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Perspective:

Update of transcatheter valve treatment

Xian-bao LIU, Jian-an WANG[†‡]
(*Cardiovascular Key Lab of Zhejiang Province, Department of Cardiology, the Second Affiliated Hospital, School of Medicine, Zhejiang University, Hangzhou 310009, China*)
[†]E-mail: wang_jian_an@tom.com
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Transcatheter valve implantation or repair has been a very promising approach for the treatment of valvular heart diseases since transcatheter aortic valve implantation (TAVI) was successfully performed in 2002. Great achievements have been made in this field (especially TAVI and transcatheter mitral valve repair—MitraClip system) in recent years. Evidence from clinical trials or registry studies has proved that transcatheter valve treatment for valvular heart diseases is safe and effective in surgical high-risk or inoperable patients. As the evidence accumulates, transcatheter valve treatment might be an alterative surgery for younger patients with surgically low or intermediate risk valvular heart diseases in the near future. In this paper, the updates on transcatheter valve treatment are reviewed.

The prevalence of valvular heart diseases such as aortic stenosis (AS) and mitral regurgitation has significantly increased with economic and social developments and the aging of the population. Surgical aortic-valve replacement (SAVR) remains the gold standard treatment for patients with valvular heart diseases. However, for those elderly patients who have multiple diseases, a history of thoracic heart surgery, and severe cardiac dysfunction, the mortality in surgery becomes very high because of a high European System for Cardiac Operative Risk Evaluation (EuroSCORE) and Society of Thoracic Surgeons (STS) score. Nowadays, transcatheter valve treatment procedures have been widely used in Europe and the USA since the techniques appeared about one decade ago. In China, six hospitals began trying interventional treatment of valvular heart diseases including our hospital. In this paper, the progress of transcatheter valve treatment is reviewed.

The first successful animal TAVI was accomplished by Andersen *et al.* (1992). To date, 11 years after Cribier *et al*. (2002)'s first TAVI application in a human being, approximately 80000 TAVI procedures have been performed worldwide. In China, about 40 patients have benefited from this new therapeutic approach since the first case in 2010.

As is well known, the PARTNER trial including cohorts A and B was the milestone for TAVI, which was the first head-to-head prospective randomized controlled trial. PARTNER-A compared TAVI with SAVR in the survival in high-risk patients with severe aortic stenosis at one year and demonstrated identical results (Smith *et al.*, 2011). A two-year follow-up showed the two treatments were similar with respect to mortality, reduction in symptoms, and improved valve hemodynamics that supports TAVI as an alternative to surgery in high-risk patients (Kodali *et al.*, 2012). As for patients with severe aortic stenosis who were not eligible candidates for surgery, PARTNER-B found that TAVI reduced the mortality and hospitalization, with a decrease in symptoms and an improvement in valve hemodynamics that were sustained during two years of follow-up (Makkar *et al.*, 2012).

Registry studies including ADVANCE, FRANCE 2 (Gilard *et al.*, 2012), SOURCE (Thomas *et al.*, 2011), Belgian TAVR (Bosmans *et al.*, 2011), and GARY (Beckmann *et al.*, 2012) showed immediate success of implantation. Survival rates at 1 day, 30 days, and one year were 93.8%–98.4%, 82.2%–92.9%, 76.1%–84.2%, respectively, indicating TAVI is a safe and feasible approach for severely symptomatic aortic stenosis patients. Therefore,

[‡] Corresponding author

Guidelines on the Management of Valvular Heart Diseases 2012 by the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) show that TAVI should be considered for high-risk patients with severe symptomatic AS who may still be suitable for surgery, but for whom TAVI is favored by a 'heart team' based on the individual risk profile and anatomic suitability (IIa, B). TAVI is indicated in patients with severe symptomatic AS who are not suitable for SAVR as assessed by a 'heart team' and who are likely to gain improvement in their life quality and to have a life expectancy of more than one year after consideration of their comorbidities (I, B) (Vahanian *et al.*, 2012). Also, TAVI was recommended in patients with severe, symptomatic, calcific stenosis of the trileaflet aortic valve, who had aortic and vascular anatomy suitable for TAVR, in the USA in 2012 (Holmes *et al.*, 2012).

However, there are still some complications concerning TAVI including paravalvular leaks, vascular complications, need for pacemaker implantation, stroke, myocardial infarction, occlusion of coronary ostia, annulus rupture, aortic dissection, new-onset of atrial fibrillation, etc. (Stortecky *et al.*, 2012). Among these, paravalvular leaks become a more and more important issue because a two-year follow-up of PARTNER-A trial found that the presence of paravalvular or total aortic regurgitation was associated with increased late mortality, and the effect of aortic regurgitation on mortality was proportional to the severity of the regurgitation. But even mild aortic regurgitation was associated with an increased rate of late deaths (Kodali *et al.*, 2012).

To overcome the shortcomings of the first-generation CoreValve and Edwards SAPIEN transcatheter heart valves (THVs), the second-generation THVs (including Sadra-Lotus, inovare, acurate valve, engager) are being developed by many more companies than Medtronic and Edwards Lifesciences (USA). The new generation valves are targeted at reducing the incidence of paravalvular leaks, vascular complications (due to large delivery system sizes), pacemaker implantation, and strokes. What's more, they will overcome the limitation of annulus size and make it retrievable, similar to the occlusion device for congenital heart diseases such as the atrial septal defect or ventricular septal defect.

Encouragingly, new evidence is continuously presenting itself about new indications of TAVI. Lange *et al.* (2012) reported that younger and lower risk patients show a trend of lower mortality and cardiovascular events, demonstrating an important paradigm shift toward the selection of lower surgical risk patients for TAVI. Significantly, better clinical outcomes can be expected in lower-risk patients undergoing TAVI (Lange *et al.*, 2012). Also, TAVI was successfully applied in degenerated aortic bioprostheses after SAVR (Greif *et al.*, 2012), aortic insufficiency (Dumonteil *et al.*, 2013), and stenotic bicuspid aortic valves (Himbert *et al.*, 2012).

As the technology advances, operator experience increases and evidence accumulates, higher procedural success and less complication will make TAVI an alternative to SAVR in even younger and low- to intermediate-risk patients with severe symptomatic aortic valve stenosis or aortic insufficiency.

Percutaneous approaches for the treatment of mitral regurgitation (MR) have aroused great interest worldwide in recent years. Because of the structural reasons, any alteration of its components (mitral leaflets, papillary muscles, tendinous cords, and annulus) will lead to MR. Transcatheter mitral valve repair is based on the same principles as surgery, such as partial resectioning of the leaflets, "edge-to-edge" technique, annuloplasty, papillary modification, and left ventricular (LV) remodeling.

Up to now, the techniques of transcatheter mitral valve repair (TMVR) have applied in the clinic as follows: indirect annuloplasty (Carillon system, Monarc device, and Viacor percutaneous transvenous mitral annuloplasty device), direct annuloplasty (Mitralign system and Accucinch (Guided Delivery Systems) device), "edge-to-edge" technique (MitraClip), direct ablation of leaflets and tendinous cords, tendinous cord implantation (Mitraflex, NeoChord, Babic system), LV remodeling (iCoapsys technique, Mardil-BACE system), and transcatheter mitral valve replacement (CardiAQ valve) (Nombela-Franco *et al.*, 2013). However, as yet, the techniques above, except for MitraClip, are scarce and some devices have high complications rates, therefore they are not widely used in clinical practice. In this paper, we focus on the most popular TMVR procedure of MitraClip that has been performed in about 9000 cases in the world.

MitraClip technique is based on the surgical "edge-to-edge" suture developed by Otavio ALFIERI in 1992. The MitraClip animal experiment was first performed in 2003 and the majority of the clinical cases have been in the Europe where the procedure started in September 2008. The evidence of this treatment was primarily achieved through the EVEREST series trial. A study of initial endovascular valve edge-to-edge repair study (EVEREST) cohort demonstrates that the technique is safe with a low complication rate, efficacy is acceptable with significant reduction of MR in more than two-thirds of patients and surgery remains an alternative if the procedure fails (Feldman *et al.*, 2009). The EVEREST II trial, a multicenter randomized clinical trial designed to compare the efficacy and safety of MitraClip with surgery, found that transcatheter MitraClip treatment is effective in MR reduction in most patients (77%). However, it is inferior to surgery mainly due to a higher need for surgery for mitral valve dysfunction (20%) although it is associated with fewer periprocedural complications. However, in comparison with the concurrent comparator group, the MitraClip device resulted in improvement in clinical symptoms, significant left ventricular reverse remodeling, and survival rate (76% vs. 55%) over 12 months in the subgroup for high-risk study (Whitlow *et al.*, 2012) . Four-year follow up of the EVEREST II trial showed that the rates of the composite endpoint (freedom from death, surgery, or 3+ or 4+ MR) were 39.8% vs. 53.4% in the percutaneous MitraClip group and surgical group, respectively (P=0.070), and no difference in the death rate and 3+ or 4+ MR was observed. However, patients after percutaneous MitraClip treatment required more surgery to treat residual MR, largely in the first year after procedure (Mauri *et al.*, 2013).

Real world research of ACCESS-EUROPE reported that the successful implant rate of the MitraClip was 99.6%. A total of 19 patients (3.4%) died within 30 d and the Kaplan-Meier survival at 1 year was 81.8%. Significant improvement in the severity of MR and New York Heart Association (NYHA) functional class was observed at 12 months with only 36 patients (6.3%) needing surgery, indicating the MitraClip procedure is safe and effective for high risk elderly patients (Maisano *et al.*, 2013). Similar results were found in PERMIT-CARE (percutaneous mitral valve repair in cardiac resynchronization therapy) investigation (Auricchio *et al.*, 2011), TRAMI (German transcatheter mitral valve interventions) registry (Baldus *et al.*, 2012), GRASP (getting reduction of mitral insufficiency by percutaneous clip implantation) registry (Grasso *et al.*, 2013), MitraSwiss registry (Sürder *et al.*, 2013), and in patients not amenable to surgery (Rudolph *et al.*, 2011).

Percutaneous pulmonary valve implantation (PPVI) was initially developed in humans as a means to extend conduit life and minimize the number of surgical procedures required by Bonhoeffer *et al.* (2000), and over 3000 cases have received this therapy since then. PPVI can postpone or spare open surgery. Several studies have demonstrated the safety and effectiveness of PPVI, and morbidity and mortality rates are lower than conventional surgery leading to good patient acceptance (Khambadkone *et al.*, 2005; Zahn *et al.*, 2009; McElhinney *et al.*, 2010; Eicken *et al.*, 2011; Gillespie *et al.*, 2012). Therefore, the American Heart Association Guidelines state that it is reasonable to consider this treatment for patients with a right ventricle to the pulmonary artery conduit and moderate or worse pulmonary regurgitation or stenosis, provided the patient meets inclusion/exclusion criteria for the available valve (IIa, B) (Feltes *et al.*, 2011). The first case in China was successfully performed by Professor Ge with the self-expandable VENUS-P valve (made in China) rather than MELODY, or Edwards valve, in May 2013.

As we know, bioprosthetic valves are often applied to reduce thromboembolic risk, avoid anticoagulation, and decrease the related risk of bleeding. However, as compared with mechanical prostheses, the durability of bioprosthetic valves is much shorter. Reoperation was the only choice for symptomatic patients with degenerated bioprosthesis until recently, but the risk is very high especially in the elderly with multiple organ diseases. The emergence of TAVI brings new hope for these patients and the first successful "valve-in-valve" case was reported in 2007 by a German group for an 80-year-old patient with a severe regurgitation of a degenerated aortic bioprosthesis using the CoreValve revalving system (Wenaweser *et al.*, 2007). Subsequently, this technique was introduced to degenerated mitral (Cheung *et al.*, 2009), pulmonary and tricuspid bioprosthesis (Webb

et al., 2010). A recent registry study that recruited 202 patients with aortic, pulmonary, mitral, and tricuspid degenerated bioprosthesis showed a "valve-in-valve" procedural success rate, adverse procedural outcome, 30 day and one year survival of 93.1%, 15.3%, 91.6%, and 85.8%, respectively, indicating the procedure is safe and effective (Dvir *et al.*, 2012).

Besides generated bioprosthetic valves, the procedure of TAVI itself may cause malposition leading to severe regurgitation. However, the current valve of CoreValve and Edwards could not be retrieved. Thus, we have no choice but to deploy a second valve when necessary (Piazza *et al.*, 2009; Stabile *et al.*, 2010).

The concept of "valve-in-ring" is similar to "valve-in-valve", and the only difference is implanting a transcatheter valve in a failing surgical mitral or tricuspid annuloplasty ring rather than a surgically degenerated mitral or tricuspid bioprosthesis. This method has been successfully reported by several groups in the world (Dahle *et al.*, 2012; Descoutures *et al.*, 2013; Mazzitelli *et al.*, 2013).

In conclusion, great changes have taken place in the field of treatment of valvular heart diseases in recent years and a lot of techniques are still at the initial application stage. Undoubtedly, transcatheter valve treatment is a very promising field for valvular heart diseases. These techniques have just started in China since 2010, and we believe more and more patients will benefit from them in the near future.

Compliance with ethics guidelines

Xian-bao LIU and Jian-an WANG declare that they have no conflict of interest.

This article does not contain any studies with human or animal subjects performed by any of the authors.

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