly.

This procedure represents the evolution of therapy for aortic valve disease. The building blocks that form the foundation for this procedure are many. Open aortic valve commissurotomy, direct valvuloplasty, and ultrasonic debridement of the aortic valve have left surgeons with the sense that valvuloplasty of the aortic valve can be done with some short-term benefit. Balloon aortic valvuloplasty has also been shown to be beneficial in the short term. Valvuloplasty of the aortic valve is not durable because the leaflets are still heavily calcified and tend to continue to be obstructive, or the one-way valve function is acutely destroyed by the valvuloplasty. Holding the leaflets open once they are cracked with a stent containing a valve solves both of these problems.

Traditional aortic valve implantation has demonstrated marked clinical efficacy, suggesting that if an aortic valve of reasonable function and durability could be placed using a

TABLE 1. PROCEDURAL SUCCESS AND MORTALITY RESULTS FROM TAVI TRIALS

Reference	N	Acute Success TAVI (%)	30-Day Mortality (%)	6-Month Mortality (%)
Ye et al[5]	26	100	23	35
Walther[7]	50	94	8	26
Zierer[8]	26	100	15	NR
Walther[9]	59	93	14	22
Svensson[10]	40	88	18	33

Abbreviations: NR, not reported.

catheter, it would be beneficial both from a hemodynamic standpoint as well as from the standpoint of avoiding the morbidity associated with traditional surgery.

The advanced wire skills that form the basis for interventional cardiology are evidence that, progressively, we have learned to use the vascular highway present in the body to get to any site safely. The x-ray unit necessary for this operation needs to be a fixed unit with high resolution. Initially, when transapical implants were done, they were performed in the OR using a portable C-arm. This has proved to be unreliable in terms of its precision when positioning the valve. Advanced ORs that include a fixed x-ray unit as a part of a more traditional OR are being built. These "hybrid" ORs will facilitate innovative therapy of this type in the future.

Valve manufacturing techniques have undergone tremendous improvement over the years. The current biologic valves are markedly more durable than the initial biologic valves. For a valve to be implanted using catheter-based techniques, it has to be deformable and able to be compacted into a relatively small size in order to be delivered using a catheter. The stent material and configurations have undergone significant development. Stent technologies have been based on what has been learned from coronary and vascular stent implantations. The materials, manufacturing techniques, and physical configuration of the stents will continue to evolve.

One of the challenges associated with TAVI today is the diameter (24 F or 8 mm) of the current delivery device. Placing transcatheter valves through the iliac and femoral artery has proven difficult, because the size of the device is too large for the iliac artery in many eligible patients due to peripheral vascular disease. The transapical approach avoids most of the size issues because of the size of the left ventricle. The transapical approach is additionally desirable, because the distance from the puncture site to the valve is short as compared to the retrograde transfemoral artery approach. The transfemoral artery approach requires a large device to be placed through the femoral and iliac artery and then threaded up the aorta and around the arch. The current delivery sheath is steerable and makes it easier for the device to get around the arch; however, concern remains for dislodging debris from the aorta during this maneuver.

The initial approach for TAVI used the femoral vein, which necessitated a septal puncture, passing the catheter containing the valve through the septal puncture across the mitral valve, and then up and out the outflow track. This circuitous journey represents the opposite end of the spectrum from the transapical approach. The current devices could not easily be delivered this way because of the angles involved and the large caliber of the delivery system.

RESULTS

Results from transapical TAVI are beginning to appear in the literature.[2-10] The number of cases and institutions involved with these patients is relatively small. Using the transpolar approach, the five reported series have shown a > 95% successful-implantation rate. One-month mortality has varied between 8% and 23%, and 6-month mortality has ranged between 22% and 35% (Table 1).

The most important statement to be made based on the literature regarding this approach is that it appears feasible and yields a relatively high success rate in initial implantations; however, the durability and long-term results are unknown.

SUMMARY

The transapical approach for TAVI is short and direct; it crosses the aortic valve from an easier and more correct direction, allows for easier manipulation of a shorter catheter, and, in all likelihood, will facilitate a more precise placement and deployment of the stent and valve.

The transapical approach is an example of building on the experience with the retrograde femoral approach. It uses essentially the same technology, but because of the geometry associated with the transapical approach, it represents an improvement in the technique. We predict that this approach will become the approach of choice for many patients as this technology matures.

The transapical approach possesses many interesting aspects. One is its potential usefulness in patients who have undergone a previous biologic valve implantation. The previous valve implant in the aortic position offers a relatively predictable platform upon which to deploy the transcatheter aortic valve. An approach through the apex in these patients is very attractive. Additionally, an

approach through the apex to a deteriorated mitral biologic valve is also relatively attractive.

Procedures to implant valves in both the aortic and mitral position in patients with malfunctioning bioprosthesis have been done, and this experience is just beginning.[11,12] This application of the transcatheter valve technology may prove to be extremely important in the long term, but there are many hurdles yet to be overcome.

The future holds promise using this technique. The problems that currently exist that have not been addressed or resolved include patients with aortic insufficiency, patients who do not have much calcium in their valve, and patients with bicuspid aortic valves, among others. Valve durability over time, and the medium- and long-term results using this technique are completely unknown. The comparative therapy of traditional aortic valve implantation remains a very high standard to be equaled or exceeded by any therapy. Current trials are underway to address these issues, and time will tell whether this technique will become an accepted method of dealing with aortic stenosis. ■

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