

# Percutaneous Aortic Valve Replacement – A Review

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### **Introduction:**

The most common type of aortic valvular disease today is senile calcific aortic disease and may result in stenosis, regurgitation, or a mixture of these. A study in 2000 by Otto and colleagues documented calcific aortic stenosis by echocardiography in 2.9% of adults older than 65 years.<sup>1</sup> Rheumatic disease continues to account for a large proportion of acquired valvular disease, though its incidence is declining.<sup>2</sup> Congenital malformations, such as bicuspid aortic valve, as well as acquired insults, such as endocarditis, myxomatous proliferation, and trauma, also contribute to the spectrum of aortic valvular disease.

Medical therapy is helpful but unlikely to modify the course of the disease, especially once symptoms or left ventricular dysfunction become manifest. The initial attempts to treat non-surgical patients with advanced aortic stenosis began with balloon aortic valvuloplasty (BAV) in 1985.<sup>3</sup> This technique, initially met with enthusiasm, was largely abandoned by clinicians as the benefits of valvuloplasty rarely lasted more than one year.<sup>4</sup> Surgical valve replacement or repair remains the mainstay of definitive treatment for both aortic stenosis and aortic regurgitation. While surgical therapy is effective, it entails the risks and morbidity associated with cardiopulmonary bypass and median sternotomy.

In 1999, the Society of Thoracic Surgeons reported an operative mortality rate from isolated aortic valve replacement (AVR) of 4.3% in >26,000 patients and up to 8% in >22,000 patients undergoing combined AVR with coronary artery bypass grafting.<sup>5</sup> A recent study of 2359 patients undergoing surgical aortic valve replacement in Sweden documented a 5.9% mortality rate at 30 days.<sup>6</sup> Higher operative mortality rates of 8% to 20% are observed in patients with concomitant left ventricular failure.<sup>7</sup> The elderly have also been

shown to have higher operative mortality from surgical aortic valve replacement.<sup>6</sup> However, almost one-third of patients with severe valvular lesions who could benefit most from intervention are declined for operative treatment because of end-stage disease, advanced age, and multiple comorbidities with subsequent short life expectancy.<sup>8</sup> The size of this untreated cohort is expected to increase in the next several years reflecting the aging population and improving therapeutic options in patients with multiple and advanced medical conditions.<sup>9</sup>

A percutaneous approach to aortic valve replacement would, therefore, be a welcome option for many patients. Though previous attempts at percutaneous valve replacement in the aortic position had been limited by the applicability to humans,<sup>10-11</sup> this percutaneous heart valve (PHV) was successfully implanted on April 16, 2002, in a patient with inoperable aortic stenosis and life-threatening comorbidities.<sup>12</sup> Since then, improvements in technique and a more complete comprehension of percutaneous aortic valve replacement have been developed and reported in small studies.

### **Challenges:**

The early experience with percutaneous pulmonary valve replacement proved the concept of transcatheter valve insertion to be technically feasible. However, the anatomy of the aortic valve presents several unique challenges. The positioning of any implanted valve must be extremely precise, as the aortic valve lies in close proximity to both the mitral valve and the coronary ostia. If the valve is to be placed in the anatomic position, malposition of the prosthesis in either direction could result in severe acute mitral dysfunction or severe acute ischemia. One must also decide, therefore, if placement in the anatomic position is indeed the most practical approach. An alternative strategy

would be to place the valve in the ascending aorta, distal to the coronary ostia. This would avoid both the mitral valve and the coronaries but might decrease coronary perfusion if the aortic pressure contiguous with the coronary ostia (and proximal to the valve prosthesis) were too low. If the prosthesis is not placed in the native position, it may be hemodynamically possible to leave a regurgitant native aortic valve in place; however, a stenotic native aortic valve would still require dilation, ablation, or explantation. The stent must be adequately fixed in place such that stent migration or embolization does not occur despite high systemic pressures. The risk of periprocedural emboli must be addressed as well.

Delivery of the prosthesis to the aortic position is challenging, and appropriate vascular access must be established. Venous access would allow easier passage of large-profile valved stents but would entail a transseptal approach with passage through (and possible damage to) the native mitral valve. A transseptal approach would, however, allow antegrade crossing of the native aortic valve, which, compared with retrograde crossing, may allow easier and more precise placement of the prosthesis due to less motion of the large delivery system during the cardiac cycle. Arterial access would allow direct retrograde crossing of the native aortic valve without the need for transseptal puncture and would avoid potential damage to the mitral valve; however, it would require a low-profile system if surgical vascular access and repair is to be avoided.<sup>13</sup>

### **Animal models**

In 1992, Anderson and colleagues published the first reports of percutaneously implanted aortic valves in animal models using porcine valves in a porcine model;<sup>14</sup> and Pavcnik and colleagues reported using artificial ball-in-cage valves in a canine model.<sup>15</sup>

In 2001, Boudjemline and Bonhoeffer described the implantation of a prosthetic aortic valve into a lamb.<sup>16</sup> The valve prosthesis, initially used for percutaneous pulmonic valve replacement, was composed of a section of bovine jugular vein

containing a native venous valve that was sewn into a platinum stent. The implanted valve continued to function normally as documented by transesophageal echocardiography at 2 weeks, and the lamb remained healthy throughout the 4-week follow-up period. In February 2002, Boudjemline and Bonhoeffer described their technique in more detail in a series of 12 lambs.<sup>17</sup>

In April 2002, Lutter and colleagues described 14 pigs into which either cadaveric porcine aortic valves or porcine pericardial valves were placed percutaneously.<sup>18</sup> The valves were sewn inside self-expanding nitinol stents, and hooks were used to anchor the stents in position. The stents ranged in length from 21 to 28 mm. To preserve coronary perfusion, the valved stents were not positioned in the native aortic position, but rather were implanted in either a subcoronary position in the left ventricular outflow tract, a supracoronary position in the ascending aorta, or in the proximal descending aorta. Technical failure occurred in 2 pigs due to twisting of the delivery assembly in the ascending aorta.

In July 2002, Boudjemline and Bonhoeffer reported their results after they placed a bovine jugular valved stent into the descending aortas of 8 lambs.<sup>19</sup> The lambs had aortic regurgitation induced by transseptal puncture of a native aortic valve leaflet followed by balloon dilation. Half the group had severe regurgitation induced using an 18-mm balloon and half had mild regurgitation induced using a 10-mm balloon.

### **Human trials**

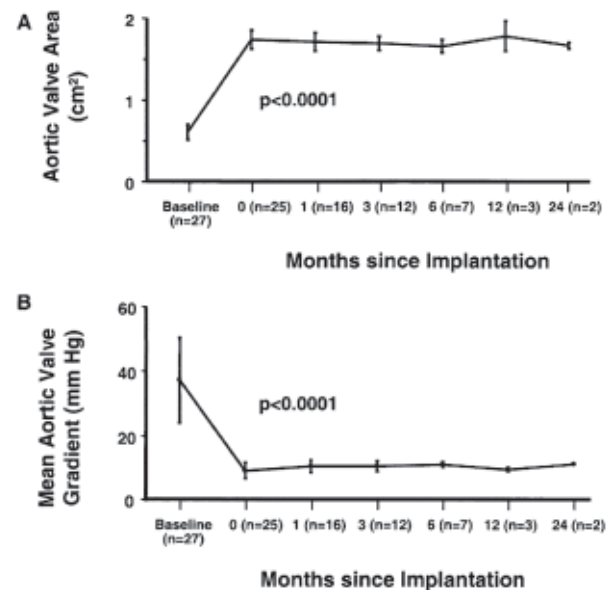
In December 2002, Cribier and colleagues described the first human implantation of a prosthetic aortic valve.<sup>20</sup> The patient was a 57-year-old man with a history of chronic pancreatitis, lung cancer, asbestosis, and severe peripheral arterial disease who had presented in cardiogenic shock due to severe calcific aortic stenosis with a bicuspid aortic valve. A prosthetic aortic valve fashioned from bovine pericardium and sewn into a stainless steel stent was placed in the native position. They used a shorter 14-mm stent to minimize the risk of coronary obstruction while allowing placement of the valved stent in the native

position. Femoral venous access was established using a 24F sheath. Follow-up transesophageal echocardiograms obtained at weeks 1, 4, 7, and 9 documented normal valve function with stable paravalvular regurgitation. The patient died 17 weeks after valve implantation due to sepsis.

In February 2004, Cribrier and colleagues reported a series of 6 additional patients in whom percutaneous aortic valve replacement was performed.<sup>21</sup> The patients ranged in age from 57 to 91 years, had severe calcific aortic stenosis, had been declined surgery due to multiple comorbidities, and had New York Heart Association functional class IV congestive heart failure. As in the patient from the December 2002 report, the valve prostheses were implanted using a venous, transseptal approach. Right ventricular pacing was performed briefly at rates up to 220 beats per minute during balloon inflation to temporarily reduce cardiac output and allow for more stable and precise positioning of the valved stent. The valve used in these patients was composed of equine pericardium sewn into a stainless steel stent. There was 1 procedural death due to premature dislodgement of the valved stent from the delivery system with embolization into the ascending aorta. In 2 other patients, severe mitral regurgitation developed. In all cases, angiography showed unobstructed coronaries and revealed an average mean gradient across the prosthesis of only 5.6 mm Hg. Three patients died of noncardiac causes at weeks 2, 4, and 18. The remaining 2 patients were reported to be alive and clinically stable at 8 weeks. In all cases, follow-up echocardiography showed normally functioning valve prostheses and only mild interatrial shunting. Varying degrees of perivalvular regurgitation were observed in all cases.

In a recent report of Cribrier and colleague, 36 patients (aortic valve area  $<0.7 \text{ cm}^2$ , New York Heart Association [NYHA] functional class IV, and severe comorbidities), formally declined for surgery, were recruited on a compassionate basis.<sup>9</sup> The PHV was implanted by retrograde or antegrade trans-septal approach. Clinical and echocardiographic outcomes were assessed serially. Twenty-seven patients were implanted successfully (23 antegrade, 4 retrograde) in the

subcoronary position with improvement in valve area ( $0.60 \pm 0.11 \text{ cm}^2$  to  $1.70 \pm 0.10 \text{ cm}^2$ ,  $p < 0.0001$ ) and transvalvular gradient ( $37 \pm 13 \text{ mm Hg}$  to  $9 \pm 2 \text{ mm Hg}$ ,  $p < 0.0001$ ). Paravalvular aortic regurgitation was grade 0 to 1 ( $n=10$ ), grade 2 ( $n=12$ ), and grade 3 ( $n=5$ ). One week post-procedure, improvement in left ventricular function ( $45 \pm 18\%$  to  $53 \pm 14\%$ ,  $p=0.02$ ) was most pronounced in patients with ejection fraction  $<50\%$  ( $35 \pm 10\%$  to  $50 \pm 16\%$ ,  $p < 0.0001$ ). Thirty-day major adverse events after successful implantation were 26% (pericardial tamponade, stroke, arrhythmia, urosepsis, and one death unexplained at autopsy). Eleven patients were alive with follow-up of 9 months ( $n=2$ ), 10 months ( $n=3$ ), 11 months ( $n=1$ ), 12 months ( $n=2$ ), 23 months ( $n=1$ ), and 26 months ( $n=2$ ). All patients experienced amelioration of symptoms ( $>90\%$  NYHA functional class I to II). Percutaneous heart valve function remained unchanged during follow-up, and no deaths were device-related. In long term follow up, the rate of progression of aortic valve area and gradient were shown in figure-1.



**Fig.-1:** (A) Improvements in aortic valve area in patients 24 h, 1, 3, 6, 12, and 24 months after successful implantation. (B) Decrease in mean aortic gradient in patients 24 h, 1, 3, 6, 12, and 24 months after successful implantation.

Descoutures and colleague published the most recent trial with PAV. Sixty-six consecutive patients >70 years (83±6 years) were referred for severe AS.<sup>22</sup> Their mortality risk predicted by the logistic European System for Cardiac Operative Risk Evaluation and the Society of Thoracic Surgeons-Predicted Risk of Mortality scores were on average 20±14% and 17±7%, respectively. Thirty-nine patients (59%) were considered at high-risk for surgery or inoperable after multidisciplinary evaluation: 12 (31%) underwent a transfemoral aortic valve implantation and 27 were considered unsuitable and treated medically (n =16) or with valvuloplasty (n = 7), or were re-directed towards surgery (n = 4). The 27 other patients underwent valve replacement. The valve was implanted in the correct position in 10 patients (83%). Valve implantation was not successful in two patients. Reasons for failure included inability to pass iliac artery and hemopericardium in one patient because of perforation of the left ventricle by the wire, leading to intraprocedural death in a 94-year-old woman. In another case, a rescue ‘prosthesis-in-prosthesis’ implantation was needed for haemodynamic compromise because of severe intravalvular leak after placement of the first

prosthesis. Otherwise, a grade-III paravalvular leak was noted in one patient, with no immediate haemodynamic consequence. All other patients had no, or <grade II aortic regurgitation. Two patients suffered iliac injury requiring vascular grafting. There were two post-procedural deaths: one occurred 4 days after the procedure and was the consequence of major vascular surgery after iliac injury, the other occurred 24 h after the procedure in an 85-year-old man with the highest EuroSCORE among the series (59%), but remained unexplained.

Outcomes at 6 months are shown in Table-1. There were no deaths in patients treated by AVR or PAVI. Twenty-nine percent of the patients died after medical treatment (2/7) or BAV (4/14). In survivors, 78% (7/9) of the patients treated by PAVI and 87% (26/30) of those treated by AVR were in NYHA classes I or II, while 60% (3/5) of the patients treated by BAV and 80% (9/10) of those treated medically remained in classes III or IV. This study indicates that a large proportion of AS patients have high risk features, and that a tailored treatment strategy using PAVI or surgical AVR may increase the number of those who can receive an effective treatment.

**Table-I**

*Six-month outcomes in 60 hospital survivors after treatment of severe aortic stenosis by percutaneous aortic valve implantation, balloon aortic valvuloplasty, medical therapy, or surgical aortic valve replacement<sup>22</sup>*

	PAVI (n=9)	BAV (n=7)	AVR (n=14)	AVR (n=30)
Death	0	2 (29)	4 (29)	0
Hospitalization				
CHF	2 (22)	1 (14)	5 (36)	2 (7)
Other cause	3 (33)	0	1 (7)	7 (23)
NYHA Class				
I	2(22)	0	0	12(40)
II	5(56)	2(40)	2(20)	14(47)
III	2(22)	1(10)	7(70)	3(10)
IV	0	2(40)	1(10)	1(3)

Values are expressed as n (%) unless otherwise stated. PAVI, percutaneous aortic valve implantation; AVR, aortic valve replacement; BAV, balloon aortic valvuloplasty; CHF, congestive heart failure; NYHA, New York Heart Association.

**Table-II**

*Inclusion criteria for PAVI using the retrograde femoral approach in the REVIVE (Registry of EndoVascular Implantation of Valves in Europe) study<sup>22</sup>*

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Age >70 years
Severe aortic stenosis from degenerative origin
Symptomatic
Valve area <0.7 cm <sup>2</sup>
Surgical mortality predicted by the logistic EuroSCORE >20%
Alternative criteria
Porcelain aorta
Radiation of the sternum or chest deformities precluding an open chest surgery
Severe chronic obstructive pulmonary disease
Patients referred for surgery and rejected by the surgeon
Adequate diameters
Aortic annulus >18 mm and <25 mm
Femoro-iliac axes >8 mm or 9mm

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**Table-III**

*Contraindication of PAVR<sup>22</sup>*

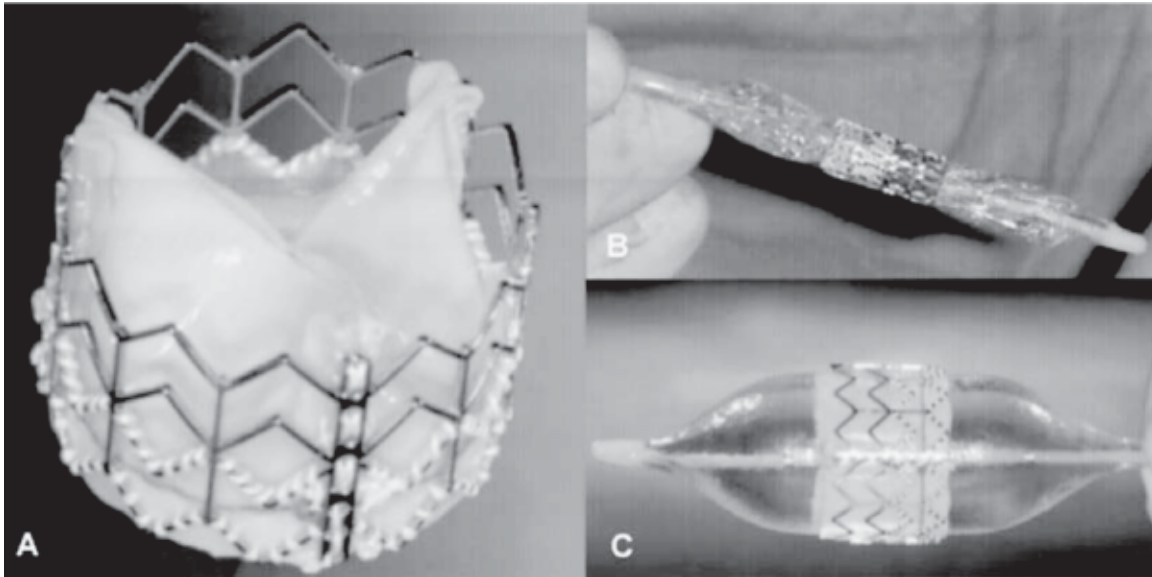
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- (i) Left main stenosis >70%, (assessed by coronary angiogram)
  - (ii) Aortic annulus diameter <18 mm or >25 mm, (measured from the echocardiographic parasternal longaxis view at the level of the leaflet attachment)
  - (ii) Iliofemoral disease or diameters, < 8 or 9 mm, according to the diameter of the sheath (22 or 24F) (by conventional angiography and computed tomography)
  - (iii) Any condition that made the quality or duration of life unlikely, despite AVR.
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### **Procedure<sup>9,22</sup>**

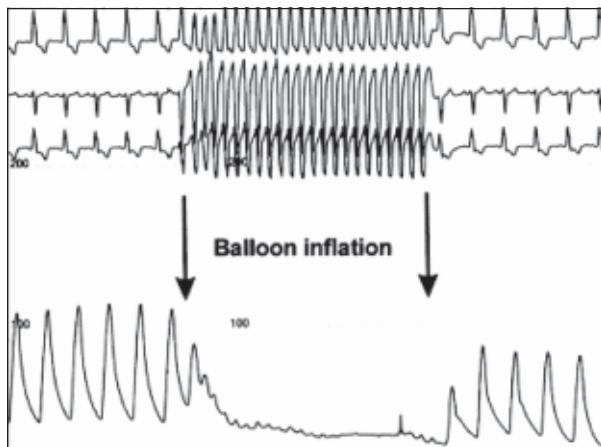
Procedures are usually performed in a catheterization laboratory, under local or general anaesthesia, with fluoroscopic and transoesophageal echocardiographic guidance. Aspirin (160 mg) and clopidogrel (300 mg) are given 24 h before valve placement; antibiotics for procedural prophylaxis (usually first generation cephalosporin) is given 1 h before. After measurement of baseline hemodynamics, supra-aortic angiography and placement of a right ventricular pacing lead are performed. Heparin 5,000 IU is given intravenously before retrograde catheterization of the aortic valve. Retrograde predilatation of the aortic valve is done with a 23-mm Z-MED balloon (NuMED Inc., Hopkinton, New York) during rapid ventricular pacing (200 to 220 stimulations/min) (Fig. 3). But antegrade dilatation of aortic valve can be done. There are two systems for delivery of the valve -an antegrade trans-septal or retrograde approach.

In the antegrade approach, atrial trans-septal catheterization is used, and a 7-F Swan-Ganz catheter (Edwards LifeSciences, Irvine, California) is used to cross the mitral valve and direct a guidewire across the aortic valve (Fig. 4A). Using the pigtail catheter as a conduit, this guidewire is exchanged for an extra stiff guidewire, which was snared and externalized through the left femoral artery sheath. The septum is then dilated with a 10-mm septostomy balloon. The PHV is advanced over the guidewire through a 24-F sheath (COOK, Bjaeverskov, Denmark) in the right femoral vein. A 7-F Sones catheter (Cordis, Miami, Florida) is advanced over the same guidewire from the left femoral artery to facilitate valve placement (Fig. 4B).

In the retrograde approach, pre-closure of the common femoral artery puncture site is done before introduction of the 24-F sheath. Two separate 10-



**Fig.-2:** (A) Top view of the percutaneous heart valve in the closed position showing the three pericardial leaflets sutured to the stainless-steel stent. (B) Side view of the percutaneous heart valve crimped over a 3-cm x 22-mm balloon catheter. (C) Side view of the percutaneous heart valve after being expanded by the delivery balloon

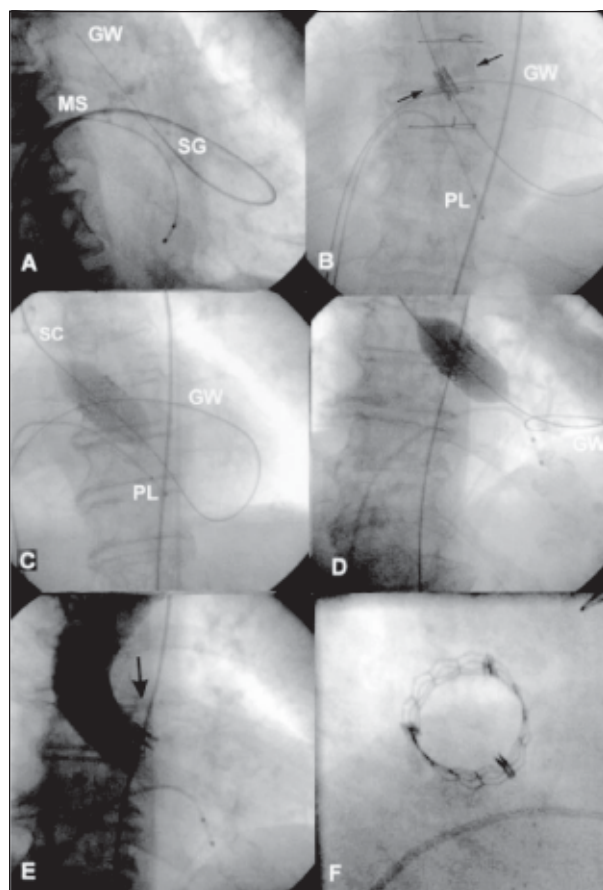


**Fig.-3:** Electrocardiogram and aortic pressure curve depicting the effect of rapid stimulation (arrows) of the right ventricle (200 to 220 stimulations/min).

F sheaths can be used. (Prostar XL devices- Abbott Vascular Devices, Redwood City, California).<sup>12</sup> After retrograde catheterization of the aortic valve, the crossing catheter was exchanged for an extra stiff guidewire, and pre-dilation of the aortic valve was done as described previously. The femoral artery is then predilated with a series of dilators of increasing size (18-, 20-, and 22-F) in order to facilitate entry of the 24-F sheath. Arterial femoral access was obtained percutaneously. A percutaneous sheath (22F or 24F) was carefully inserted in the femoral artery. After retrograde

crossing of the aortic valve and predilation with conventional BAV, the balloon-mounted valve (Edwards- Sapien, Edwards Lifesciences Inc., Irvine, CA, USA) (Fig 2) is passed through the aorta and positioned within the native aortic annulus. Transient partial standstill was induced with right ventricular burst pacing to minimize transvalvular flow. The delivery balloon is then inflated to expand and the valved stent was implanted. The femoral access site is closed surgically.

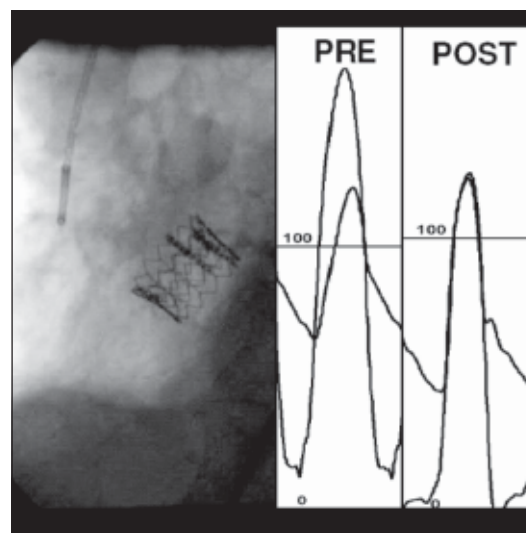
Regardless of the approach used, the final steps of PHV implantation are similar for both methods. The PHV is mounted onto a 22-mm Z-MED II balloon (NuMed Canada Inc., Cornwall, Ontario, Canada) using a specially designed crimper. The supra-aortic angiogram and native valve calcifications are used as anatomical landmarks for valve placement in the anteroposterior projection (mid-line of the stent frame was placed at the level of the calcifications). All valves are deployed (Figs.4C and 4D) during rapid pacing. Hemodynamic improvement is measured immediately afterwards, and a supra-aortic angiogram is performed in patients without renal insufficiency to verify placement as well as the presence of aortic regurgitation (Fig. 4E). A cranial view of the stent-valve is used to evaluate uniform



**Fig.-4:** (A) Swan-Ganz (SG) catheter is used to direct a guidewire (GW) across the native aortic valve in the antegrade approach. (B) Guidewire loop in the left ventricle is tracked by the percutaneous heart valve from the right femoral vein (antegrade approach). Sones catheter (SC) from the left femoral artery is used to help position the percutaneous heart valve. Native aortic valve calcifications (arrows) in the anteroposterior projection transect the mid-line of the length of the stent valve. (C) Deployment of the percutaneous heart valve using the antegrade approach. (D) Valve deployment via the retrograde method. (E) Supra-aortic angiogram showing no aortic regurgitation and the subcoronary position of the percutaneous heart valve (arrow: filling of the left coronary artery). (F) Cranial view of the percutaneous heart valve showing symmetrical and complete expansion of the stent frame. MS\_ Mullins sheath; PL\_ pacing lead.

expansion of the PHV (Fig. 4F). The change of aortic gradient can be recorded immediately (Fig 5) Arterial access is managed using closure devices and/or surgical repair before device use or in cases of device failure. Venous access is managed by

manual compression. Antibiotics are given up to 48 h after the procedure. Subcutaneous enoxaparin (40 mg/day) is administered until the day of discharge. Clopidogrel (75 mg/day) is continued for one month, and aspirin (160 mg/day) is continued indefinitely.



**Fig.-5:** Pressure change before and after percutaneous aortic valve implantation

#### Complication of PAVI:<sup>9,22</sup>

PAVI is plagued by several types of complications. Vascular injury at the access site, usually femoral or iliac arteries, may be serious and may be the primary cause of the death. The incidence of significant periprosthetic regurgitation was initially >25% and, although it is reduced after the introduction of larger prostheses, still occurs in at least 10% of the cases. A high incidence of A-V block has necessitated pacemaker implantation in up to a quarter of the cases. Last, but not least, incorrect implantation of the prosthesis occurs in a significant number of cases. Tamponade specially as a complication of transeptal puncture can be occurred. The implantation procedures are far from being standardized and are not easily reproducible. Procedural success rate is around 75-80%.

#### High-risk features in elderly patients with severe aortic stenosis:

Recent surgical registries consistently observed that overall mortality after AVR is low, around 3%<sup>8</sup>. However, they also showed that the risk is doubled if AVR is combined with CABG.<sup>23</sup>

Moreover, in the Euro Heart Survey, the risk increased up to 25% in a large subset of patients, and 32% of patients with severe, symptomatic single valve disease were not referred for intervention.<sup>8</sup>

Thus, the question of the accurate risk evaluation for AVR is essential to select the best strategy. Several variables have been isolated as independent predictors of early mortality after AVR and have been included in various predictive risk scores, most important of which are the EuroSCORE, the STS-PROM, and the Ambler’s score.<sup>24</sup> All of these scores suffer limitations. However, they are helpful and should be routinely used as an adjunct to multidisciplinary clinical evaluation. A recent study by Dewey et al. suggested that the EuroSCORE overestimated the mortality and that the STS-PROM was the most reliable model for identifying the highest risk patients.<sup>25</sup> The present series confirms the overall expected high risk of mortality in this aged population. It also shows that the mortality risks

predicted by the logistic Euro- Score and STS-PROM scores are closer in low-risk than in high-risk groups, with a trend towards a higher predicted mortality with the EuroSCORE.

**High-Risk Aortic Valve Replacement: Are the Outcomes as Bad as Predicted?**

Percutaneous aortic valve replacement (PAVR) trials are ongoing in patients with an elevated European System for Cardiac Operative Risk Evaluation (EuroScores), patients believed to have high mortality rates and poor long-term prognoses with valve replacement surgery. It is, however, uncertain that the Euro- SCORE model is well calibrated for such high-risk AVR patients<sup>26</sup>. In fact, the EuroScore system has been shown to be one of the most accurate risk-stratification models for cardiac surgery. Geissler and colleagues reported that the EuroScore had the highest predictive value among the six most commonly used risk scores for open heart surgery.<sup>27</sup> Nilsson and colleagues<sup>28</sup> further compared 19 preoperative risk stratification models and found the

**Table-IV**  
*Variables for EuroScore<sup>26</sup>*

Factors	EuroScore
Patient-related factors	
Chronic pulmonary disease	Long-term use of bronchodilators or steroids
Extracardiac arteriopathy	Claudication; >50% carotid stenosis or previous arterial interventions
Neurologic dysfunction	Severely affecting function
Previous cardiac surgery	Requiring opening of pericardium
Serum creatinine	>200 mmol/L preoperatively
Active endocarditis	Requiring antibiotics at surgery
Critical preoperative state	VT/VF, cardiac arrest, mechanical ventilation, inotropic or IABP, acute renal failure
Cardiac-related factors	
Unstable angina	Rest angina requiring IV nitrates
Left ventricular dysfunction	Moderate (EF, 0.30–0.50); poor (EF <0.30)
Recent myocardial infarct	<90 days
Pulmonary hypertension	Systolic PA pressure >60 mm Hg
Operation-related factors	
Emergency	Surgery <1 day after referral
Other than isolated CABG	
Surgery on thoracic aorta	
Postinfarct septal rupture	



discriminatory powers for death at 30 days and 1 year were highest with the EuroScore algorithm. However, studies looking at octogenarians undergoing valvular surgery have demonstrated that the additive and logistic EuroScore models overestimate the mortality in such patients, suggesting that the EuroScore may not be well calibrated for high-risk patients undergoing valvular procedures.<sup>29,30</sup> In a recent trial, from January 1996 through March 2006, 731 patients with EuroScores of 7 or higher underwent isolated AVR. In this cohort, 313 (42.8%) were septuagenarians, 322 (44.0%) were octogenarians or nonagenarians, 233 (31.9%) had had previous cardiac procedures, 237 (32.4%) had atheromatous aortas, and 127 (17.4%) had cerebrovascular disease. The mean EuroScore was 9.7 (median, 10), and the mean logistic EuroScore was 17.2%. Actual hospital mortality was 7.8% (57 of 731). Long-term analysis revealed freedom from all cause death, including hospital mortality, was 72.4% at 5 years. The operative mortality of 7.8% reported in this series is comparable with that in other series of high-risk patients undergoing valve procedures.<sup>26,30</sup> This current report tests the calibration of EuroScore in a cohort of high-risk patients undergoing isolated AVR. We found that the EuroScore is a flawed metric that greatly overestimates.

### Does PAVI replacing AVR?<sup>31</sup>

PAVI has attracted an unprecedented interest and enthusiasm, especially amongst young cardiologists and surgeons, some of who would be ready to do their 'first' tomorrow. This may become one of its most dangerous aspects. The current reports originate from a group, which is famous for their experience with catheter-based valve interventions. However, these procedures are far from being standardized and are not easily reproducible. Therefore, and at least for the near future, they must rest in the hands of very specialized teams of cardiologists and surgeons working, in association, in high-volume units, operating in specially adapted environments, preferably in hybrid (cath lab and operating) suites. The procedure is also not applicable to cases other than calcific aortic stenosis. Use in aortic regurgitation is unlikely in the foreseeable future, as is the use in other pathologies, such as complex

infective endocarditis. So far, PAVI has been limited to the so-called compassionate cases, i.e. elderly patients with severe aortic stenosis who have a very limited life expectancy and who are judged to be at unacceptably high risk for surgery. However, this classification is very subjective. Risk models, such as the EuroScore and the STS score, are not specifically designed for aortic stenosis and tend to overestimate the risk. Also, they are not widely applicable, as it is now well accepted that the risk is also related to the particular surgical team. Surgical AVR is a time-honoured technique, which has produced excellent results in probably more than 1 million patients over the last four decades. Its mortality and morbidity rates have been extensively investigated and discussed. Most experienced surgeons can perform it today with single-digit mortality, close to values of other common cardiac surgeries, even in septuagenarians and octogenarians, and beyond. At this stage, and probably for quite some time, its safety cannot be matched by PAVI.

### Conclusion:

The availability of less-invasive techniques, combined with lengthened life spans, is likely to increase the referral of elderly with AS with a high-risk profile. This challenging perspective stresses the need for a thorough evaluation of new techniques, and longterm studies as well as randomized trials are required. The Placement of AoRTic TraNscathetER valves (PARTNER) multicentre trials are currently ongoing in Europe (PARTNER-EU) and in the United States (PARTNER-US). It will also be necessary to improve the knowledge of the natural history of AS in the elderly and its determinants. The predictive value of multivariate predictive scores should be improved to guide the individual choice between AVR, transfemoral or TAVI, or abstention. It remains that the final therapeutic decision should rely on clinical judgment based on a team approach. This will be mandatory to individualize decision-making according to the expected risks and benefits of the different treatments and the wishes of the informed patient. In the present series, the availability of PAVI and thorough reconsideration of AVR increased the number of patients benefiting from an effective treatment of their AS.

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