REVIEW

Transcatheter aortic valve implantation: technical aspects, results and indications

Implantation de valves aortiques par voie percutanée : aspects techniques, résultats et indications

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Summary

The development of the percutaneous heart valve (PHV) may become a primary therapeutic modality for the high risk and inoperable patients with critical symptomatic aortic stenosis. The first human percutaneous aortic valve implant was performed by our group in April 2002. To date, more than 500 Cribier-Edwards-PHV have been implanted worldwide using arterial trans-femoral or trans-apical approach. Data on the retrograde transfemoral approach is growing with more than 270 patients implanted as of October 2007. Procedural success rate is high (86%) and the 30-day mortality is 12%. Today, 2 patients are alive at a follow-up of more than 4 years. The same Cribier-Edwards-PHV can be implanted using trans-apical approach. In this procedure, PHV is introduced under direct vision into the left ventricle via a mini-thoracotomy. This obviates the concerns regarding vascular access in the presence of small caliber vessels and/or vascular occlusive disease. More than 200 patients have been treated with this approach. In the European experience 30-day mortality is 14%.

There is intense interest in PHV technology, and there are multiple devices at various stages of development in animals and humans. The most developed is the CoreValve Revalving® Technology. More than 350 patients have been treated with this technique. The immediate and mid-term results with this device are promising with a procedural success of 92% and a 30-day mortality of 15%.

The future of this technology and its application is dependent on the continued collaboration between general internists, cardiologists, surgeons, engineers, and industry.
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Résumé

L'implantation percutanée d'une bioprothèse pour le traitement du rétrécissement aortique dégénératif a fait entrer la cardiologie interventionnelle dans une ère nouvelle et constitue aujourd'hui un espoir thérapeutique pour un nombre croissant de patients à trop haut risque chirurgical pour un remplacement aortique conventionnel. Le premier cas d'implantation chez

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Sténose aortique ;
Voie fémorale ;
Voie transapicale.

l'homme a été réalisé en avril 2002 par notre équipe. Depuis, plus de 500 patients ont été traités à travers le monde avec la valve de Cribier. Les implantations par voie artérielle fémorale se multiplient avec plus de 270 patients traités. Le taux de succès est de l'ordre de 90 % et la mortalité à 30 jours est de 12 % dans les études multicentriques récentes. Deux patients ont dépassé les 4 ans de suivi. La même valve peut être implantée par voie-transapicale, après mini-thoracotomie sous anesthésie générale. Les résultats portent sur plus de 200 patients avec un taux de mortalité à 30 jours de 14 % dans la série européenne.
L'intérêt pour cette technique est croissant et de nombreux modèles sont en développement. Plus de 350 patients ont été traités par implantation d'une CoreValve. Les résultats sont également très prometteurs avec un taux de succès de 92 % et une mortalité à 30 jours de 15 %. L'avenir de ces technologies et leur application future dépendra de la collaboration étroite entre médecins traitants, cardiologues, chirurgiens, ingénieurs et industrie.

A definitive non-surgical answer to the problem of restenosis following balloon aortic valvuloplasty (BAV) is under intense investigation. The development of the percutaneous heart valve (PHV) may become a primary therapeutic modality for the high risk and inoperable patients with critical symptomatic aortic stenosis (AS). As described in the EuroHeart Survey on valvular disease [1], patients with valvular heart disease are often undertreated. Approximately one-third of symptomatic patients with severe AS do not undergo surgical treatment as a consequence of their age or the presence of left ventricular dysfunction.

In our center, the concept of catheter based valve replacement emerged during the early 1990s as a potential therapy for patients with non-surgical calcific AS, and as a possible solution of the high restenosis rate observed after balloon valvuloplasty. In 1994, we confirmed the ability to anchor a balloon expandable stent in the calcified and fibrotic aortic annulus of human cadavers with aortic stenosis. These experiments also provided the initial data regarding optimal stent length and diameter. Five years later, with the creation of PVT (Percutaneous Valve Technologies, Fort Lee, NJ, USA), a prototype PHV was developed and tested in the sheep model [2, 3].

The first human percutaneous aortic valve implant was performed by our group in April 2002 [4]. An initial series of human implantations for compassionate use followed and were serially reported [5-7]. Following the acquisition of PVT by Edwards LifeSciences in 2004, further modifications of the valve (Cribier-Edwards and Edwards-Sapien percutaneous heart valve) and its implantation instruments preceded multicenter clinical trials. The technique was exported to Canada in 2005 and widely evaluated by John Webb in Vancouver [8, 9]. To date, more than 500 Cribier-Edwards-PHV have been implanted worldwide.

This article will provide a current overview of the procedural techniques, results, and future strategies with the Cribier bioprosthesis. The Corevalve Revalving® System (CoreValve Inc, Irvine, Ca), another percutaneous valve with a self-expanding stent will be discussed as well [10-12].

Percutaneous heart valve implantation using the Cribier-PVT/Edwards bioprosthetic valve

The first in man percutaneous aortic valve was implanted using an antegrade (venous) approach since the patient had severe occlusive peripheral vascular disease and no suitable arterial access [4]. Since then, there have been numerous refinements in the device. With ongoing experience, several changes have been introduced in the implantation protocols. Currently the valve is placed through a retrograde arterial approach or through a trans-apical minimally invasive surgical approach.

Percutaneous valve and delivery systems

The Edwards valve delivery system consists of the bioprosthetic valve, balloon catheter, retroflex catheter, and the crimping tool (figure 1 and 2).

The valve

The Cribier-Edwards valve is a trileaflet valve composed of three equal sections of equine pericardium integrated into a stainless steel balloon expandable stent frame. A second generation valve made of bovine pericardium known as the Edwards Sapien valve has replaced the previous model (figure 1). A fabric cuff is sewn onto the frame covering one third of the stent which is oriented towards the left ventricle when deployed. The original stent measured 14.5 mm in length and was designed for a maximal expansion of 23 mm diameter. Due to the variability of aortic annulus size and an important rate of perivalvular leak, a larger stent with a 26 mm diameter and a 16 mm length was introduced. This valve is intended to be implanted in the subcoronary position, using the native calcific valve to anchor the stent. Bench testing has established a greater than 10 year durability.

The balloon catheter

To deliver and deploy the PHV a custom balloon catheter manufactured by NuMed (Z-MED II, NuMed, Inc., Hopkinton, NY, USA) is used.

The crimping tool

A unique crimping device is used to symmetrically compress the PHV from its expanded size to its minimal delivery profile. The 23 mm PHV is compatible with a 22F sheath and the 26 mm PHV with a 24F sheath.

The retro-flex guiding catheter

This catheter (figure 2) was introduced in 2005 to facilitate the retrograde delivery of the PHV [8]. Its tip changes direction when activated by rotation of an external hub
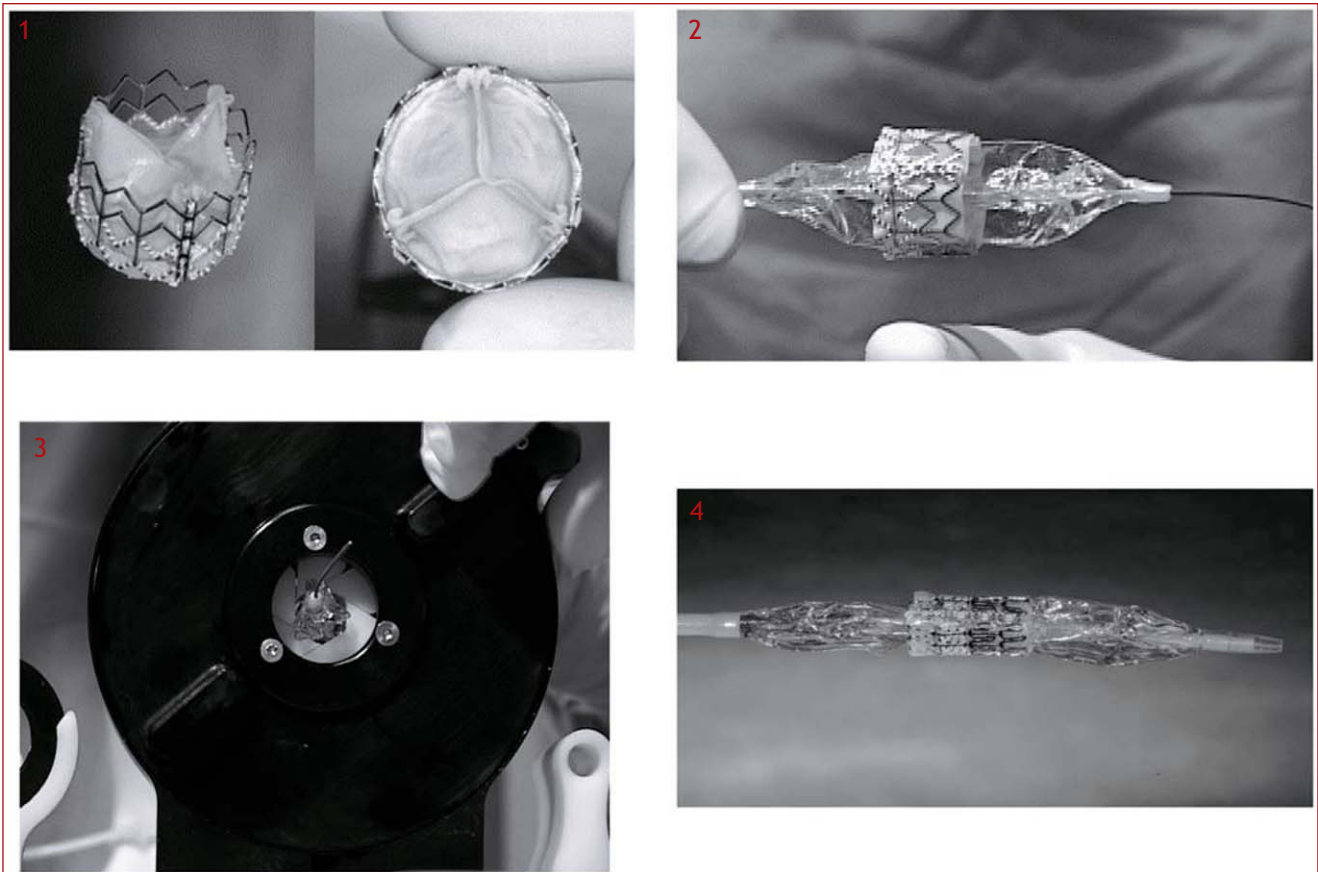
Figure 1. The Cribier-Edwards Bioprosthesis. From top to bottom and left to right: 1. Side and upper view of the stented valve; 2. the bioprosthesis in position at mid-part of the balloon before crimping; 3. the crimping phase; 4. a view of the crimped valve over the balloon

incorporated into the handle. The PHV assembly protrudes distally, and is not covered by the guide catheter. The guide catheter is then used to direct the Retro-Flex catheter-PHV assembly through the arterial system, around the aortic arch, and across the aortic valve. This provides a less traumatic passage of the PHV through a tortuous and diseased aorta. There is also improved ability to center and push the PHV assembly across the calcified and stenotic
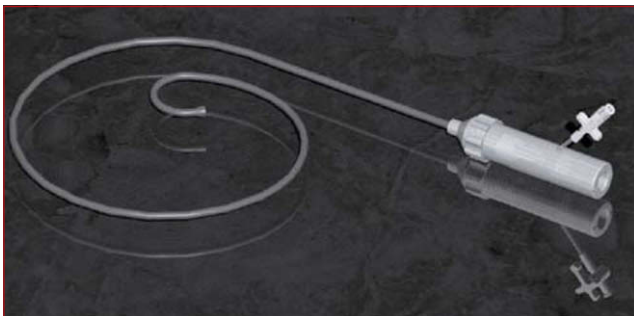

Figure 2. The Retro-Flex catheter. Its distal end can be deflected to help advancing the delivery system within the tortuous arterial access and to centralize the guide wire at the time of native valve crossing.

native valve. This system also allows precise positioning of the PHV at the aortic annulus.

Technical aspects for PHV implantation using the Cribier-PVT/Edwards valve

The techniques that will be described below include the antegrade transeptal approach, the retrograde approach, and the transapical approach that we have used in our center. Enrollment into one of the approved PHV trials is necessary to receive the device. Patient prerequisites for enrollment are: presence of severe symptomatic aortic valve stenosis (≤ 0.7 cm^2, with associated dyspnea class III/IV by NYHA classification) that are expected to benefit from isolated valve replacement, surgical refusal for standard aortic valve replacement, or classification as high operative risk by a Parsonnet's score ≥ 30 in the earlier feasibility studies or logistic Euroscore > 20% in the recent trials. Major exclusion criteria include the following: unprotected stenosis of the left main coronary artery not amenable to percutaneous intervention, prosthetic heart valves, active infection, active bleeding, coagulopathy. Patients who cannot be fully dilated with a 23 mm aortic valvuloplasty balloon (notable waist), have a native aortic valve annulus size > 25 mm, or < 19 mm are also currently excluded.

Baseline measurements and patient's premedication

Baseline transthoracic echocardiogram (TTE), right and left heart catheterization, left ventriculography, supra-aortic angiography, and coronary angiography are obtained prior to the planned PHV. This is necessary to determine the severity of the AS, the diameter of the aortic annulus, left ventricular function, associated coronary artery disease, and visualize the amount and distribution of valvular calcification. Supra-aortic angiography is performed to establish the optimal projection for PHV deployment. This view (generally antero-posterior) should profile the aortic valve and its annulus as well as demonstrate the coronary ostia clearly. A frame is stored for display on an adjacent monitor screen during the PHV implant. Aortography with angiography of the iliac and femoral arteries prior to the procedure, CT angiography, or MR angiography of the aorta and pelvic vessels are necessary to plan the strategy for a retrograde femoral artery approach or antegrade trans-apical approach.

Aspirin 160mg and clopidogrel 300 mg are given orally at least 24 hours prior to the procedure. Antibiotic prophylaxis is administered prior to and up to 48 h after the procedure. Clopidogrel (75 mg/day) is continued for one month, and aspirin (160 mg/day) indefinitely.

Predilatation of the native valve

Common to each technique is BAV prior to PHV deployment to prepare the native aortic valve and to facilitate its crossing. This is achieved using a 23 mm diameter balloon (20 mm diameter balloon in the case of a small calcified annulus) and rapid ventricular pacing (RVP). RVP pacing was developed by Alain Cribier for optimal PHV delivery (figure 3). A pacemaker lead is positioned in the right ventricle and used to pace the heart at 180 to 220 beats per minute. RVP will immediately lead to a drop in aortic blood pressure below 60 mmHg and a decrease in cardiac output allowing balloon stabilization across the aortic valve. A brief period of RVP (< 10 sec) is sufficient to inflate and deflate the balloon (figure 3).
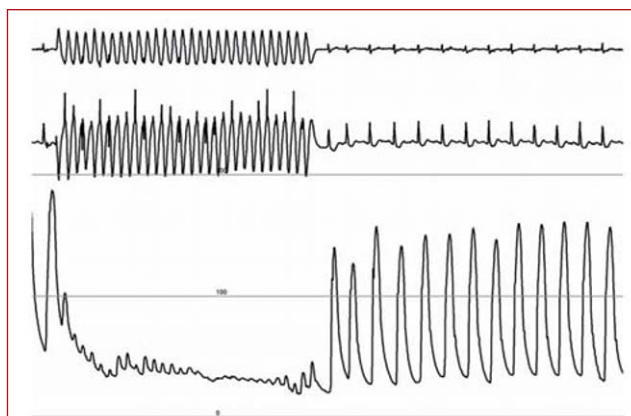

Figure 3. Effect of rapid pacing (200 beats/min) on aortic blood pressure at the time of balloon inflation for valve delivery.

The antegrade trans-septal approach

Technical steps related to this approach have been described earlier [5, 6] and will not be detailed here. This approach was used per protocol in 85% of patients included in the feasibility trials I-REVIVE and RECAST and has not been used in the recent multicenter trials.

The advantage of the antegrade approach is that it is truly percutaneous and performed under local anesthesia. This technique avoids the potential complications related to small caliber diffusely diseased tortuous iliac and femoral arteries encountered in the elderly. The PHV assembly is positioned and deployed in the direction of blood flow across the surface of the valve which is usually less diseased, resulting in smoother passage and greater stability. Failure to cross the native aortic valve using the antegrade approach was never experienced. Although the interatrial septum is crossed with a large profile device problems with residual shunting were not encountered.

This approach is technically demanding and more complicated than the retrograde approach. The antegrade technique
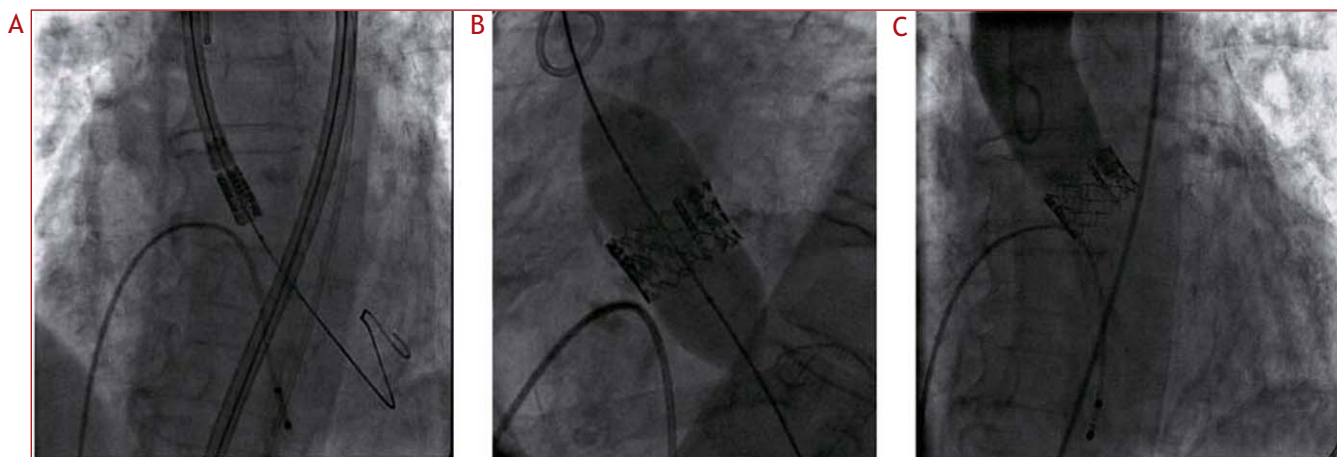

Figure 4. Three phases of PHV implantation using the retrograde approach. A. the PHV has been advanced over a wire entering the femoral artery and is positioned at the level of the native valve's calcifications. B. The PHV is delivered by balloon inflation under rapid pacing. C. A supra-aortic angiogram is performed after PHV delivery to assess the degree of paravalvular leak (no regurgitation in this case).

requires a significant learning curve limiting its widespread use. Because of the complexity of the antegrade approach, and the hemodynamic instability that can arise from interference or injury to the mitral valve if the guidewire is not handled properly, there was renewed emphasis on refining the retrograde approach. However, there will always be patients with small caliber vessels, severe arterial tortuosities, obstructions of the femoral and iliac arteries, or extensive atherosclerotic disease of the abdominal or aortic arch who will need an antegrade approach.

The retrograde approach

This approach is the most frequent approach in the trials since 2005. It was facilitated by the development of a specific catheter, the RetroFlex catheter described previously.

Femoral puncture, retrograde crossing of aortic valve, pre-dilation of valve and femoral artery

Baseline measurements are obtained as described previously. In our center, the procedure is performed under local anesthesia and mild sedation after surgical cut down of the femoral artery and puncture. In the vast majority of centers, the procedure is done under general anesthesia and transesophageal echocardiographic (TEE) guidance. The common femoral artery is either exposed surgically or punctured percutaneously.

After retrograde catheterization of the aortic valve, the straight-tip 0.35 inch guidewire is exchanged for an extra stiff guidewire, and pre-dilation of the aortic valve is done as described previously. The femoral artery is then pre-dilated with a series of dilators of increasing size (18F, 20F, and 22F) in order to facilitate entry of the 22 F or 24F sheath.

PHV delivery and deployment

The PHV is advanced over the extra stiff guidewire, placed within the native valve and deployed using RVP (figure 4). Post-implantation hemodynamic (figure 5) and angiographic measurements are performed with special attention to the supra-aortic angiogram to assess any paravalvular leak. Arterial access is managed by surgical repair in the cath-lab.

The retrograde approach's main advantage relies on its similarities with routine BAV, a familiar technique for the Interventional Cardiologists. Its main limitations center on the arterial sheath size required for device insertion and the lack of ability to reposition the prosthesis after deployment.

Clinical experience with the Cribier-PVT/Edwards bioprosthesis

Following the report of our first PHV implant [4], initial patient series were selected on a compassionate basis after being formally declined for valve replacement by two independent cardiac surgeons. They were part of either the I-REVIVE trial (using either the antegrade or retrograde approach) or the RECAST trial (using solely the antegrade approach) [5, 6]. From April 2006 through April 2007, patients were included in the multicenter European trial REVIVE (Registry of EndoVascular Implantation of Valves in Europe). The follow-up of this study is ongoing and one-year results are expected by mid-2008. Following the REVIVE
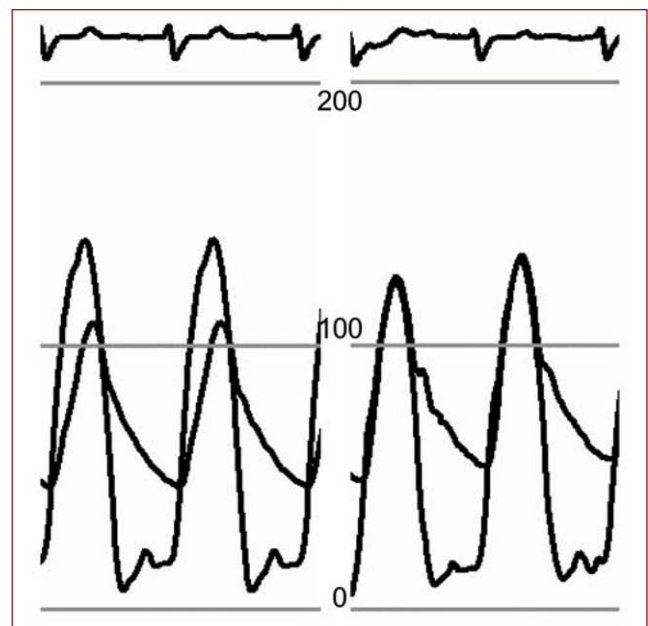

Figure 5. Transvalvular gradient at baseline (left) and after (right) PHV implantation. The lack of gradient after PHV implantation is observed in each case.

trial, the multicenter European PARTNER Trial has started in July 2007. Results of these series will be detailed below.

Feasibility studies I-REVIVE and RECAST

The results of this "first in man" series of patients initial results have been published and will not be detailed here [5, 6]. In summary, these studies demonstrated the feasibility of the technique. Despite compassionate use in 36 patients, implantation success rate was high (85%) and hemodynamic results were remarkable. Final AVA increased from $0.60 \pm 0.11cm^2$ to 1.70 ± 0.10 cm^2, p < 0.0001 and residual gradient was negligible (< 10 mm Hg). There was no coronary obstruction. Close clinical and echocardiographic follow-up did not show any valve dysfunction or secondary valve migration. Two patients are alive 4 years after implantation with perfectly stable clinical and echocardiographic results.

Retrograde arterial approach studies

To enhance the effectiveness of the retrograde approach, a lower profile system with better ability to traverse the vascular system and aortic arch, as well as to overcome wire bias and resistance to crossing the native valve was needed. Furthermore, because of the concern of PHV migration and paravalvular leaks, a larger diameter PHV was designed and produced. These two major advances led to the revival of the retrograde arterial trans-femoral approach. For regulatory reasons, these technologic advances could not be used in France before 2006 and were evaluated initially by J. Webb in Canada [8, 9]. The technique was also evaluated in the United States in 55 patients in 3 centers included in the REVIVAL II Trial.

Data on this retrograde transfemoral approach is growing with more than 270 patients implanted as of October 2007. After a preliminary series of 18 patients [8], Webb et al recently reported the updated series of 50 patients [9]. Pro-

cedural success rate was high (86%) and the 30-day mortality was 12%. His data also showed improvement following a learning curve of 25 procedures. The ongoing REVIVE trial in Europe/Canada (> 85 patients implanted) and the REVIVAL II trial in the US (55 patients implanted) are aimed at assessing the acute and long term results using this new technology. The results are very promising, currently similar to those reported by John Webb. Implantation success rate is approximately 90% in all the series. Thirty-day mortality is 8% in the REVIVAL II trial and 12% in the European REVIVE Trial. From these results, there is no doubt that transarterial retrograde PHV implantation represents a significant enhancement with respect to delivery and procedural simplicity.

Further improvements are on the way. In order to facilitate advancement of the PHV assembly up to and then across the stenotic aortic valve, a covered sheath delivery system (Harmony, Edwards Lifesciences, Irvine, CA) has been developed and is under investigation in Canada. A decrease of 3 to 5F will probably allow a fully percutaneous procedure. An increase in the width of the fabric sleeve sewn onto the stent, another device improvement, allows a greater liberty for prosthesis positioning across the calcified aortic valve. A cobalt-chromium stent platform that will decrease the device's profile is also foreseen in the near future.

The trans-apical approach

The feasibility of the transapical approach for PHV implantation was shown in an animal model, and has been recently reported in humans [13-16]. In this approach, the same Cribier-Edwards PHV and its delivery catheter are introduced under direct vision into the left ventricle via a mini-thoracotomy. After ventricular puncture they are directed across the aortic valve under guidance of TEE and fluoroscopy. This obviates the concerns regarding vascular access in the presence of small caliber vessels and/or vascular occlusive disease. It potentially reduces the risk for stroke related to passage of a stiff device through a diseased and tortuous aorta to zero, as was seen in Walther's recently published series [16]. Patients with a "porcelain aorta", previous cardiac surgery, or mediastinal radiation may be suitable for this approach. Currently, general anesthesia and mechanical ventilation are required limiting the applicability in patients with chronic lung disease or other disorders which would contra-indicate general anesthesia. More than 200 patients have been treated with this approach. In the European experience 30-day mortality is 14% (TCT 2007). Data on 59 patients from 4 centers were recently published [16]. In-hospital mortality rate was 13.6% and actuarial survival was 75.7 ± 5.9% at a follow-up interval of 110 ± 77 days. Neither coronary obstruction nor migration of the prosthesis was observed, and all valves had good hemodynamic function.

In the future, the interventional cardiologist will have several technical alternatives to ensure the procedural success of PHV implantation, depending on various anatomic and clinical features.

Future strategies

Pulmonary valve and degenerated bioprosthetic valve

Placement of PHV technology in the pulmonary position has been reported in animals [17]. Human implantation has been reported once in an adolescent boy who had a prior Ross procedure with subsequent replacement with a homograft in the pulmonary position [18]. When the homograft became stenotic, the patient had stenting of the pulmonary valve followed by deployment of the Cribier-Edwards valve with a successful result.

Balloon valvuloplasty has been carried out for stenotic bioprosthetic valves in the aortic, tricuspid, or mitral positions [19-22]. Since the bioprosthetic "stent" can provide the means of anchoring the PHV, there is future potential for non-surgical management of bioprosthetic valve failure with this balloon expandable device [23]. A surgical valve-in-valve procedure has been performed in a patient with a failed bioprosthetic mitral valve, suggesting the feasibility of this approach [24].

The CoreValve and other competing technologies

There is intense interest in PHV technology, and there are multiple devices at various stages of development in animals and humans. The most developed is the CoreValve Revalving® Technology. The first patient to be treated with this technology was in 2004, 2 years after the first human implantation with the Cribier-Edwards bioprosthesis. The CoreValve PHV is a self-expanding nitinol stented porcine valve, which is being developed for the treatment of aortic regurgitation and AS. The stent has three parts: the lower portion with high radial strength to keep the aortic valve leaflets open; the middle part where the bioprosthesis lies; and the superior portion which flares into the ascending aorta and provides longitudinal stability. The device was initially available on a 24 F platform and was placed with extracorporeal circulation. A second generation 21 F valve proceeded, which has been currently replaced by an 18-F device which makes it a truly percutaneous procedure. More than 350 patients have been treated with this technique. The immediate and mid-term results with this device are promising [10-12] with a procedural success of 92% and a 30-day mortality of 15%. However, the risk of stroke (5%-7%) and tamponade (7%) in their recent series are non-negligible. Pacemaker implantation rate is also high at 16%-24% in recent series (TCT 2007). The major advantages of the Corevalve prosthesis include a smaller sheath size and the ability to reposition the valve when it is partially deployed. This provides liberty to the operator to optimize the valve if its position is not exact. The higher incidence of stroke and permanent pacemaker requirements illustrate its limitations.

Conclusion

The future of this technology and its application is dependent on the continued collaboration between general internists, cardiologists, surgeons, engineers, and industry. Because there is a substantial learning curve with each of the techniques and for each device, there must be collaboration between cardiologists and cardiac surgeons in order to disseminate the necessary knowledge and skills. Only a portion of the technique can be taught in a lecture hall or on a simulator. There is a fundamental knowledge, skill set, and clinical wisdom of general physicians, imagers,

interventionalists, and surgeons which must be shared, coordinated, and in fact, synchronized to ensure successful outcomes and future development of the new techniques.

Selecting the appropriate patients for surgical conventional aortic valve replacement, percutaneous valve implantation, balloon valvuloplasty, or palliative hospice care is becoming more complex. This demands an attention to individual patient's desires regarding their quality and quantity of life. A broader array of therapeutic options, including PHV, for the treatment of these high risk and inoperable patients with severe calcific AS is within reach.

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