EDITORIAL COMMENT
Transcatheter Valve Replacement: A New Era of Percutaneous Cardiac Intervention Begins*

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Tetralogy of Fallot with or without pulmonary atresia accounts for approximately 10% of all forms of congenital heart disease. Establishing unobstructed blood flow between the right ventricle (RV) and the confluence of the pulmonary arteries using the transannular patch technique or via the insertion of an interposition graft valve between the RV and pulmonary artery have been the main surgical options for such defects. Such operations are associated with long-term complications, including pulmonary insufficiency with its sequelae on the RV, and pulmonary stenosis, resulting in RV hypertension and arrhythmias requiring graft valve replacement (1). Operations to replace or insert grafts are associated with certain mortality and morbidity. However, resurrecting the pulmonary valve is associated with improved RV function, functional class, and atrial arrhythmias (2). Homograft or porcine valve placement in infants and children require replacement because of graft degeneration and growth of the child. Depending on the type of valve in the pulmonary position, two to four surgeries are required to replace such grafts in a lifetime of a child (3–5). Therefore, a nonsurgical option to resuscitate the pulmonary valve and to eliminate pulmonary insufficiency and or stenosis will be welcomed by both patients and their families. Such a process would require a safe technique for the replacement and a valve that may last for many years.

The technique that will be adopted by the majority of cardiologists has to be safe with very low risk of mortality and morbidity and should be easy to perform even in smaller children. The valve to be inserted has to be ideal, meeting certain characteristics (wish list), including that is biocompatible with no long-term morbidity; should last preferably for a lifetime, but at least 7 to 10 years before its degeneration; expandable to accommodate growth of the child; can accommodate a large right ventricle outflow tract; requires small delivery system; if it malfunctions, does not lead to a catastrophe; and last but not least, economical. Furthermore, the operator should have full control of the prosthesis with the ability to adjust position before its full deployment.

Bonhoefer et al. (6,7) reported on the first experimental and initial clinical human application of a percutaneous valve in the pulmonic position. The prosthesis they used was made of a balloon-expandable stent with a bovine jugular valve. The major limitations of that valve assembly were the size of the delivery sheath required (18F), rendering the application in smaller children very difficult, if not impossible, and the size of the valve available (up to 18 mm), rendering the application limited to homografts <18 mm in diameter. This size may not be adequate for an adult patient, especially if one takes into consideration that the native valve is not removed in the process, creating further narrowing in the valve (8). However, this valve assembly will certainly eliminate or reduce the number of operations needed in a lifetime of a patient with pulmonary insufficiency/stenosis due to graft dysfunction. All patients who received this valve in the pulmonary position had either a synthetic graft or a homograft with a diameter that does not exceed 22 mm (Dr. P. Bonhoefer, personal communication, 2003). Therefore, it was relatively easy to secure the balloon-expandable valve in that position. However, a large number of patients after tetralogy of Fallot repair have undergone the transannular patch repair technique. This technique of repair results in significant enlargement of the RV outflow tract with aneurysmal dilation rendering placement of any stented valve <25 mm in diameter to be very difficult if not impossible.

During surgical valve replacement (synthetic or biological) in such patients with large RV outflow tract, the surgeon usually reduces the size of the outflow tract and places a valve in that position. However, such operations are associated with morbidity and mortality. Therefore, a percutaneous technique of RV outflow tract reduction and placement of a valve will broaden the scope of this technique and will render the majority of patients with pulmonary insufficiency/stenosis eligible for percutaneous valve replacement.

In this issue of the Journal, Boudjemline et al. (9) report on a novel technique of percutaneous reduction of the RV outflow tract in an animal model. They described two techniques of achieving the reduction and placement of the valve: in one group of animals, the authors created a covered self-expandable stent with a restricted diameter in the middle of 18 mm and 15 mm in length and proximal and distal ends of 30 mm in diameter to assure fixation of this stent to the outflow tract and the distal main pulmonary artery. The venous valve segment was sewn in the middle of the restricted part. The authors implanted the entire assembly in these animals and achieved very good valve function with good results. In the other group, the valve insertion was done in two steps. The first step was to reduce the RV outflow tract by implanting the covered self-expandable stent by itself; this was followed 6 to 10 weeks later by

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implanting the stented valve (bovine jugular vein valve) using similar technique to what they have reported previously (6–8). There are obvious advantages and disadvantages to each technique. The first technique can be performed in one procedure, thus eliminating a second procedure; however, the delivery system requires a large sheath, rendering its application in smaller children very difficult. The second technique, however, requires two catheter procedures with the inherent technical difficulties met when trying to cross the stent that was implanted previously. However, the delivery sheaths required are smaller and hence increase the number of small children eligible for the valve.

I believe the first technique will be the one that operators choose the most. Miniaturization of equipment used (balloon catheters, stents) will certainly render this technique applicable in the treatment of patients with pulmonary insufficiency/stenosis after surgical repair of tetralogy of Fallot.

The valve used in the study was harvested from the bovine jugular vein. However, one needs to know that data are still missing on the mid- and long-term results of this valve in humans. If this valve proves to be as good as homografts or porcine valves, then I am certain that it will be applied in more patients needing competent valve. This new era of percutaneous cardiac intervention will open the door for thousands of patients to benefit from this technology. Clinical trials will commence in the very near future in the U.S. to assess the safety and effectiveness of such percutaneous valves for children post-tetralogy of Fallot repair.

Interest in percutaneous valves has sparked few companies to design and develop percutaneous aortic and pulmonic valves. Already after the first successful human case report of a percutaneous aortic valve (10), many companies are developing percutaneous aortic and pulmonic valves. I am aware of the following companies that are currently engaged in percutaneous aortic and or pulmonic valve development:

1. Percutaneous Valve Technologies, who already have a balloon-expandable aortic valve stent made of equine pericardium and stainless steel. Nine patients (at the time of writing this editorial) have received this valve.
2. Medtronic Corporation/NuMED Inc., and their balloon-expandable valve stent (6–8) composed of bovine jugular vein and platinum/iridium and designed for the pulmonic position. Twenty-eight patients received this valve.
3. Core Valve’s self-expandable valve made of tissue and nitinol designed for the aortic valve.
4. Shelhigh Inc.’s self-expandable valve made of porcine valve and nitinol and designed for the pulmonic position.
5. Cook Inc.’s self-expandable valve made of small intestinal submucosa of pigs and nitinol and designed for the pulmonic position.
6. Palmaz/Bailey’s self-expandable valve made of nitinol membrane and nitinol stent. It is designed for the aortic valve.

There are few other companies that are designing valves but are still at the very early stages of development.

This is very exciting era for percutaneous cardiac intervention. If such valves and procedures are proved safe and effective, hundreds of thousands of patients with calcific aortic stenosis and thousands of patients with pulmonic insufficiency may benefit from this exciting new technology and certainly mark a new era for the interventional cardiologist.

**REFERENCES**