

Original Research

Transcatheter Aortic Valve Implantation, Patient Selection Process and Procedure: Two Centres' Experience of the Intervention Without General Anaesthesia

MANOLIS VAVURANAKIS¹, VASILEIOS VOUDRIS², DIMITRIOS A. VRACHATIS¹,
SOFIA THOMOPOULOU², KONSTANTINOS TOUTOUZAS¹, GEORGE KARAVOLIAS²,
IOANNIS TOLIOS³, EFTIHIA SBAROUNI², GEORGE LAZAROS¹, CHRISTINA CHRYSOHOOU¹,
MAZEN KHOURY², STELLA BRILI¹, MARINA BALANIKI², CARMEN MOLDOVAN¹,
CHRISTODOULOS STEFANADIS¹

¹First Department of Cardiology, Hippokraton Hospital, National & Kapodistrian University of Athens, ²Second Department of Cardiology, Onassis Cardiac Surgery Centre, Athens, ³Department of Anaesthesiology, Hippokraton Hospital, Athens, Greece

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Address:
Manolis Vavuranakis

13 Astypaleas St.
145 69 Anoixi
Attiki, Greece
e-mail: vavouran@otenet.gr

Introduction: Transcatheter aortic valve implantation (TAVI) is an emerging technique for the treatment of aortic stenosis. With the advent of percutaneous suture devices for the access point and prosthesis delivery systems of smaller diameter, TAVI has become a truly percutaneous procedure: percutaneous aortic valve replacement (PAVR). Thus, PAVR may be conducted without general anaesthesia (GA).

Methods: We report two centres' experience from PAVR without GA. CoreValve aortic bioprostheses were utilised. The patient selection process and PAVR procedure are described in detail.

Results: A total of 30 patients (pts) were treated with PAVR. In 4 pts correction of the initial malposition of the prosthesis required a special technique (2 pts: "snare"; 2 pts: "removing and reinserting"). At 1-month follow up, haemodynamic and clinical improvements were observed: left ventricular ejection fraction increased from $50.8 \pm 9.3\%$ to $54.3 \pm 8.3\%$ ($p=0.02$); peak aortic valve gradient decreased from 90.3 ± 26.4 mmHg to 14.8 ± 9.7 mmHg, ($p<0.001$); NYHA functional class decreased from 3.53 ± 0.93 to 1.45 ± 0.94 ($p<0.001$). Overall 1-month mortality was 3.3% (1 patient died).

Conclusion: PAVR without general anaesthesia is a feasible technique, however the role of anaesthesiologists is still important.

Aortic stenosis is the most common valvular abnormality in the western world.¹ Although surgical aortic valve replacement (AVR) remains the gold standard for the treatment of severe symptomatic aortic stenosis,² transcatheter aortic valve implantation (TAVI) is an emerging technique that offers an alternative to patients suffering from severe symptomatic aortic stenosis who are rejected for surgery because of increased age and left ventricular dysfunction or co-existing comorbidities.^{3,4} During the last

few years, increasing numbers of successful TAVI procedures have been reported worldwide, with encouraging short- and mid-term results.⁵⁻⁷

Currently, there are two CE marked prosthetic valves for TAVI: the CoreValve (Medtronic, Inc.) and the SAPIEN (Edwards Life Sciences, Inc.) both of which can be introduced transfemorally. Furthermore, the former may potentially be introduced through a subclavian artery,⁸⁻¹⁰ while the latter can be introduced transapically.⁵

In the early experience with both prosthetic valves, a large diameter arterial sheath was required. Thus, surgical cut-down of the artery was compulsory in order to acquire vascular access. However, the advent of the 18 F diameter delivery sheath for the CoreValve bioprosthesis allowed interventionalists to conduct TAVI truly percutaneously. Such an intervention is feasible only when vascular access is acquired through a femoral artery, and it may be performed under either general or local anaesthesia. A more precise term for this procedure is percutaneous aortic valve replacement (PAVR), rather than TAVI.

In this study we report the initial experience from two collaborating centres, of TAVI conducted truly percutaneously (PAVR), without general anaesthesia, using the CoreValve bioprosthesis. The patient selection process, pre-procedural evaluation and implantation procedure are described in detail.

Methods

Patient selection

After evaluation by a team consisting of at least a cardiologist and two cardiac surgeons, patients diagnosed with severe aortic stenosis requiring AVR were considered as TAVI candidates if the risk for surgical AVR was “high” or if they were considered “inoperable”.¹¹

All patients underwent implantation of a CoreValve bioprosthetic aortic valve in a procedure that did not use general anaesthesia. Each patient-candidate for TAVI underwent a process of screening and selection according to the “CoreValve Registry Criteria”. The PAVR procedure itself was performed in a separate session. All subjects provided informed consent prior to the intervention.

Surgical risk assessment

High risk patients

Surgical risk is largely evaluated by two risk-assessment systems: the logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE)¹² and the Society of Thoracic Surgeons (STS) score.¹³ Lately, the accuracy of the EuroSCORE has been under dispute, with reports suggesting that it overestimates the surgical risk.¹⁴ Nevertheless, logistic EuroSCORE is widely used to assess surgical risk in the patient selection according to the “CoreValve Registry Criteria”.

The logistic EuroSCORE is calculated using a special algorithm.¹² The parameters taken into account to compute the logistic EuroSCORE are divided into three categories:

- Patient-related factors: patient’s age, sex, presence of pulmonary disease, presence of extracardiac arteriopathy, presence of neurological dysfunction, history of previous cardiac surgery, presence of active endocarditis, presence of critical preoperative state.
- Cardiac-related factors, which include presence of unstable angina, assessment of left ventricular function (poor, moderate, good), history of recent myocardial infarction, presence of pulmonary hypertension.
- Four operation-related factors: the patient being in an emergency state (for patients who need operation before the beginning of the next working day), operation other than isolated coronary artery bypass grafting (always applies for AVR), surgery on the thoracic aorta, and post-infarct septal rupture.

Patients were defined as “high-risk” for surgical aortic valve replacement if the Logistic EuroSCORE was $\geq 20\%$.

Inoperable patients

Inoperable patients were defined as patients ≥ 65 years old who suffered from at least one of the following conditions: liver cirrhosis (Child A or B), pulmonary insufficiency (forced expiratory volume $< 1L$), previous cardiac surgery, pulmonary hypertension (pulmonary arterial pressure > 60 mmHg), recurrent pulmonary embolisms, right ventricular failure, hostile thorax (radiation, burns, etc.), severe connective tissue disease, cachexia.

Screening process: “CoreValve Registry Criteria”

All patients underwent comprehensive screening prior to the procedure. A synopsis of the screening process is presented in Figure 1.

Pre-interventional screening with echocardiography consisted of assessment of heart anatomy and functionality. The presence of atrial or ventricular thrombus, mitral regurgitation $> \text{Grade } 2$, left ventricular ejection fraction $< 20\%$, severe left ventricular hypertrophy (≥ 1.7 cm) and presence of sub-aortic stenosis were all exclusion criteria.

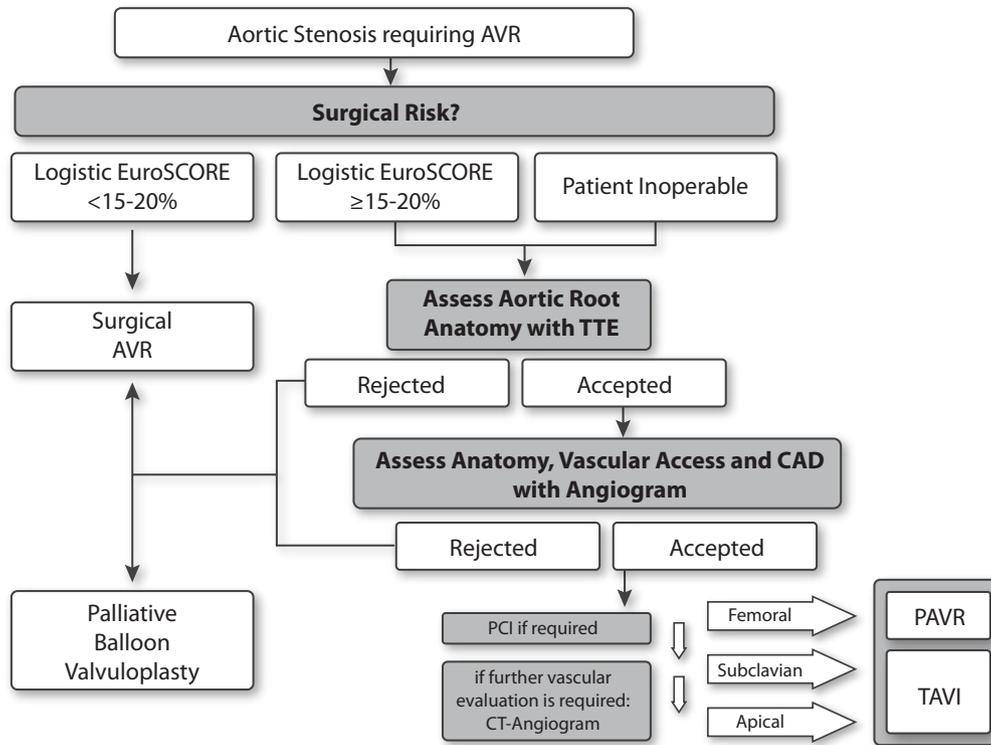


Figure 1. Patient screening process algorithm for transcatheter aortic valve implantation (TAVI) or percutaneous aortic valve replacement (PAVR). CAD – coronary artery disease; PCI – percutaneous coronary intervention; TTE – transthoracic echocardiography.

Angiographic evaluation followed the ultrasound analysis. Initially, a coronary angiogram was performed. In patients who suffered from proximal coronary stenosis $\geq 70\%$ revascularisation was conducted prior to valve implantation.

Aortic annulus (Figure 2) width had to be 20-23 mm or 24-27 mm for the 26 mm and 29 mm devices, respectively. Patients with an annulus width < 20 mm or > 27 mm were not eligible for TAVI with the Core-Valve Revalving System.

The angle between the axis of the ascending aorta within its first 7 cm and a perpendicular line across the aortic valve (i.e. annulus-to-aorta angle) ideally should be $< 30^\circ$. However, an annulus-to-aorta angle from 30° up to 45° was not considered as a reason to reject the patient, whereas an angle $> 45^\circ$ was unacceptable.

In addition, the height of the sinuses of Valsalva was measured on angiography. A height ≥ 15 mm was preferred, while 10-14 mm was considered as borderline. A patient with a borderline height could be successfully treated only if the coronary sinus width was > 27 mm. This provides adequate space for coronary ostium perfusion outside the neck of the valve. An as-

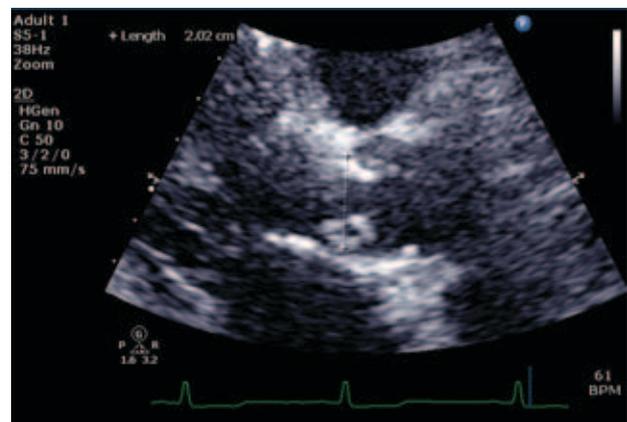


Figure 2. Aortic annulus measurement on the transthoracic echocardiogram.

ending aortic arch diameter > 43 mm, a low “take-off” position of the coronary ostia (the distance between the coronary ostia and the aortic annulus), high angulation or sharp bend of the aortic arch, were also considered as exclusion criteria. In order to evaluate the approach for vascular access, all patients underwent a subclavian and an abdominal aorto-iliac angiogram.

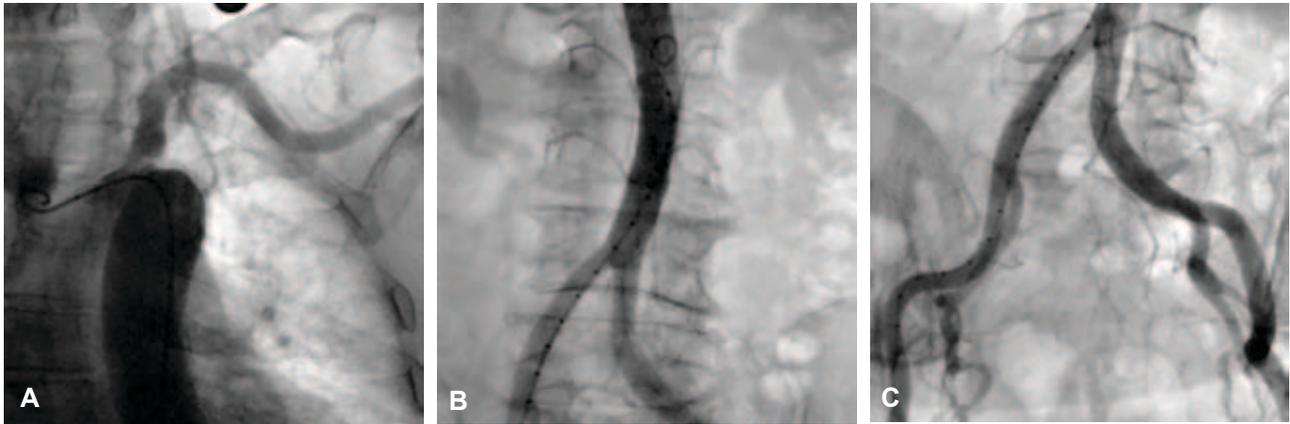


Figure 3. Pre-procedural angiograms with a 5 F metric pigtail catheter: A – left subclavian artery; B – aorto-iliac angiogram; C – femoral artery angiogram.

All angiographic measurements were performed using a 5F metric pigtail (Figure 3). In cases where more imaging was required to clarify some of the previously mentioned parameters, patients were further screened with transoesophageal echocardiography or a CT angiogram.

Femoral artery access: exclusion criteria

PAVR through a femoral artery using a CoreValve prosthesis (Figure 4) is contraindicated, because of the increased risk of vascular complications, in the following situations: excessive angulation or calcifi-

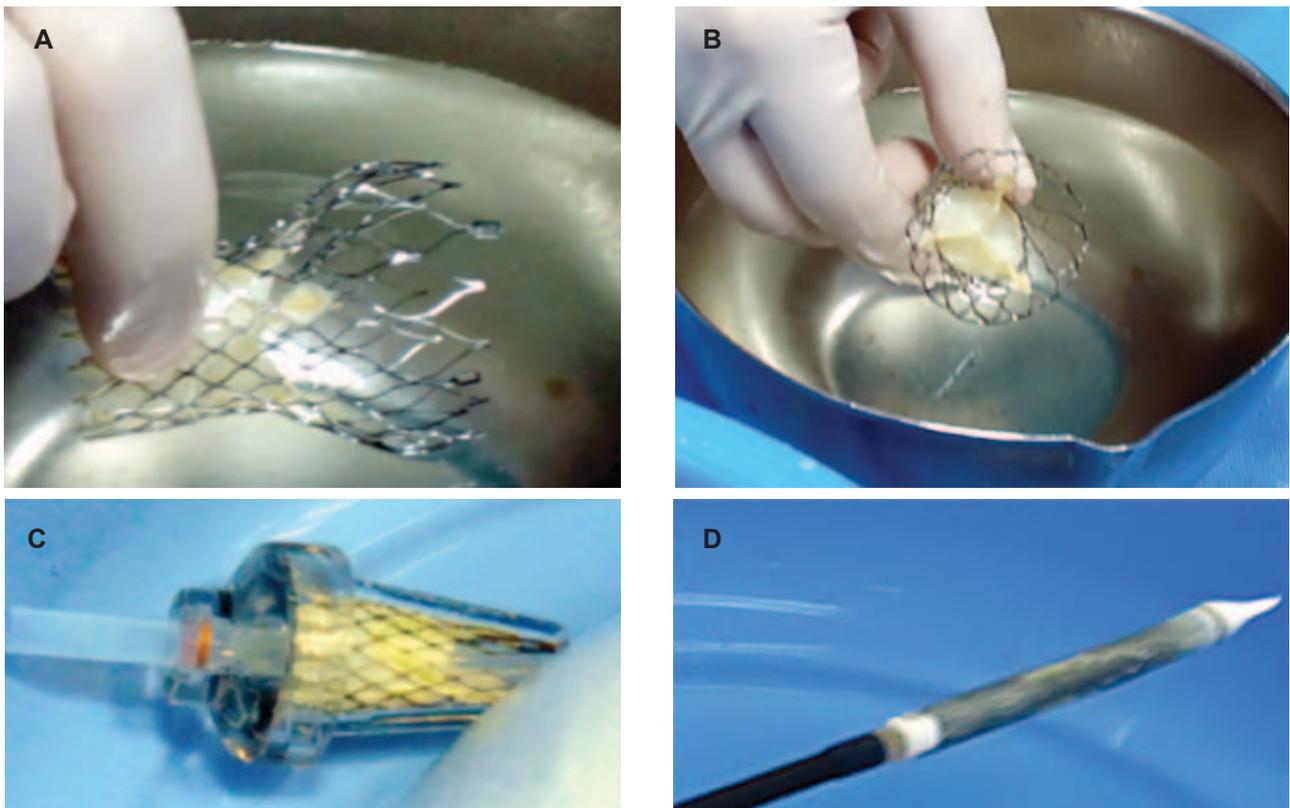


Figure 4. CoreValve bioprosthesis: A – side view; B – aortic outflow view; C – partially “compressed” prior to mounting on the delivery device; D – completely mounted on the delivery system.

cation in the aorta, iliac or femoral arteries; diameter less than 6 mm in the iliac/femoral arteries; significant obstructive atherosclerotic disease; ulcerated plaques or dissections.

Device description and procedure

The CoreValve prosthesis consists of a tri-leaflet bio-prosthetic porcine pericardial tissue valve, which is mounted and sutured in a self-expanding nitinol stent (Figure 4). The prosthetic frame (stent) is manufactured by laser cutting and has an overall length of 50 mm.

Pre-procedurally all patients were pre-treated with acetylsalicylic acid (100 mg/day). They were also given a 300 mg loading dose of clopidogrel. During intervention, patients received weight-adjusted intravenous heparin with a target of an activated clotting time of 250-300 s for the duration of the procedure. Post-procedurally, a 75 mg/day maintenance dose of clopidogrel for at least 6 months and lifelong 100 mg/day acetylsalicylic acid were prescribed.

The procedure was conducted in the catheterisation laboratory with operating-room-like sterile precautions.⁵ Vascular access was obtained with standard percutaneous access techniques through the femoral artery and percutaneous closure was performed using a preloaded Prostar XL suture device (Abbott Vascular, Abbott Park, IL) (Figure 5).¹⁵

All patients received only local anaesthesia (1% lidocaine was applied subcutaneously at the vascular access sites) and mild sedation (propofol, midazolam; doses adjusted by the anaesthesiologist). In addition, an oxygen face-mask (FiO₂ 50%) was applied during the intervention, while oxygen blood saturation was monitored with pulse oximetry.

Prior to prosthesis implantation, aortic angiography was conducted. Subsequently, balloon valvuloplasty was performed with a 22-25 mm diameter balloon under rapid ventricular pacing. Then, the deployment procedure was initiated.

The CoreValve prosthesis was advanced retrogradely over a stiff guidewire and deployed within the aortic annulus. Deployment of the prosthetic valve

consisted of three stages.¹⁶ During the first stage, the operator had full control of the valve expansion, without being forced to rapidly deploy the valve, since the valve was deployed under the patient's native rhythm. During the second stage, the partially deployed prosthesis obstructed the aortic valve flow, blood pressure was compromised and the operator performed deployment in an uninterrupted mode until blood pressure returned to baseline. The third step was then completed, without any need for hurry, since sufficient blood flow was maintained through the deployed valve.

Haemodynamic outcomes, proper prosthesis placement and potential aortic valve regurgitation were assessed serially by aortograms.

After PAVR, patients were transferred to the intensive care unit. Post-procedurally, patients were evaluated clinically and with transthoracic two-dimensional echocardiography immediately after implantation, at hospital discharge (~5 days), and at 1 month.

Statistical analysis

Continuous variables are presented as mean \pm standard deviation unless stated otherwise. The non-parametric Kolmogorov-Smirnov test and histograms were used to assess, statistically and graphically, the normality of distribution of continuous variables. Differences between groups were evaluated by two-tailed, independent samples Student t-test (or Wilcoxon non-parametric test when appropriate) for continuous variables. A 2-sided p-value <0.05 was considered to represent statistical significance. Statistical analysis was performed using SPSS 15 for Windows (SPSS Inc, Chicago, Illinois, USA).

Results

Patient population

During 2008 and 2009, 30 patients had a successful PAVR. A total of 16 patients were enrolled for the 26

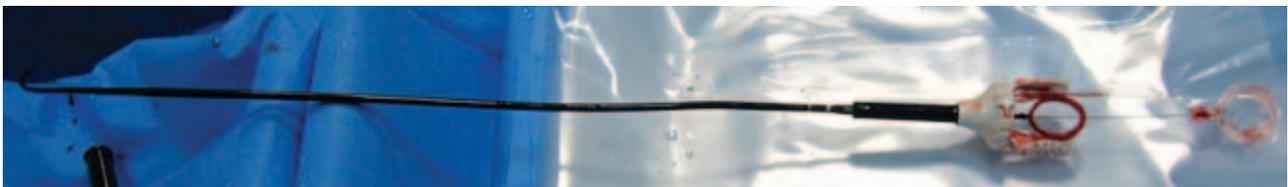


Figure 5. Prostar XL suture device after removal from the puncture site.

mm and 14 patients for the 29 mm prosthesis. Baseline patient characteristics are shown in Table 1.

All patients had severe symptomatic aortic stenosis. The mean calculated logistic EuroSCORE of the population was $27.1 \pm 14.4\%$, while 14 and 16 patients were assigned to New York Heart Association functional classes III and IV, respectively. Mean aortic valve pressure gradient was 57.4 ± 17.3 mmHg and peak aortic valve pressure gradient was 90.3 ± 26.4 mmHg. Pre-procedural mean aortic valve area was 0.63 ± 0.15 cm² and mean systolic left ventricular ejection fraction was $50.8 \pm 9.3\%$.

Acute post-procedural evaluation

Immediate post-procedural evaluation showed stable prosthesis placement and adequate function in 26 patients. However, in 4 patients the initial positioning of the prosthesis was not optimal and the prosthesis was successfully repositioned by performing the “removing and reinserting technique” (2 patients) or the “snare technique” (2 patients).¹⁶

Direct haemodynamic improvement was observed in all patients. Intubation and general anaesthesia were not required in any patient; thus, all interventions were successfully completed with the patient under local anaesthesia. Neither coronary flow impairment nor aortic dissection was observed in any patient. Major cardiovascular and cerebral events (death from any cause, myocardial infarction, cardiac

tamponade, stroke) or major bleeding (requiring surgery and/or blood transfusion) were not observed in any patient within the first 48 h after PAVR.

One-month follow up and clinical evaluation

Overall 30-day mortality was 3.3%; 1 patient died on day 26 post-PAVR due to severe pulmonary fibrosis and multiple organ failure. Overall, the patients' New York Heart Association functional classification improved compared to their initial state (to 1.45 ± 0.1 from 3.53 ± 0.1 , $p < 0.001$) (Figure 6A). Moreover, left ventricular ejection fraction showed a significant increase, while peak and mean aortic valve pressure gradient, as assessed from the transthoracic echocardiogram, decreased significantly (Table 3). Additionally, the peak aortic valve pressure gradient of each and every individual remained decreased at one month (Figure 6B).

Discussion

This study's main finding is that TAVI without the use of general anaesthesia is a feasible technique. We reproduced similar results to those reported for the implantation of CoreValve prosthesis under general anaesthesia. The need for aortic valve replacement is expected to escalate as mean life expectancy increases.¹¹ Over time, the patient selection criteria for TAVI/PAVR will be expanded and we will see further device enhancement and improvement in the opera-

Table 1. Baseline population characteristics.

Variable	Centre 1	Centre 2
Patients (n)	20	10
Female sex	12 (60)	4 (40)
Age (years)	77.1 ± 7.0 (61-85)	77.2 ± 7.5 (67-90)
Hypertension	12 (60)	10 (100)
Hyperlipidaemia	6 (30)	7 (70)
Diabetes mellitus	7 (35)	4 (40)
Smoking	4 (20)	7 (70)
NYHA functional class:		
Class III	10 (50)	4 (40)
Class IV	10 (50)	6 (60)
Logistic EuroSCORE (%)	24.1 ± 13.9 (6.0-57)	33.0 ± 14.1 (11.4-59.3)
Aortic valve area (cm ²)	0.59 ± 0.16 (0.30-0.90)	0.70 ± 0.13 (0.57-0.90)
LVEF (%)	51.25 ± 8.54 (30-65)	49.8 ± 11.1 (30-60)
Peak AV gradient (mmHg)	96.8 ± 25.0 (67-156)	77.4 ± 25.3 (55-141)
Mean AV gradient (mmHg)	59.3 ± 15.7 (39-96)	53.6 ± 20.5 (31-100)

Values are expressed as number (%) or mean \pm SD (range).

NYHA – New York Heart Association; LVEF – left ventricular ejection fraction; AV – aortic valve.

Centre 1: 1st Department of Cardiology, Hippokraton Hospital, National & Kapodistrian University of Athens, Greece.

Centre 2: 2nd Department of Cardiology, Onassis Cardiac Surgery Centre, Athens, Greece.

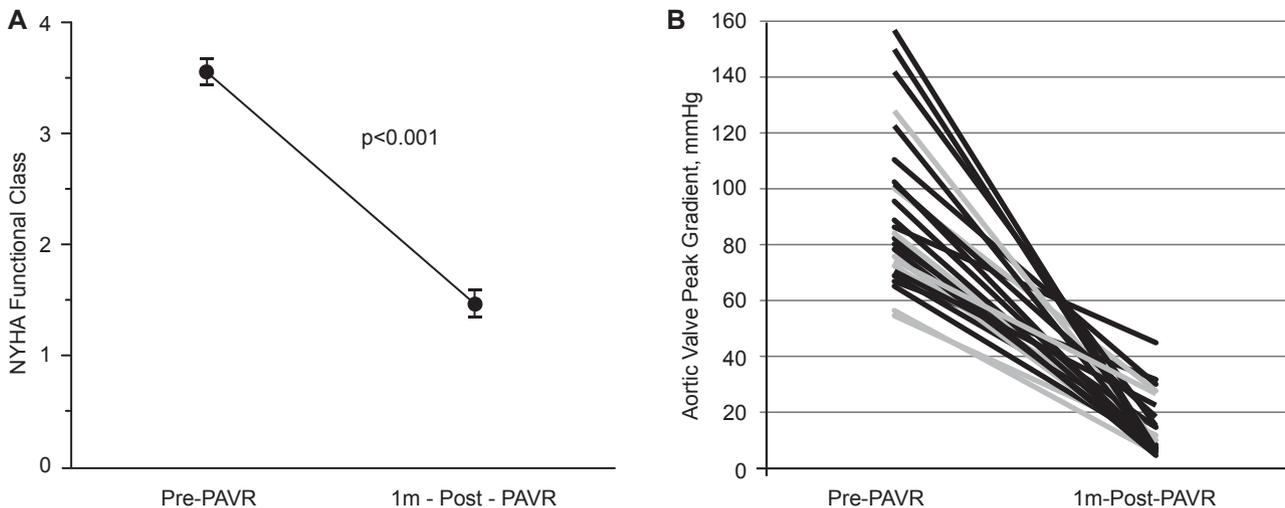


Figure 6. A. New York Heart Association functional class before and 1 month after percutaneous aortic valve replacement (PAVR), displayed as mean \pm standard error (3.53 ± 0.093 and 1.45 ± 0.094 , respectively; $p < 0.001$). B. Aortic valve peak gradient before and 1 month after PAVR for each individual patient.

tors' experience. Therefore, simplification of the procedure is important for its widespread use.

The choice between general and local anaesthesia is a point of dispute. Currently, there are no guidelines regarding which patients should receive one or the other. Thus, the final decision depends upon the consensus of the heart-valve team.

It is important to note that local anaesthesia may be used only when a femoral artery is the site of access. In fact, femoral access is preferred for the majority of

the patients. Yet, when any absolute or relative contraindications¹⁷ apply, subclavian or transapical access (with CoreValve or SAPIEN prosthesis, respectively) should be reassessed.

In a procedure performed under general anaesthesia, the patient is completely immobile, which facilitates the interventionalist's manipulations. This is not always the case under local anaesthesia; the patient has to remain in the same position throughout the whole procedure, which may be stressful. On

Table 2. One-month clinical follow up.

Variable	Centre 1	Centre 2
Patients (n)	20	9
NYHA functional class (n):		
Class I	11	5
Class II	9	4
LVEF (%)	54.6 ± 7.2 (35-65)	53.6 ± 10.7 (35-60)
Peak AV gradient (mmHg)	15.7 ± 10.9 (5.5-45.0)	12.7 ± 6.2 (7.0-23.0)
Mean AV gradient (mmHg)	8.4 ± 6.5 (3.0-28.0)	6.9 ± 2.9 (4.0-13.0)

Abbreviations and notes as in Table 1.

Table 3. Total population before (Pre-PAVR) and 1 month after (1m-Post-PAVR) percutaneous aortic valve replacement.

Variable	Pre-PAVR	1m-post-PAVR	p
LVEF (%)	50.8 ± 9.3 (30-65)	54.3 ± 8.3 (35-65)	0.002
Peak AV gradient (mmHg)	90.3 ± 26.4 (55-156)	14.8 ± 9.7 (5.5-45)	<0.001
Mean AV gradient (mmHg)	57.3 ± 17.3 (31.0-100.0)	7.9 ± 5.6 (3.0-28.0)	<0.001

Other abbreviations as in Table 1.

the other hand, the intervention itself does not induce any major surgical stimulation. However, mild sedation can make it more convenient for the patient and the operators. Another advantage of general anaesthesia is the option of transoesophageal echocardiography as a supplementary imaging modality.

Nevertheless, general anaesthesia makes the intervention more complex. Its potential complications, predominantly respiratory, may not be well tolerated in the high-risk patients who undergo PAVR. Moreover, the metabolic capacity of such patients is a significant point to be taken into account.

Despite the fact that general anaesthesia seems not to be a prerequisite for a PAVR procedure, the role of the anaesthesiologist is still important. The catheterisation laboratory should be properly equipped for an emergent conversion to general anaesthesia, while close monitoring of the patient during the operation is crucial. Thus, the anaesthesiologist is an integral part of the team performing a PAVR.

The stepwise process for prosthesis delivery and implantation is not altered if the patient is under general anaesthesia or under mild sedation. However, it must be strongly stressed that, in the case of major complications, general anaesthesia provides a more controlled and safe environment. Still, operators should pay close attention to the manipulation of the sheaths (18 F diameter) used for valve introduction as they are currently the "Achilles' heel" for vascular complications. Delivery sheaths of a smaller external diameter, which are to be developed by the biotechnology industry, should render PAVR a much safer intervention in the near future.

Another critical point to confront is the accurate positioning of the prosthesis; this is not affected by the absence or presence of general anaesthesia. Nonetheless, initial malposition may be corrected with repositioning manipulations ("removing and reinserting technique", "snare technique").^{16,18,19} These techniques should be considered as "bail-out" techniques, while the degree of the operator's familiarity (or unfamiliarity) with them should be kept in mind. Implantation of a second valve within the first ("valve-in-valve technique" or "Russian doll concept") has been proposed as an alternative.^{20,21} We underline that these techniques can be successfully conducted without the need for crossover to general anaesthesia. If none of them is possible, urgent conversion to surgical aortic valve replacement should be considered.

Finally, we must admit that a selection bias could occur during the decision to conduct a PAVR without

general anaesthesia. Our study supports the view that this is a good alternative, but it does not suggest any selection criteria for deciding between PAVR with or without general anaesthesia.

Conclusion

Based on our initial experience, PAVR without general anaesthesia using a CoreValve prosthesis is a safe procedure, provided that the patients selected for the intervention are comprehensively screened in advance. However, it is still a technically demanding procedure, which requires a multidisciplinary team of interventionalists and anaesthesiologists.

Indisputably, the choice of device to be implanted (CoreValve or SAPIEN) and the route of implantation (transfemoral PAVR, trans-subclavian or trans-apical TAVI) are critical and should be based on a patient-centred view, rather than the operator's skills. Thorough investigation and understanding of the comorbidities prior to decision making are the key to success.

Further studies are needed to evaluate the long-term durability of the prosthetic valve, so that the appropriate patient population for this procedure may be expanded.

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