Journal of Clinical & Experimental Cardiology

Said, J Clinic Experiment Cardiol 2011, S:3
DOI: 10.4172/2155-9880.S3-003

Review Article Open Access

Currently Applied Non-Surgical Techniques for Treatment of Severe Aortic Stenosis in Inoperable High-Risk Adult Patients

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Abstract

Background: Patients with severe valvular heart disease associated with significant comorbidities have a high risk to undergo conventional surgical replacement procedures. Alternative catheter-based endovascular interventions have recently been developed to treat such a group of patients.

Aim: To review the indications, short- and long-term outcome, success rate and complications of transcatheter aortic valve implantation (TAVI).

Materials and method: A case with severe aortic stenosis and significant comorbidities is presented and the literature is reviewed regarding the currently applied TAVI.

Results: Presented is a 63-year man with severe aortic valve stenosis and significant concomitant disorders including diabetes, multifactorial anaemia, chronic renal impairment, chronic obstructive pulmonary disorder, peripheral arterial disease and bilateral renal carcinoma. The patient was eligible for TAVI but had inaccessible vascular approach. Transapical and transaortic access were excluded because of poor respiratory function. Medical treatment was continued. Recent data from international literature showed that the success rate of TAVI varied from 83.1% to 100%, complications such as vascular and conduction disorders were between 3.3-18% and 0-34.4%, respectively and the reported 30-day mortality rate ranged from 0% to15.2% in different series.

Conclusions: Our patient with severe aortic stenosis and significant comorbidities had a high-risk for conventional aortic valve replacement and was inaccessible for TAVI. He remained on medical treatment. The TAVI procedure in eligible patients is safe and efficacious with not infrequent procedure-related complications due to advanced age, pre-existent poor conditions of respiratory and renal systems and co-morbidities of the selected subjects.

Keywords: Aortic stenosis; Transcatheter aortic valve implantation

Introduction

Aortic valvular stenosis is the most common valvular heart disease (VHD) in adult population [1]. Conventional treatment of choice for VHD in ageing population is surgical valve replacement [2] which is associated with relief of symptoms and a high survival rate. Surgical aortic valve replacement is the treatment of choice in patients with severe aortic stenosis [3] which is associated with low morbidity and mortality. Several life-threatening co-morbidities or contraindications could render some of these patients at high risk for surgical intervention. Alternative techniques have been developed to treat these high-risk patients such as balloon valvuloplasty which has been limited by its high rate of restenosis [4,5]. In 2002, the first report in humans of a successful transcatheter aortic valve implantation (TAVI) was performed by Cribier and coworkers using an antegrade transseptal approach [6]. Recently several bioprosthetic valves have been developed and techniques have been improved for TAVI. Safety and efficacy of TAVI have been objectively shown by Figulla et al [7]. It should be emphasized that TAVI is contraindicated in patients with ventricular septal defect and infective endocarditis [8]. The occurrence of strokes, requirement for permanent pacemaker and early tamponade related to TAVI procedures have been reported with an incidence varying from 0%-9.6% [9,10], 3.4%-34.4% [11,12] and 1.1%-3.8% [11,13], respectively. Comparison between transcatheter aortic valve implantation (TAVI) and medical therapy has learned that at one-year follow-up, the mortality rate from any cause was lower (30.7%) in the TAVI group as compared with 50.7% in the conventionally treated group [11]. It has been reported that one-year survival rate of unoperated patients with aortic valvular stenosis is estimated at 60% [14]. One-year survival rate for TAVI was 75.9% compared with 62.4% for medically treated patients and moreover, the survival rate after transvascular approach (79.2%) was higher than following transapical procedures (73.6%) [7].

Herein, the case of a 63-year old man with symptomatic severe aortic stenosis with concomitant significant co-morbidities is discussed and the literature is reviewed.

Case Report

A 63-year-old man was admitted to the hospital with a 5 week history of dyspnoea on the slightest exertion and reduced exercise tolerance. On physical examination, he was tachypnoeic with a blood pressure of 180/67 mm Hg, pulse regular at 108 bpm. The heart sounds were normal with a crescendo-decrescendo systolic murmur. Normal respiratory sound with rhonchi were heard on auscultation of the lungs. His body mass index was 23.4 (length 174 cm and weight 71 kg). The patient was in New York Heart Association functional class III. He was a smoker. De "novo" diabetes mellitus was recently

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Received November 01, 2011; **Accepted** December 18, 2011; **Published** December 22, 2011

Citation: Said SAM (2011) Currently Applied Non-Surgical Techniques for Treatment of Severe Aortic Stenosis in Inoperable High-Risk Adult Patients. J Clinic Experiment Cardiol S3:003. doi:10.4172/2155-9880.S3-003

discovered. Chest X-ray revealed infiltrative lesions. Computed Tomography of the chest and abdomen demonstrated bilateral pleural effusion, bilateral infiltrative lesions, mediastinal lymphadenopathy and bilateral renal masses (maximal diameter right 5.2 cm and left 12.3 cm). Admission ECG depicted sinus tachycardia, with signs of left ventricular hypertrophy (LVH) and secondary repolarisation disturbances. Transthoracic echocardiography revealed normokinetic left and right ventricles with heavily calcified aortic valve with aortic valve area of 0.8 cm^2 with peak gradient of 52 mmHg (mean 33 mmHg) and transvalvular velocity of 3.6 m/sec, moderate mitral regurgitation (MR) and aortic regurgitation (AR) and moderate LVH with a left ventricular ejection fraction of 45% and normal estimated pulmonary artery pressure (36 mmHg). At coronary angiography, both coronary arteries had normal origin without significant atherosclerotic changes. He was treated medically with insulin, aspirin 80 mg, long-acting nitrate 25 mg, bumetanide 1mg, spironolacton 12.5 mg, metoprolol retard 25 mg, atorvastatine 40 mg, tamsulosine 0.4 mg and antibiotic course. Few weeks later he was readmitted with incapacitating symptoms of dyspnoea and decreased exercise tolerance. The patient was evaluated at a multidisciplinary team for surgical aortic valve replacement (AVR). The patient had an EuroScore of 20% was rejected for AVR because of a multiple co-morbidities, including type I diabetes mellitus, chronic moderate renal impairment, chronic obstructive pulmonary disorder, bilateral renal carcinoma, multifactorial anaemia and suspected urinary bladder papillary carcinoma. He was selected by the multidisciplinary team, for TAVI. The patient was referred to an academic center for TAVI. Transfemoral (TF) access failed due to tortuousity and calcification of the iliofemoral trajectory. The subclavian artery (TSc) was inaccessible because of its small diameter of 5.7 mm. The patient had Poor respiratory function. Due to lack of improvement of the pulmonary function, following intensive treatment course, the patient was ineligible for transapical (TA) or transaortic (TAo) approach. He remained on a medical regimen. The patient succumbed at home four months after discharge. Autopsy was refused by his family.

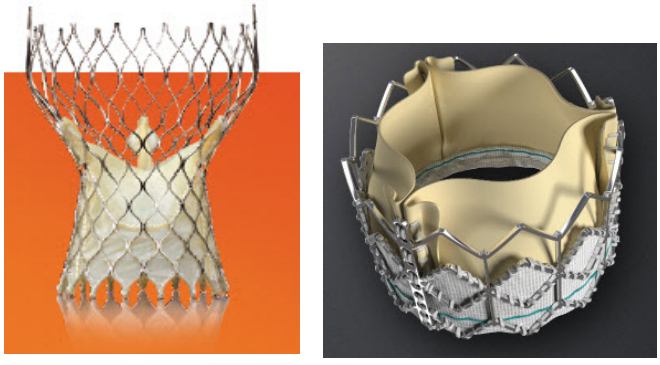
Discussion

In the current patient, transcatheter aortic valve implantation (TAVI) was considered by two heart teams, but TF access failed because of severe tortuousity of the ilio-femoral vessels. In the series of Bleiziffer et al, in 20% of patients TF approach was contraindicated due to peripheral artery disease [15]. TAVI is a novel technique for treatment of severe aortic valve stenosis in patients who are ineligible for conventional surgical aortic valve replacement (AVR) due to significant co-morbidities or presence of contraindications. TAVI has been proven to be safe and efficacious compared to surgical AVR [8]. The success rate of TAVI regardless the bioprosthetic valve used was generally less than 90% before the year 2008 [16-18] but showed - due to gained experience, improved materials and modifications of devices besides inspired heart team formation- a tremendous increase up to 98-100% in the year 2011 [11, 12, 19, 20]. Figulla et al reported objectively in a systematic review the safety and efficacy of TAVI and the mean 1-year survival rate of patients undergoing TAVI was significantly higher (75.9%) compared with medical treatment (62.4%) [7]. It was pointed out that medical management alone is associated with a high mortality rate (42.3%) [21]. TAVI has been performed via transapical (TA) [19,22] or transvascular (arterial) approaches. The transvascular access was possible via femoral (TF) [10,19,22], subclavian (TSc) [23], axillary (TAx) [12] arteries or transaortic route (TAo) [20]. No differences were found between the use of either 18 or 21 French CoreValve devices in symptomatic patients undergoing TAVI [18]. Since balloon valvuloplasty prior to TAVI may be partially incriminated for the occurrence of distal embolisation and atrioventricular block, Grube et al in a pilot study performed TAVI without predilatation. In this study, TAVI was feasible and safe but the rate of new pacemaker implantation (11.7%) and stroke (5%) in patients undergoing TAVI procedures without prior valvuloplasty [24] were similar to that with predilatation, 11.8% [19] and 5% [22], respectively. The bioprosthesis currently used are CoreValve (Medtronic, Minneapolis, Minnesota, USA) introduced mainly via TF route and Edwards Sapien (Edwards Lifescience, Irvine, California, USA) (Figure 1 A and B) introduced via TA or TF route. Comparison between the two available valves is outlined in Table 1.

The pivotal PARTNER trial was the first randomized clinical trial comparing TAVI with surgery presenting patients who could benefit from either procedure. This trial was conducted as a noninferiority trial with the primary endpoint of death from any cause at 1 year [11]. In addition, it has been demonstrated that at 1-year follow-up, the rate of death from any cause was significantly lower in the TAVI group (30.7%) than in the standard-therapy group (50.7%) and the 30-day mortality was 3.4% for TAVI group and 6.5% for surgical AVR group (predicted death was 11%), this was achieved at the cost of higher bleeding rates and stroke rate seen with TAVI group [11].

Prerequisite conditions, besides healthy clinical judgment and accessible route for performing percutaneous (transfemoral, transaxillary or subclavian) or operative TAVI (transaortic or transapical) procedures, are among others left ventricular ejection fraction of > 20%, appropriate diameter of the aortic annulus (18-25 mm), adequate renal and respiratory functions. Excluded from the PARTNER trial were all patients with bicuspid or noncalcified aortic valve, acute myocardial infarction, severe MR or AR, transient ischaemic attack or stroke within the previous 6 months, severe renal insufficiency, left ventricular ejection fraction of < 20% and a diameter of the aortic annulus < 18 mm or > 25 mm [11]. Our patient was free of the aforementioned conditions but vascular routes for percutaneous TAVI (TF or transsubclavian) were inaccessible. Moreover his poor respiratory condition deprived "the last resort" of operative TAVI (TA or transaortic) approach.

In patients undergoing TAVI, severely elevated pulmonary artery systolic pressure (above 60 mmHg) has been associated with high mortality rate [25]. EuroScore logistic score was not well correlated with the predicted mortality in aged high-risk patients with cardiac and



A: CoreValve B: Edwards Sapien

Figure 1: A: CoreValve (Medtronic, Minneapolis, Minnesota, USA) and **B:** Edwards Sapien (Edwards Lifescience, Irvine, California, USA).

	CoreValve	Edwards Sapien
Access	Retrograde: TF, transsubclavian	Retrograde and antegrade: TF, transsubclavian, TA
Valve size	26, 29, 31 mm	23, 26 mm
Valve height	55, 53, 52 mm	14.3, 16.1 mm
Aortic annulus diameter	20-23, 23-27, 26-29 mm	18-22, 21-25 mm
Delivery system	18 Fr introducer	21 or 24 Fr introducers
Device	Bioprosthetic trileaflet porcine pericardial tissue valve mounted and sutured in a self-expandable nitinol stent frame	Bioprosthetic trileaflet bovine pericardial tissue valve mounted on a balloon expandable stainless steel stent. The 2d generation has a cobalt-chromium frame
Success rate	98%	97%
Occurrence of a new left bundle branch block	38%-60%	16%
Need for a new pacemaker	22%-28%	5%

TF=transfemoral;TA=transapical

Table 1: Comparison between the CoreValve (Medtronic, Minneapolis, Minnesota) and Edwards Sapien (Edwards Lifescience, Irvine, CA) [19,20,22,36-38].

Author/year/reference	Patients / valves	Success rate	Approach	30-day mortality	Type of study
Eltchaninoff 2011[19]	244 ES68%, CV32%	98.3%	TV 71% TA 29%	12.7%	Prospective multicenter national registry
Ewe 2011[13]	104 ES100%	92.5%	TV 44% TA 56%	9.6% TV 11.1% TA 8.5%	Prospective single center with retrospective analysis
Leon 2010 [11]	173/358 ES100%	95.4%	TV 100%	6.4%	Prospective multicenter randomized trial
Bosmans 2011[22]	328 ES43%, CV57%	97%	TV 73% TA 27%	ES 12% CV11%	Prospective non-randomized multicenter national registry
Buellesfeld 2011[10]	126 CV100%	83.1%	TV100%	15.2%	Prospective multicenter study
Conradi 2011[9]	28 ES89%, CV11%	96.4%	TV 32.1% TA67.9%	7.1%	Case series: comparative study
Bapat 2011[20]	193 ES100%	100%	TV 44% TA 47.2% TAo 8.8%	TA 7.7% TAo 11.8%	Case series study
Ben-Dor 2011[8]	111	NA	NA	11.7%	Prospective cohort study
Johansson 2011[27]	40 ES100%	92.5% TV91% TA 93%	TV 25% TA 75%	5%	Case comparative study
Lopez-Otero 2011[12]	186 CV100%	98.8-100%	TV 100%	8.4%	Multicenter study
Bleiziffer 2009[15]	137 ES17% CV83%	98.5%	TV 82% TA 17% TAo 1%	12.4%	Single center study
Abdel-Wahab 2011[36]	690/697 ES16% CV84%	98.6%	TV95.5% TA3.7% TAo0.7%	6.7%-15.1%	Multicenter prospective registry
Grube 2011[24]	60 CV100%	96.7%	TV100%	6.7%	Multicenter prospective pilot study
Baan 2010[38]	30 CV100%	90%	TV100%	20%	Single center study
Piazza 2008 [42]	646 CV100%	97%	TV100%	8%	Multicenter registry
Dewey 2008 [21]	21 ES100%	NR	TV TA	9.5%	Single center study
Grube 2007[18][18]	86 CV100%	88%	TV100%	12%	Multicenter study
Webb 2007[17]	50 ES100%	86%	TV100%	12%	Single center study
Grube 2006[16]	25 CV100%	84%	TV100%	20%	Single center prospective nonrandomised study

TV=transvascular (transfemoral, transaxillary and subclavian artery); TA= transapical; NA: not available, TAo= transaortic, PCI= percutaneous coronary intervention, ES= Edwards Sapien bioprosthesis, CV= CoreValve bioprosthesis, NR=not reported.

Table 2: Current success rate and short-term outcome of transcatheter aortic valve implantation.

non-cardiac co-morbidities [15]. It has been elucidated in high-risk patients undergoing TAVI that the Society of Thoracic Surgeons (STS) score is superior to logistic EuroScore in predicting 30-day mortality [8]. Ben-Dor et al found that the observed and predicted by STS score mortality rates were 11.8% and 11.7%, respectively. The predicted logistic EuroScore was 4-fold (41.2%) of the STS score. Our current patient had an EuroScore of 20% implicating considerable risk but was considered at higher risk due to his significant co-morbidities. In TAVI, conditions and co-morbidities which may be associated with very high procedure death rates are porcelain aorta, chest wall deformity, chest wall radiation, severely compromised respiratory function, frailty, renal function impairment, diabetes mellitus and peripheral vascular disease [26]. Survival after TAVI with either the transapical or transvascular (transfemoral) approaches is similar to that following surgical aortic valve replacement [27] (Table 2). Since most complications associated with TAVI are vascular in nature, preprocedure evaluation and assessment of the access route is crucial for the safety and success of the procedure [26]. The highest rate of procedure-related vascular complication was reported by Ewe et al [13] (18%) and Johansson et al [27] (30%), in both series a percutaneous TAVI approach was applied. Bagur et al reported an incidence of 11.7% of acute renal injury following TAVI which was associated with increased risk of post procedure mortality but TAVI was associated with a significant lower incidence of acute renal injury than surgical aortic valve replacement (25.9%) [28]. Poor renal function is not considered a contraindication for TAVI, further deterioration can be prevented using diluted contrast medium and periprocedural hydration of the patient [26].

Author/year/reference	Stroke	Cardiac tamponade	Pacemaker requirement	Vascular complication	
				TV	TA
Eltchaninoff 2011 [19]	3.6%	2%	11.8%	6.9%	5.6%
Ewe 2011 [13]	2.9%	3.8%	3.8%	18%	5%
Leon 2010 [11]	6.7%	1.1%	3.4%	16.2%	NA
Bapat 2011 [20]	6.6%	None	None	3.3%	NA
Buellesfeld 2011 [10]	9.6%	None	26.2%	None	
Bosmans 2011 [22]	5%	None	13%	None	
Johansson 2011 [27]	7.5%	None	None	30%	0%
Bleiziffer 2009 [15]	5.1%	None	19.7%	11.7%	NA
Lopez-Otero 2011 [12]	0.5%	None	34.4%	4.3%	NA
Abdel-Wahab 2011 [36]	2.7%	None	23%	4.1%	NA
Baan 2010 [38]	0%	6.7%	23.3%	NR	NA
Grube 2007 [18]	10%	7%	NR	NR	NR
Grube 2011 [24]	5%	None	11.7%	10%	NA

TV=transvascular (Transfemoral, trans-axillary, subclavian artery), TA= transapical, NA= not applicable, NR=not reported.

Table **3:** Complications of transcatheter aortic valve implantation.

Although TAVI is less invasive than surgical procedure, it is associated with several complications (Table 3): Fatal and non-fatal complications have been reported. Careful interpretation of the figures is warranted due to disparities of the study populations included in the different publications.

Transvascular approach: Major complications occurred in 3/10 (30%) of TAVI treated patients using TF approach [27]. Fatal complications are infrequently reported. Reported fatal complications of TAVI following transvascular access are rupture of papillary muscle causing severe mitral regurgitation [29] and perforation of the descending thoracic aorta [30].

Transapical approach: Additional reported complications of TAVI following transapical access are development of false aneurysm of the left ventricle [31]. Dislocation and migration of the Edwards Sapien aortic valve prosthesis (Edwards lifesciences, Irvine, California, USA) into the left ventricle has been observed 2 weeks after transapical procedure [32]. Furthermore, using either CoreValve or Edwards Sapien valve, reports of single cases of acute occlusion of left main coronary artery [33], ostial occlusion of the right coronary artery requiring percutaneous coronary intervention [34] and may be associated with hemodynamic deterioration due to bilateral obstruction of right and left coronary ostia necessitating coronary artery bypass grafting [35] were published.

Valvular complications: Significant aortic regurgitation (≥ 2) was angiographically detected in 119/690 (17.2%) which was associated with higher rates of in-hospital mortality, low cardiac output and respiratory failure [36]. Fatal AR was described by Bosmans et al [22]. Lower figures were reported by Ewe et al (4.7%) and by Leon et al (11.8%) [11,13]. Considerable AR (>2) was not seen in the series of Lopez-Otero et al, either in the TF or in the TAx treated patients [12]. It was found that the occurrence of significant AR was neither related to the type nor to the size of the valve applied in TAVI and there was no difference found between patients treated via either the TF or TA approach [36].

Conduction disorders and need for new permanent pacemakers implantation: In a report of 154, TAVI was performed via percutaneous TF approach in (47%) and by operative TA access in (53%) of patients. Pre-existent left bundle branch block (LBBB) was found in 15 patients (10%). In 40/139 (29%) a new LBBB was detected after TAVI. Persistence of LBBB was seen at 30-days follow-up in 18/40(45%). Implantation of CoreValve was associated with higher frequency of development of new LBBB (38%) versus Edwards Sapien (16%) valve implantation. Considered predictors of new LBBB were prosthesis implantation depth into the left ventricular outflow tract (LVOT) and use of CoreValve bioprosthetic valve [37]. Furthermore, new 2nd or 3rd degree AV block was reported in 156/690 (23%) of patients treated by either available valves using TF or TA access [36]. Baan et al reported the occurrence of new LBBB in 60% of patients following CoreValve implantation [Baan] [38]. In the series of Fraccaro et al treated with CoreValve, they observed worsening of the pre-existent conduction disorders after TAVI in 77% of the patients. Of those 39% required permanent pacemaker implantation. New left bundle branch block was the most frequent (44%) occurring conduction disorder. In addition, it was disclosed that the independent predictors of permanent pacemakers were the depth of prosthesis implantation and pre-existing right bundle branch block [Fraccaro]. Permanent pacemakers were required in 11.8% of patients in the series of Eltchaninoff et al. [19]. Overall 34% needed definitive pacemaker implantation for atroiventricular block in 64/186 (34%) patients [12]. In the series of Lopez-Otero et al, 8/19 (42%) of patients required permanent pacemaker in the group treated via axillary approach and 56/167 (33%) in the femoral access group [12]. Avanzas et al found that 38/108 (35.2%) needed permanent PM for acquired atrioventricular block [40] and Grube et al reported 30/102 (33.3%) [41]. In the series of Leon et al, in only 3.4% of patients, permanent pacemaker was required at 30-days and 4.5% at 1-year follow-up [11] in contrast with the finding of Buellesfeld et al. of 26.2% who required definitive pacemaker [10]. The percutaneous approach was transvascular in 100% of cases in both series. In the series of Bosmans et al, the percentage of patients requiring permanent pacemaker was significantly higher in the CoreValve receiving patients (22%) compared to the Edwards Sapiens treated patients (5%) [22]. Conradi et al found a comparable figure of (7.1%) [9].

Coronary artery occlusion

Single reports were published regarding occlusion of left main coronary artery [33] and this was seen in 1.2% of cases [19].

Myocardium and valvular

False aneurysm of the left ventricle [31], rupture of papillary muscle causing severe mitral regurgitation [29] and aortic dissection have occurred [22].

Pericardium

Pericardial effusion was not frequently reported occurring in 3.6%-5.9% of patients [15,20]. Cardiac tamponade was described in 2% of cases in one series [19] and in 3.8% of patients in another series [13]. Late fatal tamponade has rarely been reported [22].

Vascular and aortic

Vascular complications are encountered more often in patients treated via the femoral access (18%) compared to the transapical access (5%) [13]. Rupture of the femoral artery after insertion of the introducer sheath has been described [27]. In the series of Lopez-Otero et al, they reported 4.2% vascular complications [12]. Vascular complications were seen in 7.3% in one study [19] and reported in 16.2% in another publication [11]. Perforation of the descending thoracic aorta [30] has occurred once and it has been observed that peripheral vascular disease was more frequent in patients treated with TA approach [13].

Cerebrovascular events

These are the "Achilles heel" of the procedure. [27] in the series of Johansson et al, it was reported in three patients 3/40 (7.5%). Also 5.3% [12]. Stroke was reported by Eltchaninoff in 3.6% of cases [19]. Leon et al described 6.7% in their series [11] which is comparable to the findings of Bapat et al 6.6% [20]. The lowest reported rate of 2.7% was recently published in the largest series of Abdel-Wahab et al. [36]. In the series of Ewe et al, this was 3.8% [13]. The differences between these series may be related to the pre-existent condition of patients, the definition and imaging method used for the diagnosis of cerebrovascular events. In the series of Conradi et al, none of the patients developed minor or major stroke [9].

Endocarditis

Early infective endocarditis is rare which was reported by Lopez-Otero et al in one patient 1/186 (0.5%) [12] and seen in 1.1% (2/179) of patients reported by Leon et al. [11].

Acute renal failure

Was found in 7.1% (2/28) of patients [9]. But Bagur et al reported that acute kidney injury occurred in 12% which was associated with 4-fold increase in postoperative death [28]. It has been reported that transapical approach is associated with significantly lower total volume of contrast medium [13,27]. This approach may be highly preferable, if the peripheral vascular status is accessible, in patients with poor renal function [13,27].

Conclusion

Based on the reviewed current literature, TAVI, performed in specialized centers with highly qualified specialists either by surgical team alone and/or combined with interventional cardiologists and radiologists, is safe and efficacious procedure in high-risk patients who are not amenable for conventional surgical AVR. Currently 2 bioprosthetic valves are available for percutaneous implantation using the transapical, transaortic or transvascular (transfemoral, transaxillary, subclavian) approach. Each approach has its own success rate and associated procedure-related complications.

Acknowledgements

The authors wish to thank Mrs. A. Geerdink and Mr. D. Maas, librarian of hospital Group Twente for their assistance during the preparation of the manuscript.

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This article was originally published in a special issue, **Valvular Heart Diseases** handled by Editor(s). Dr. Peter A. McCullough, Oakland University, USA; Dr. Yasmin S. Hamirani, University of New Mexico, USA