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Jacobs Journal of Experimental Cardiology and Research

Review Article

State of the Art: Transcatheter Aortic Valve Replacement

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Received: 04-10-2015

Accepted: 07-05-2015

Published: 08-11-2015

Abstract

Transcatheter aortic valve replacement determined a paradigm shift in the treatment of elderly patientswith severe symptomatic aortic stenosis at high or prohibitive risk for traditional surgical aortic valve replacement. Different prostheses are nowadays available for implantation via retrograde transfemoral, retrograde subclavian, transaortic or an antegrade transapical approach. Along with an increased experience and a growing body of literature the inherent procedural risks steadily decreased yet with the first generation of prostheses. Nevertheless, newer prostheses aim to overcome the limitations of the predecessors by optimizing results and further reducing the risk of complications. In this scenario, the "heart team" will still play a key role for the success of the TAVR therapy.

Background

The development of the transcatheter aortic valve replacement (TAVR) technology fulfilled the need for an effective treatment for those patients with severe symptomatic aortic stenosis deemed at high or prohibitive risk for surgical replacement. Since the seminal implants from 2002 different prostheses and delivery systems have received CE approval and more than 40.000 procedures have been done worldwide [1]. Nowadays, there is a large consensus that the TAVR procedure should be considered in high risk patients with relevant comorbidities following the heart team evaluation [1]. In the present review we describe the main issues related to the TAVR procedure.

Patients

Patients with relevant aortic valve disease, mostly aortic stenosis, suffer relevant clinical symptoms such as dyspnea on exertion, angina or even syncope. Medical therapy can alleviate symptoms but only marginally impact on prognosis [1]. Conventional aortic valve surgery has evolved as a standardized and low risk procedure (risks of approximately 1% in experienced centers) with excellent long term outcomes thus becoming the gold standard approach for decades. Elderly and higher risk patients, however, have frequently neither been referred for nor have been accepted for conventional surgery [1]. Therefore TAVR offers a perfect additional therapeutic option. According to the current guidelines older age and increased risk profiles should be present in order to select a patient for TAVR [2]. Many patients, that may not have been referred several years ago, are nowadays being treated. Despite the treatment of high risk elderly patients by means of TAVR, in addition quite some intermediate risk patients may receive TAVR as well. In order to perform best practice, clear interdisciplinary heart team decisions should be performed taking individual patient related factors into account. A prospectively randomized all-comers trial comparing TAVR to conventional surgery in intermediate risk patients would be ideal, however, such a trial is neither avail-

able nor in view.

Regarding outcomes there are several studies showing acceptable and good outcomes with TAVR [3-11]. Selected studies, however, may be at risk of reflecting a "selected reality", whereas larger scale "all-comers" registries may reflect the effective therapeutic outcomes in a better way.

Imaging tools

Exact patient screening is crucially important before TAVR. As TAVR is performed without direct measurement of the annular dimensions, annular sizing by transesophageal echocardiography in a two dimensional and three dimensional view as well as computed tomography (CT) are of outmost importance [12]. For CT assessment there are specific software tools allowing for precise and automated measurement of the aortic root including the effective aortic annulus based on its area and/or perimeter. Over the past years, these specific assessments have been an important contributing factor to the further improvement of the results of TAVR procedures throughout. The slightly decreasing incidence of severe paravalvular regurgitation after TAVR may be clearly related to improved preoperative patient assessment by improved imaging.

Vascular Access

Access for TAVR is gained using a retrograde transfermoral (TF), a retrograde transaortic (TAo), a retrograde subclavian (TS) or an antegrade transapical (TA) approach. Some reports are published concerning a carotid retrograde approach [13].

There are specific differences, including advantages and disadvantages of the antegrade versus retrograde approaches [14]. Important factors are the size and invasiveness of the respective incision and sheath, the distances to the targeted aortic valve, potential manipulations on the aortic arch, coaxial versus oblique access with direct or remote control, feasibility of commissural alignment during valve implantation, and potential advantages and disadvantages of perform TAVR under conscious sedation versus fast track general anesthesia.

Procedure Set Up

Any vascular access, in a hybrid operating theatre or in a catheterization lab, performed by an experienced heart team leading to a minimal complication rate is ideal [14]. Nowadays, there is no difference between procedures done in a hybrid surgical theatre or in a catheterization lab in terms of outcome. Nevertheless, the latter, is less expensive [15].

TAVR devices

Current devices to perform TAVR mostly are first or second generation valves that have been used clinically over the past years. Newer systems are being developed, aiming at offering additional solutions for improved patient outcomes and enhanced safety. This includes specific features to minimize paravalvular leakage, further reduction in crimped sheath diameter in order to allow for an easy insertion, options to retrieve the device in part or completely (if possible after it is already fully functional), possibly commissural orientation with exact anatomical positioning, potential features to further ease perfect positioning and eventually automated functionality.

TAVR devices consist of a specifically designed valve and a delivery system, which is usually inserted over a guidewire by means of a sheath or in a sheathless manner. The valve consists of a thin stent, which is balloon expandable (stainless steel or cobalt-chromium) or self-expandable (usually nitinol). Valve leaflets consist of bovine pericardium, porcine pericardium or porcine leaflets. Some of these valves have an additional anti-calcification treatment similar to conventional surgical xenografts in order to protect against tissue degeneration and thus achieve optimal valve durability. Examples of common TAVR valves are shown in Figure 1.

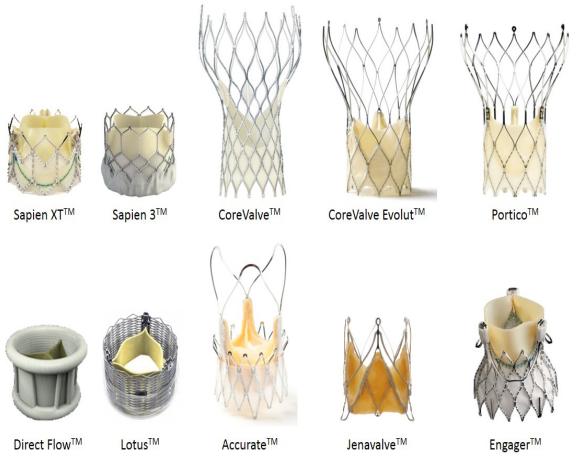

Figure 1. Common valves for trancatheter aortic valve implantation.

In the early years the Edwards SAPIEN™ balloon expandable valve and the Medtronic COREVALVE™ self expandable valve were available. These are the two devices having the largest clinical experience worldwide. Whereas the SAPIEN™ valve is available for retrograde (TF, TAo, TS) and antegrade (TA) insertion the COREVALVE™ is available for retrograde implantation only. The SAPIEN™ is a rather short device (16 to 22mm) designed for subcoronary implantation whereas the COREVALVE™ stent has a length of almost 50mm, thus requiring an implantation which surpasses the coronary ostia while obtaining additional aortic stabilization. After implantation the leaflets are in a rather intraannular position with the SAPIEN™ whereas they are slightly supraaannular with the COREVALVE™. Available valve sizes are 23mm, 26mm and 29mm for both and an additional 31mm for the COREVALVE™, respectively. The initial SAPIEN™ prosthesis was replaced by the SA-

PIEN XT™ prosthesis from 2009 onwards.

Recent developments of these two devices are the SAPIEN 3™ valve which just received CE approval and the COREVALVE EVOLUT prosthesis. The SAPIEN 3™ offers smaller sheath diameters (14 to 18 F) and an additional outer skirt to minimize the risk of post-implant paravalvular leakage. The COREVALVE EVOLUT™ offers improved stability during positioning and some retrieval options.

Besides these "large players in the field" several other devices have been developed in the past years:

For a retrograde TF access the PORTICO™ (St.Jude Medical), DIRECT FLOW™ (Direct Flow Medical Inc.) and SADRA™ Lotus valve (Boston Scientific Inc.) have received CE approvals whereas further devices are being studied (ACCURATE TF™, Symetis Inc.) or are being developed (JENAVALVE TF™).

The PORTICO™ device consists of a nitinol stent of approximaltely 50mm length which looks a bit similar to the previously mentioned Corevalve™. It allows for retrieval after up to 80% of implantation, a position where valve functionality can already be assessed. At present the 23mm and the 25mm PORTICO™ valves have received CE-approval whereas the 27mm and 29mm versions will undergo further clinical evaluation. A transapical version is being further developed in parallel.

The DIRECT FLOW™ valve is unique in design, as it avoids any metal and is made from two inflatable circular structures that are connected by cloth. It has a unique implantation and fixation technique which leads to good outcomes in experienced hands.

The SADRA LOTUS™ valve consists of a nitinol mesh which is quite long in the crimped position and foreshortens during implantation. It allows for complete retrieval of the device.

For TA access the ACCURATE™ (Symetis Inc.) system has gained the largest clinical expertise with more than 1000 implants at the end of 2013. The Accurate valve has a self-expanding nitinol stent that can be placed in an anatomically correct position matching the commissures to the native ones quite easily. Furthermore it allows for partial repositioning. The overall implantation procedure is strikingly easy. Future developments will include larger application system diameters down to 18F and an active mechanism to seal against paravalvular leaks. Clinical results with the first generation ACCURATE™ valve are promising.

The JENAVALVE™ (Jenavalve Inc.) TA system received CE approval in parallel to the previously mentioned device and has seen several hundred implantations since. The JENAVALVE™ has a unique self expandable stent with additional "feelers" to guide positioning at the annular level together with commissural alignment and safe anchoring.

The ENGAGER™ (Medtronic Inc.) system has some comparable functionality as the previously mentioned Jenavalve™ in terms of three "arms" that are being placed at the three nadirs during implantation. The ENGAGER™ consists of a self expanding frame, it has been implanted into several hundred patients, respectively.

Future developments

TAVR is still a relatively young procedure considering that the first reports are dated in 2002 [16]. However, it could have already reached a steady state of performance due to the fast growing enthusiasm that led to its worldwide implementation, perhaps reflected by the large amount of literature already published. Nevertheless, several issues still merit further efforts from researchers and companies.

- Currently available Risk Scores (EuroScore I and II, STS score) which have been validated in surgical populations, scarcely apply to the TAVR population, meaning that a reliable tools to stratify the risk of TAVR is still lacking.

- Imaging will further evolve towards an increasing use of 3D views along with online overlay of relevant structures thus becoming a more "in vivo" visualization.

- The indication for TAVR to less compromised patients ("moderate" risk) will definitely be based on long term follow up data coming from the already published registries. However, considering the advanced age of the current TAVR population, it is hard to imagine such a scenario.

- The concept of "futility" is having increasing strength, after the initial enthusiasm. A more precise definition of life expectancy in this very old population will help to select the right candidate to the procedure.

Conclusions

After only 10 years of clinical practice TAVR has already evolved towards a highly standardized and relatively safe procedure for a less invasive treatment of severe symptomatic aortic stenosis in elderly and high risk patients.

Key issues for procedural and clinical success include: 1) an expert multidisciplinary Heart Team, 2) a standardized procedural workflow from first evaluation to the follow up, 3) a well equipped operative room with optimal imaging modalities, and 4) an experienced environment where the whole team is expert in dealing with such a complex patients population.

References

1. Nishimura RA, Otto CM, Bonow RO, Carabello BA, Erwin JP 3rd, Guyton RA, O'Gara PT, Ruiz CE, Skubas NJ, Sorajja P, Sundt TM 3rd, Thomas JD; ACC/AHA Task Force Members. 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. 2014, 129(23): e521-643.

2. Vahanian A et al. Transcatheter valve implantation for patients with aortic stenosis: a position statement from the European Association of Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC), in collaboration with the European Association of Percutaneous Cardiovascular Interventions (EAPCI). Eur Heart J. 2008, 29(11): 1463-1470.

3. Smith CR, Leon MB, Mack MJ, Miller DC, Moses JW et al. PARTNER Trial Investigators. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med. 2011, 364: 2187-2198.

4. Leon MB, Smith CR, Mack M, Miller DC, Moses JW, Svensson LG et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med. 2010, 363: 1597-1607.

5. Zahn R, Gerckens U, Grube E, Linke A, Sievert H et al. German Transcatheter Aortic Valve Interventions-Registry Investigators. Transcatheter aortic valve implantation: first results from a multi-centre real-world registry. Eur Heart J. 2011, 32: 198-204.

6. Gilard M, Eltchaninoff H, Iung B, Donzeau-Gouge P, Chevreul K et al. Registry of transcatheter aortic-valve implantation in high-risk patients. N Engl J Med. 2012, 366: 1705-1715.

7. Bedogni F, Laudisa ML, Pizzocri S, Tamburino C, Ussia GP et al. Transcatheter valve-in-valve implantation using Corevalve Revalving System for failed surgical aortic bioprostheses. JACC Cardiovasc Interv. 2011, 4: 1228-1234.

8. Testa L, Brambilla N, Laudisa ML, De Carlo M, Lanotte S et al. Right Subclavian Approach As A Feasible Alternative For Transcatheter Aortic Valve Implantation With CoreValve Revalving System. Eurointervention 2012, 8(6): 685-690.

9. Testa L, Latib A, De Marco F, De Carlo M, Agnifili M et al. Clinical impact of persistent left bundle branch block after Transcatheter aortic valve implantation with CoreValve Revalving system. Circulation. 2013, 127(12): 1300-1307.

10. Testa L Latib A, Rossi ML, De Marco F, De Carlo M et al. Corevalve Implantation For Severe Aortic Regurgitation: A Multicenter Registry. Eurointervention. 2014, 10(6): 739-745.

11. Bedogni F, Latib A, De Marco F, Agnifili M, Oreglia J,Interplay between Mitral Regurgitation and Transcatheter Aortic Valve Replacement with the CoreValve Revalving system. A multicenter registry. Circulation. 2013, 128(19): 2145-2153.

12. Saikrishnan N, Kumar G, Sawaya FJ, Lerakis S, Yoganathan AP. Accurate Assessment of Aortic Stenosis A Review of Diagnostic Modalities and Hemodynamics. Circulation. 2014, 129(2): 244-253.

13. Guyton RA, Block PC, Thourani VH, Lerakis S, Babaliaros V. Carotid artery access for transcatheter aortic valve replacement. Catheter Cardiovasc Interv. 2013, 82(4): E583-586.

14. Kappetein AP, Head SJ, Généreux P, Piazza N, van Mieghem NM et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. J Am Coll Cardiol. 2012, 60: 1438-1454.

15. Babaliaros V, Devireddy C, Lerakis S, Leonardi R, Iturra SA et al. Comparison of Transfemoral Transcatheter Aortic Valve Replacement Performed in the Catheterization Laboratory (Minimalist Approach) Versus Hybrid Operating Room (Standard Approach): Outcomes and Cost Analysis. JACC Cardiovasc Interv. 2014, 7(8): 898-904.

16. Cribier A. Percutaneous Transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. Circulation. 2002, 106: 3006-3008.