Steps Toward Percutaneous Aortic Valve Replacement

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Background—To date, the surgical approach is the only option to replace the aortic valve. Percutaneous pulmonary valve replacement has recently opened new perspectives on transcatheter replacement of cardiac valves. We report our experience of aortic valve replacement through a percutaneous technique in lambs.

Methods and Results—A bovine jugular vein containing a valve was dissected and sutured into a stent. Twelve lambs were divided into 3 groups. In the first, a valved stent was implanted in the descending aorta after creation of an aortic insufficiency. In the second, the valve was implanted in the native position. In the third, we inserted a valved stent in the native position using an orientation mechanism. All valves were successfully delivered and functioned perfectly in short-term evaluation. All experiments in group 2 failed: 1 valve obstructed the coronary artery orifices, 1 stent was responsible for a major mitral valve insufficiency, and the third implant migrated prematurely. A paraprosthetic leak occurred in the last animal in this group. Animals in group 3 had successful implantation of the valved stent. The orientation mechanism allowed perfect alignment of the device without any damage to the coronary circulation or to mitral valve function.

Conclusions—Nonsurgical implantation of an aortic valve is possible in lambs in the descending aorta and in the native position. An orientation mechanism is obviously needed to avoid obstruction of the coronary orifices. With further improvements, this technique should be feasible in humans. (Circulation. 2002;105:775-778.)

Key Words: heart disease • aorta • valves
A Mullins sheath was first positioned in contact with one of the aortic leaflets. A transseptal needle was then inserted into the Mullins sheath so that the aortic leaflet was perforated. The sheath was subsequently advanced in the left ventricle through the hole in the leaflet. The transseptal needle was then retrieved, with the Mullins sheath left in the left ventricle. A guidewire was inserted into the sheath that was retrieved thereafter. An 18-mm balloon catheter was loaded on the guidewire, advanced, and inflated in the aortic valve. The inflation of the balloon tore the involved leaflet, which created an acute massive aortic valve insufficiency.

The valved stent was crimped on the outer balloon of the delivery system (Figure 3). The stent was then covered by the plastic sheath of the delivery system and percutaneously inserted through the right carotid artery onto a previously positioned guidewire. In the first group, the device was advanced and deployed in the descending aorta as described previously for pulmonary implantation. In group 2, to avoid obstruction of the coronary ostia, the stent was deployed 1 cm below the aortic annulus. The external balloon was overinflated to fix the stent to the aortic wall. In group 3, the implantation technique was different (Figure 4). The valved stent was uncovered in the left ventricle, which deployed the nonsutured part of the nitinol stent. The system was thereafter pulled back in the area of the native aortic valve and pushed in the ventricle again. This push-and-pull technique was repeated until the free wires of the nitinol stent were positioned in the bottom of the native leaflets, with care taken to avoid pushing the stent inside the ventricle again. At this time, the balloons were inflated successively to deploy the valved stent to its final diameter. The balloons were deflated, and the delivery system was retrieved carefully, with the stent left in position. Thus, the native valve was trapped between the 2 stents and applied to the wall, which impinged its function.
Cardiac Catheterization and Testing of Implanted Valve Competence

Left ventricular and aortic pressures were measured at each step of the implantation. In the first group, left pressures were obtained before and after creation of the aortic insufficiency and after implantation in the descending aorta. Measurements were made below and above the implanted valve in the descending aorta, respectively, through a catheter inserted in the femoral artery and in the right carotid artery. In the remaining groups, pressures were measured on both sides of the implanted valve through the carotid artery. Angiographic evaluation consisted of aortography, left ventriculography, and selective coronary artery angiograms. Angiograms were performed before the procedure to define the anatomy of the aortic root and to measure the size of the annulus and/or the descending aorta. Studies were also repeated after implantation to confirm the appropriate position of the stent and to verify the function of the implanted valve.

Graft Retrieval

All grafts were explanted 1 hour after implantation. Before harvest, heparin (300 UI/kg) was given intravenously. The aortic root was dissected carefully to accurately determine the position of the implanted valve with regard to the coronary ostia, native aortic valve, and mitral valve. All grafts were rinsed with a saline solution and inspected, and finally, valvular competence was tested ex vivo.

Results

In Vivo Testing of the New Device in the Descending Aorta

A massive aortic insufficiency was created in all lambs (Figure 5), and valves were then successfully implanted in the descending aorta. Mean size of the descending aorta was 20±2 mm. All implanted valves were 18-mm valves dilated at 18, 20, and 22 mm. Short-term evaluation showed perfectly competent valves. The valvular function of all retrieved grafts was perfect. Pressures in the descending aorta decreased from 115 (systolic) over 78 (diastolic) mm Hg (mean 95 mm Hg) to 108 (systolic) over 40 (diastolic) mm Hg (mean 55 mm Hg) after creation of the aortic insufficiency. After implantation of the valve, pressures in the descending aorta behind the valve were normal, which created a mean diastolic gradient at valve closure of 40 mm Hg.

Native Aortic Valve Replacement

The mean size of the aortic annulus was 23.25±1 mm. Despite the big annulus with regard to implant availability, we decided to perform the implantation to test the orientation mechanism and to assess the competence of overdilated grafts.

Lambs from group 2 died suddenly during the procedure despite successful (but inappropriate) delivery of the device.

Indeed, 1 valve obstructed the coronary artery orifices, which led to rapid ischemic arrhythmia. One stent encroaching on the left ventricle below the coronary arteries was responsible for a major mitral valve insufficiency. The third implant was deployed in precise position but migrated prematurely during angiography in the ascending aorta. The last valve impinged neither the function of the mitral valve or the coronary artery flow but was completely incompetent despite a dilatation diameter of 22 mm (Figure 6). At postmortem examination, the insufficiency was related to a paraprosthetic leak secondary to inappropriate placement of the stent.

Devices were successfully implanted in all lambs from group 3. The mean systolic transprosthetic gradient was 6±2 mm Hg. There was no stent migration in group 3. Angiographic evaluation revealed perfect position of all implants, with no mitral insufficiency and no coronary artery obstruction. The valve, with a diameter of 22 mm after dilatation, was competent angiographically and hemodynamically (Figure 7). The remaining 3 18-mm implanted valves were overdilated to respective diameters of 23, 24, and 25 mm. These were incompetent in various degrees ranging from mild to severe. At autopsy, the insufficiency was attributed to noncoaptation of the valve leaflets, which led to a central leak (Figure 8). As expected, the aortic native leaflets were trapped between the outer nitinol stent and the inner platinum stent, which totally inactivated this valve. Anterograde and retrograde catheterization of coronary arteries confirmed the nonobstructive position of the device. The commissures of the implanted valve were entirely aligned with the commissures of the native valve.

Discussion

We recently developed a valve that can be implanted by a percutaneous technique. The device is a biological valve harvested...
from the bovine jugular vein and mounted in a stent. It was initially developed for pulmonary valve replacement.

In vitro studies before human application showed that this valve could function in a simulated state of pulmonary hypertension (data not shown). These good results gave us the idea to enlarge the indications to the aortic valve. The close proximity of the coronary artery ostia to the aortic valve creates hurdles to percutaneous valve implantation. Moreover, the continuity between the aortic and mitral valves made the use of the initially designed device impossible. Therefore, we modified the stent to liberate a space for the coronary arteries. The venous wall was dissected along the commissures while attention was paid to leave the supporting valve tissue. Removal of the unnecessary tissue did not interfere with the function of the valve during in vitro testing. We then verified that this newly designed stent was competent in an acute in vivo test. Because in situ aortic valve replacement was unthinkable at this time, we successfully implanted the valved stent in the descending aorta in a group of lambs with traumatically created massive aortic insufficiency. Short-term evaluation with a mean diastolic transprosthetic gradient of 40 mm Hg showed perfect competence of all implanted valves. Moreover, 3 of 4 valves were dilated to a diameter that exceeded the original diameter without altering the function of the valve. This new valved stent design theoretically allowed for orthotopic valve replacement, but its precise placement was difficult. Indeed, the bad results from animals included in the second group highlighted the need for perfect orientation and anchoring of the device. Therefore, we developed a new implantation strategy based on a 2-step stent deployment. The first step ensured the orientation and hooking of the device in the desired position. The second step was the delivery of the valve itself. Thus, to achieve the orientation goal, we fixed a nitinol stent onto a valved stent. This material has the advantage of allowing precise placement of the valved stent by an anchoring device. Therefore, regurgitation was related to lack of anchoring mechanism. After further improvements, human application might be feasible. In particular, studies with longer follow-up are needed to appreciate the function and durability of bovine venous valve in systemic pressures. Further careful anatomic studies related to the implantation strategy must be performed on the pathological aortic valve in humans.

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