Transcatheter Tricuspid Valve Replacement

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Abstract
Despite the explosion in the field of transcatheter aortic valve implantations over the last 10 years, only a handful of transcatheter tricuspid valve-in-valve implants have been described to date. This review describes the basic anatomy and pathology of the tricuspid valve. Current treatment remains surgical repair or replacement and the shortcomings is discussed. Results of surgical replacement are varied but generally not very good. Redo surgery has even more problems and this is the field where transcatheter valve-in-valve implants may have its biggest role. Technical aspects of the procedure is discussed, including the choice of valve, the approach and positioning of the device.

Keywords
Tricuspid valve, valve replacement, valve-in-valve replacement, rheumatic heart disease, transcatheter valve replacement

Disclosure: The author has no conflicts of interest to declare.
Received: 9 January 2012 Accepted: 30 January 2012 Citation: Interventional Cardiology, 2012;7(1):59–62
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There has been a recent explosion in the field of transcatheter aortic and pulmonary valve replacements, but the atrio-ventricular valves have lagged behind for various reasons with the tricuspid valve undoubtedly the least treated valve of the four. Despite the fact that tricuspid regurgitation (TR) can result in significant symptoms, patients are rarely referred for isolated surgical tricuspid valve repair, and most repairs are done in the context of other planned cardiac surgery. Significant TR appears to be a marker for advanced myocardial disease and re-operations for recurrent TR are therefore especially high-risk surgical procedures (up to 37 % in-hospital mortality). Transcatheter tricuspid valve replacement (TTVR) offers a new solution to this dilemma and this article will focus on transcatheter approaches to tricuspid valve replacement.

The Tricuspid Valve
Anatomy
The tricuspid valve complex consists of three leaflets (anterior, posterior and septal), the chordae tendinae, two discrete papillary muscles, the fibrous tricuspid annulus, and the right atrial and right ventricular myocardium. Successful valve function depends on the integrity and co-ordination of these components. The smaller septal wall leaflet is relatively fixed and when the annulus dilates, this occurs primarily in its anterior/posterior (mural) aspect, it can result in significant functional tricuspid regurgitation (TR) as a result of leaflet malcoaptation.

Pathology
The most common pathology is TR, which may be due to dilatation of the annulus, increased right ventricular preload and afterload as well as right ventricular systolic dysfunction. The influence of intravascular volume status and underlying right ventricular function on tricuspid valve function stems from the fact that the tricuspid annulus is very dynamic and can change markedly with loading conditions. Even during the cardiac cycle, there is a 30 % reduction in annular area with each atrial systole.

TR is most commonly caused by annulus dilatation, often secondary to left heart failure, right ventricular volume overload and dilatation of the right heart (see Table 1). TR is frequently present in patients with mitral valve disease, and more than one-third of the patients with mitral stenosis have at least moderate TR. Clinically severe TR has been reported in 23–37 % of patients after mitral valve replacement (MVR) for rheumatic heart disease. In 14 % of patients, TR occurred in the absence of significant left heart disease, pulmonary hypertension or obvious organic TV disease.

Rheumatic involvement of the tricuspid valve is seen mostly in the developing world and fortunately, surgery is rarely required. The exact incidence is not known as most cases of tricuspid involvement is diagnosed while patients are undergoing evaluation or treatment of left heart valvular disease. In a study of 525 patients undergoing catheterisation for rheumatic heart disease, TR was found in 137 patients (26 %), of whom 46 (33.5 %) had additional tricuspid valve stenosis (TS). All of the patients with TS had significant TR. In a study of 328 patients undergoing tricuspid valve surgery for rheumatic heart disease, only 12 cases had isolated tricuspid lesion, 199 had triple-valve disease, 114 had tricuspid and mitral valve disease and three had aortic and tricuspid valve disease. Most patients (72 %) had predominantly TR.

Current Treatment
Indications for surgical intervention include severe symptomatic TR or TS, especially if the patient requires mitral valve surgery. They are summarised by the American College of Cardiology/American Heart
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Table 1: Causes of Tricuspid Regurgitation

| Primary Causes                     | Secondary Causes                      |
|------------------------------------|---------------------------------------|
| Rheumatic                          | Pulmonary hypertension due to left heart disease |
| Ebstein’s anomaly                  | Cor pulmonale                         |
| Endocarditis                       | Pulmonary hypertension due to left to right shunting |
| Carcinoid                          | RV myocardial dysfunction (infarction, cardiomyopathy) |
| Myxomatous                         |                                        |
| Systemic lupus erythematosis       |                                        |
| Traumatic (penetrating/blunt)      |                                        |

**Table 2: American College of Cardiology/American Heart Association 2008 Practice Guidelines for the Surgical Management of Patients with Tricuspid Regurgitation**

| Class I | Class IIa | Class IIb | Class III |
|---------|-----------|-----------|-----------|
| 1 Tricuspid valve repair is beneficial for severe TR in patients with MV disease requiring MV surgery – level of evidence: B | 1 Tricuspid valve replacement or annuloplasty is reasonable for severe primary TR when symptomatic – level of evidence: C | 1 Tricuspid annuloplasty may be considered for less than severe TR in patients undergoing MV surgery when there is pulmonary hypertension or tricuspid annular dilatation – level of evidence: C | 1 Tricuspid valve replacement or annuloplasty is not indicated in asymptomatic patients with TR whose pulmonary artery systolic pressure is less than 60 mm Hg in the presence of a normal MV – level of evidence: C |
| 2 Tricuspid valve replacement or annuloplasty is reasonable for severe TR secondary to diseased/abnormal tricuspid valve leaflets not amenable to annuloplasty or repair – level of evidence: C | 2 Tricuspid valve replacement is reasonable for severe TR secondary to diseased/abnormal tricuspid valve leaflets not amenable to annuloplasty or repair – level of evidence: C | 2 Tricuspid valve replacement or annuloplasty is not indicated in patients with mild primary TR – level of evidence: C | 2 Tricuspid valve replacement or annuloplasty is not indicated in patients with mild primary TR – level of evidence: C |

MV = mitral valve; TR = tricuspid regurgitation.

Surgery for tricuspid valve disease is rarely done in isolation with the majority of cases carried out in combination with left heart valve replacement.5,6,7 Valve repair is the procedure of choice in all cases where feasible with valve replacement being performed in only 16 out of 260 (6 %) cases reported by Kuwaki et al.8 and even in rheumatic involvement, repair was performed in 297 out of 328 (91 %) patients reported in the series of Bernal et al.6 Repair techniques include rigid or flexible annuloplasty rings, posterior annular bicuspidation and edge-to-edge repair.9 Commissurotomy (either balloon or open surgical) is often possible for rheumatic involvement.10

The reluctance to perform tricuspid valve replacement (TVR) stems from early results showing that mechanical valves do not perform well in this low-flow situation11 and the bioprosthetic valves have a limited lifespan, especially in younger patients. In a series of 42 cases, Iscan et al. showed an in-hospital mortality of 26 % and 10-year survival after TVR was only 37 %.12 Kuwaki et al. showed better outcomes with 10-year survival of 78 % in patients with functional TR.10 This is further delineated by data from the Society of Thoracic Surgeons’ database showing that in the US, mitral valve surgery is performed in 10 times more patients than tricuspid valve surgery (see Figure 1).7

Redo valve surgery for bioprosthetic valve failure is challenging due to the fact that the patients are often in a poor clinical condition and the procedure is frequently technically very demanding. The mitral and tricuspid bioprostheses are usually extensively covered by neoendocardium and their struts are deeply embedded into the ventricular wall. In these cases, the removal of a mitral and/or tricuspid bioprosthesis becomes difficult, and, rarely, irreparable damage may occur. Furthermore, the remaining annulus can be structurally weak and perivalvular leaks may ensue.11 An early alternative to removal of the degenerate bioprosthesis was excision of the leaflets of the bioprosthesis and fixation of the new mechanical valve within the bioprosthetic ring. This was performed in the mitral and aortic positions only with good results.13 These factors led to a search for safer and less invasive alternatives.

Valve-in-valve Replacement

**History**

Philipp Bonhoeffer performed the first transcatheter valve replacement in a human.14 This valve (currently called the MelodyTM) is still used in a significant number of pulmonary implants but more recently also in tricuspid valve-in-valve implants – see below. He, however, also developed a valve designed for replacement of the atrio-ventricular valves and tested it in the tricuspid position in seven ewes. The valves performed well in the short term but the question remained whether this design would suffice for the higher pressures in the left heart (see Figure 2).15 Bonhoeffer postulated that the design and structure of the atrio-ventricular valves is too complex to allow satisfactory transcatheter replacement. His theory was that the first valve replacement should be performed surgically and that this prosthesis then forms a “docking station” for further (transcatheter) replacements (personal communication, 2003). The first TTVR was performed via a direct right atrial puncture which necessitated a thoracotomy. An Edwards SAPIENTM (Edwards Lifesciences, Irvine, CA) balloon expandable valve was used.16 Van Garsse et al. then described a transjugular implant in a very sick 74-year-old patient requiring cardiopulmonary bypass. An

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**Figure 1: Total Number of Tricuspid Valve Surgeries Performed in the US**

Shown are Society of Thoracic Surgeons National Cardiovascular Database estimates for total tricuspid valve operations. Totals presented are for tricuspid valve replacements (TVR, dark bars) or repairs (light bars). Each bar represents the total tricuspid replacements or repairs in that year, as the sum of isolated tricuspid valve repair/TVR, TVR with mitral valve repair/replacement (MVR), TVR with coronary artery bypass grafting and TVR with MVR/coronary artery bypass grafting. This should be compared to the >40 000 mitral valve surgeries performed annually in the US.1
Edwards SAPIEN 23 mm valve was placed inside a degenerate 25 mm Carpenter-Edwards bioprosthesis. The patient had three prior operations including a MVR. This was followed by the first transjugular off-pump TTVR in a 39-year-old patient who was a surgical candidate. She had a functional mitral mechanical prosthesis and a 26 mm Edwards SAPIEN XT valve was placed within a degenerate 31 mm Carpenter-Edwards tricuspid valve. These valves were all designed for the aortic position and functioned well in the tricuspid position.

An alternative prosthesis for TTVR is the Medtronic MelodyTM (Medtronic, Irvine, CA) valve. It is a development of Bonhoeffer’s initial design for the pulmonary position and like the Edwards valve, use in the tricuspid position in considered ‘off label’. The largest series of 15 implants in the tricuspid position was described by Roberts et al. with good immediate results but one death from multi-organ failure at 20 days in a patient who was very sick prior to the procedure, one case of heart block and one case of endocarditis at two months. Their group also described implantation into surgically created right atrio-ventricular conduits. Jux et al. described a case where two Melody valves were implanted in a single patient (tricuspid valve-in-valve and pulmonic valve-in-conduit) via the femoral route.

Technical Aspects of the Procedure
The Team
No single operator can claim to have the experience or skill to perform this procedure alone. Knowledge of the design and shape of the degenerate bioprosthesis is the domain of the surgeon and this may be crucial in deciding on the best orientation and position of the new TTVR prosthesis. An interventional cardiologist with experience with transcatheter valve replacements should be part of the team as well as an echocardiography expert. Continuous transoesophageal echo (TOE) monitoring is not a prerequisite for positioning the device but is an important tool to diagnose complications rapidly. This necessitates an anaesthesiologist as part of the team.

The capability to instill cardio pulmonary bypass rapidly is preferable as complications may be difficult to predict and lead to rapid haemodynamic compromise.

Approach
Although the initial experience with this procedure is via a direct transatrial approach, transvenous access is now probably well established and preferable. The jugular approach seems logical as the perception is that the inflow of the tricuspid valve is from a cranial angle, downward into the right ventricle. This is, however, not the case in many patients where the valve is oriented more horizontally and pushing forces a cranial approach results in the device prolapsing downward when pushed from above. Pre-operative radiographic evaluation of the bioprosthesis may therefore provide detail on the orientation of the valve and help decide on the best approach.

Valve Choice
There are three transcatheter valves on the market but the CoreValve (Medtronic, Irvine, CA) aortic valve is probably too bulky to be considered for the tricuspid position. The Melody valve has an established track record for TTVR but is suitable for implants up to 22 mm only. This limits its use to younger patients as most surgeons would prefer to do the initial surgical implant with the largest possible prosthesis. The Edwards device is available in a 23, 26 and now also 29 mm size. The smaller two valves are available in the SAPIEN valve (traditionally mounted on the balloon and inserted via a 24 or 25 French sheath) or the SAPIEN XT (mounted on the shaft behind the balloon and inserted via 18 or 19 F sheath). The SAPIEN XT aortic valve is passed through the insertion sheath and then once in the aorta, the balloon is pulled back into the prostheses. When this device is used in the right heart, the prosthesis has to be mounted in the opposite orientation on the shaft and when the balloon is pulled back there is a theoretical risk that the valve leaflets may be folded back or damaged. This has, however, been done in two published cases without any short-term sequelae and formal testing is required to provide a definitive answer.

Edwards Lifesciences elected not to use this valve for their pulmonary prosthesis: a decision that may in part be due to concerns about this “inverted orientation” of the valve on the delivery system. Sizing of the valve may be difficult. Knowledge of the inner diameter of the surgical bioprosthesis is important and this can usually be obtained from the manufacturers’ website. Many of the published cases were implanted into bioprostheses significantly larger than the transcatheter valve and it would appear that the low pressure
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Tricuspid position is rather forgiving in this regard. Predilatation or use of a dedicated sizing balloon may provide information on the suitability of a specific device size.

Predilatation

Predilatation may not be an absolute prerequisite but it may have a number of benefits: valve sizing is aided, stability of the balloon with or without rapid ventricular pacing may be evaluated, the resistance to dilatation may be evaluated and finally the predilated valve should be easier to cross with the prosthesis than if it was not dilated.

Rapid ventricular pacing. Some of the described cases were done with rapid ventricular pacing to reduce the cardiac output during valve deployment but numerous cases were done without it[18,19] and it is probably not required in the majority of cases.

Positioning of the Valve

TOE guidance is less important than radiographic positioning as the vast majority of surgical prostheses have a metal frame that makes radiographic positioning ideal. TOE has a place in the rapid evaluation of procedural success and diagnosis of complications. The decision on where in the degenerate surgical prosthesis to position the TTVR device should be made after studying the specific surgical prosthesis, and a surgeon’s opinion is invaluable here.

Tricuspid valve replacements are performed very rarely and may in part be due to fears that repeat surgery will be required not too long after the initial operation. With the advent of TVTR implantation, the management of this condition may change significantly over the next few years but manufacturers would have to improve on current designs and further testing is required.

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