

## Case Report

# Percutaneous Aortic Valve Implantation of the Medtronic CoreValve Self-Expanding Valve Prosthesis Via Left Subclavian Artery Access: The First Case Report in Greece

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## Key words:

**Aortic stenosis, percutaneous valve implantation, subclavian artery.**

This case report describes a percutaneous aortic valve implantation with the Medtronic CoreValve self-expanding valve prosthesis in a patient with severe aortic stenosis. The approach was made via the left subclavian artery because of the lack of femoral vessel access. The patient was a 78-year-old female with breathlessness on minimal effort, a recent hospitalisation due to pulmonary oedema, and frequent episodes of pre-syncope; surgical valve replacement had been ruled out. The prosthetic valve was successfully implanted with mild paravalvular aortic regurgitation. At 30 days, the patient's clinical condition had significantly improved, with excellent functioning of the aortic valve prosthesis.

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**P**ercutaneous aortic valve implantation (PAVI) utilising stent-based prostheses is a rapidly evolving field; the procedure is currently being performed in selected patients with high surgical risk.<sup>1-5</sup> However, the number of patients is increasing and numerous newly-designed devices are being developed. Two types of aortic valve prosthesis have been introduced into clinical practice for transcatheter aortic valve implantation: the Edwards Sapien balloon-expandable bioprosthesis and the CoreValve self-expanding bioprosthesis. Cribier et al performed the first human implantation of a balloon-expandable aortic valve prosthesis in a 57-year-old man with calcified aortic stenosis and cardiogenic shock using an antegrade transseptal approach.<sup>3</sup> Webb et al preferred the retrograde approach, using 22 and 24 F sheaths from the femoral artery and, along

with the development of smaller and more flexible delivery catheters, reported more favourable results and an incremental procedural success.<sup>5</sup>

In the meantime, a self-expanding aortic valve prosthesis intended for retrograde delivery across the aortic valve had been developed (Medtronic CoreValve Inc., Paris, France), offering several potential advantages over a balloon-expandable device.<sup>6</sup> In this case report, we describe the first percutaneous implantation in Greece of the self-expanding Medtronic CoreValve aortic valve prosthesis via the subclavian artery.

## Case presentation

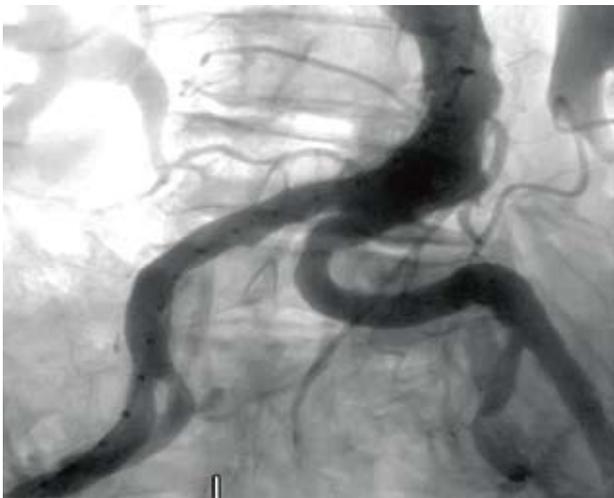
A 78-year-old female patient with known severe aortic stenosis was electively admitted to our hospital because of episodes

of pre-syncope and breathlessness on minimal effort with rapid deterioration in the past 2 months (New York Heart Association classification, NYHA, III-IV). She had been hospitalised with pulmonary oedema 3 months before. The patient was an ex-smoker with a history of hypertension and dyslipidaemia. Transthoracic echocardiography indicated a severely calcified tricuspid aortic valve with a peak transvalvular gradient of 124 mmHg and a mean of 76 mmHg (calculated valve area  $0.45 \text{ cm}^2$ ), in association with moderately reduced left ventricular function (ejection fraction 45%) and grade 1-2 aortic, mitral and tricuspid regurgitation. Left and right heart catheterisation revealed moderate atheromatous disease of the coronary arteries, confirmed the severe aortic stenosis (peak-to-peak aortic valve gradient 114 mmHg, valve area  $0.4 \text{ cm}^2$ ) and gave an estimated pulmonary artery pressure of 65 mmHg. Angiography of the peripheral arteries showed moderate peripheral vascular atherosclerosis with significant tortuosity (Figure 1).

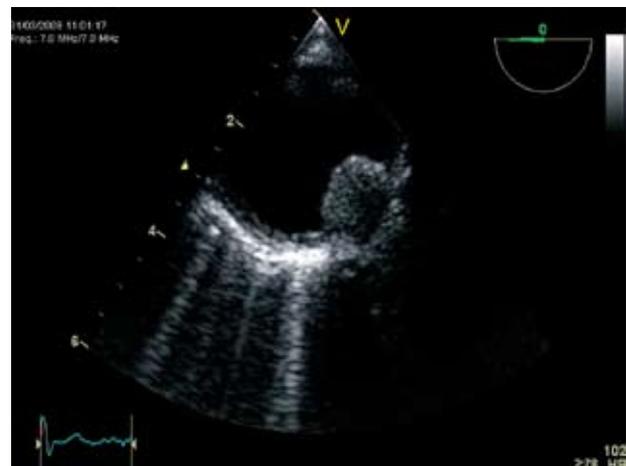
The patient was rejected for surgical aortic valve replacement because of the high risk of mortality (Euroscore 23.85%). On re-evaluation of the patient, transoesophageal echocardiography was performed for the better assessment of the native valve and the aortic root and revealed the presence of thrombus in the descending thoracic aorta (Figure 2). Given the anatomical variables described above, transfemoral valve implantation was considered impossible. Computed tomography angiography was then performed in order to assess the feasibility of valve implanta-

tion via the subclavian artery. The angiogram showed moderate calcification and no significant stenosis of the left subclavian artery, with a minimal diameter  $>6 \text{ mm}$  (Figure 3). Therefore, a valve implantation with the CoreValve Revalving System<sup>TM</sup> via this vessel was planned.

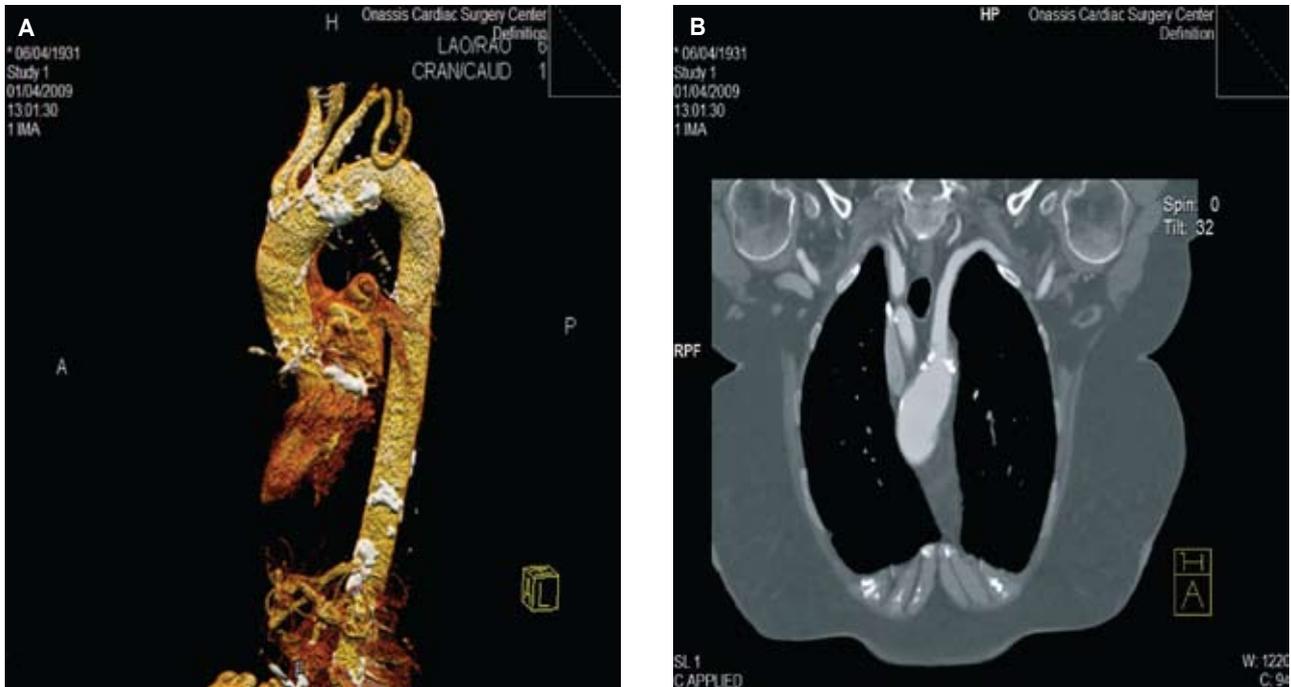
The procedure was undertaken under general anaesthesia and mechanical ventilation. The left subclavian artery was surgically exposed through a 4-5 cm incision below the clavicle (Figure 4). A transvenous pacemaker was inserted via a 6 F sheath placed in the right femoral vein. An Amplatz Left 1 catheter was advanced into the left ventricle over a guidewire, revealing a mean transvalvular pressure gradient of 92.7 mmHg (Figure 5D). A scaled pigtail catheter was placed into the right coronary aortic sinus in order to determine the optimal positioning of the prosthesis with a left aortogram, via a 6 F sheath placed in the right femoral artery. After exchanging the crossing catheter with an extra stiff 0.035" guidewire, predilation of the aortic valve was performed twice using a 22 mm diameter balloon under rapid ventricular pacing (Figure 5A). Following valvuloplasty, a 26 mm Medtronic CoreValve prosthesis was successfully deployed with careful retraction of the 18 F delivery catheter (Figure 5B & C). Immediately after the implantation, the patient's haemodynamics showed a marked improvement of the mean transvalvular pressure gradient (5.2 mmHg) (Figure 5E). A left aortogram demonstrated patent coronary ostia and mild paravalvular regurgitation (Figure 5C). Transthoracic



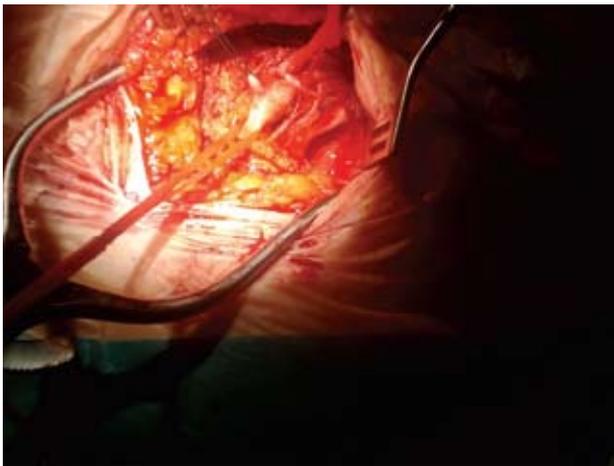
**Figure 1.** Significant tortuosity and moderate peripheral vascular atherosclerosis.



**Figure 2.** The transoesophageal echo showing the thrombus in the descending thoracic aorta.



**Figure 3.** Computed tomography angiogram showing the left subclavian artery with moderate calcification and no significant stenosis.



**Figure 4.** Surgical cutdown of the left subclavian artery.

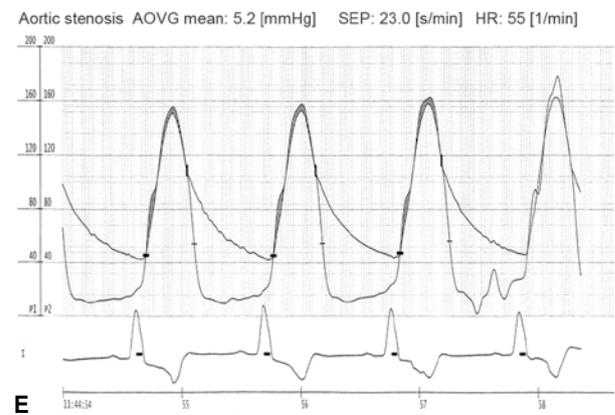
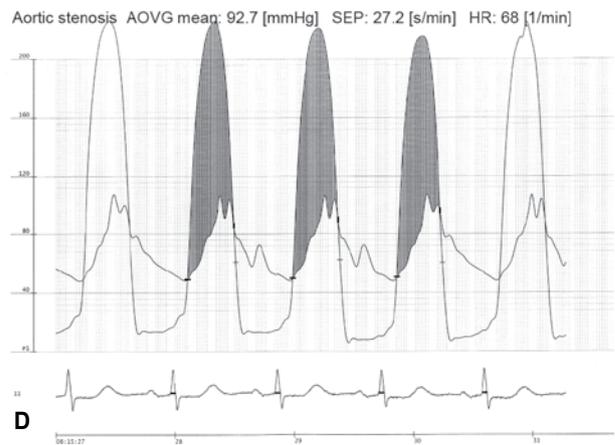
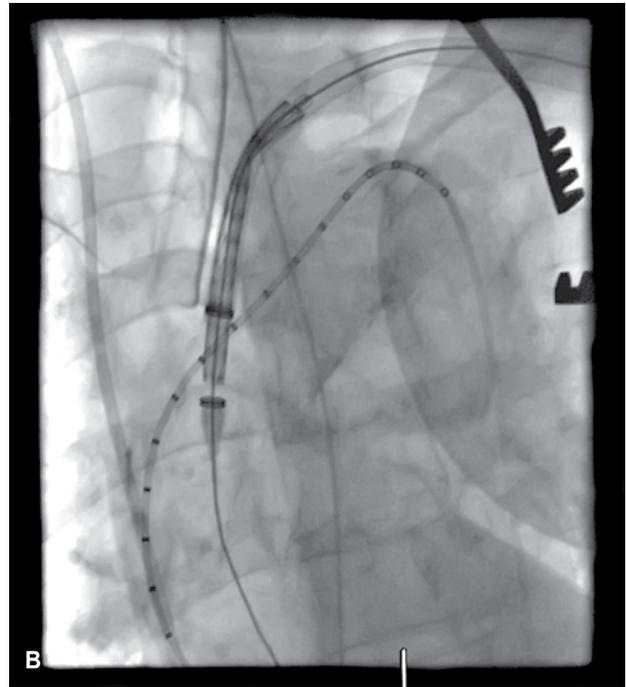
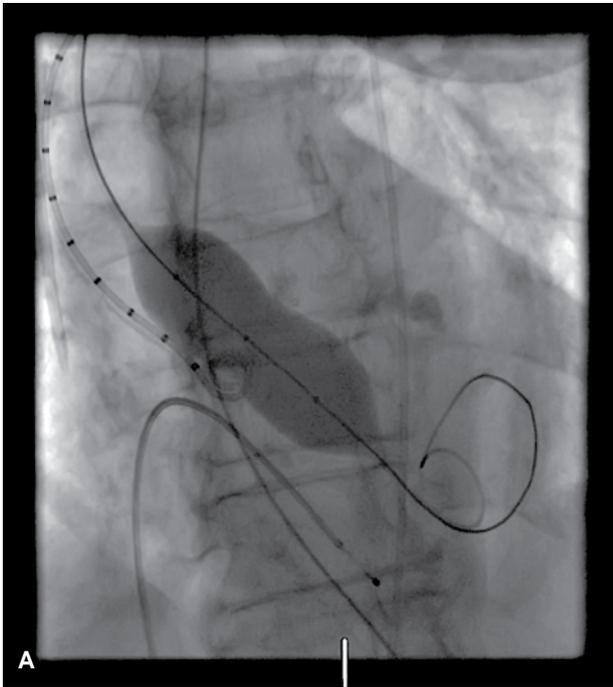
echocardiography was performed the day after the procedure and repeated before discharge and in both cases revealed excellent function of the aortic valve prosthesis, with mild paravalvular regurgitation, and an improved left ventricular ejection fraction of 50%. The post-implantation electrocardiogram showed first degree atrioventricular block and left bundle branch block, which remained unchanged by the patient's discharge date. The post-procedural course was uncom-

plicated and the patient was discharged in a relatively improved condition on the 7th post-procedural day. Thirty days later, her clinical condition had further improved (NYHA II) and echocardiography showed excellent function of the aortic valve prosthesis with a stabilised left ventricular ejection fraction of 50%.

## Discussion

We present the first percutaneous implantation in Greece of the self-expanding Medtronic CoreValve aortic valve prosthesis via the subclavian artery. The described approach was performed because of severe peripheral vascular disease, with the presence of thrombus in the descending thoracic aorta and significant tortuosity of the femoral and iliac arteries.

Aortic valve replacement is the treatment of choice for severe aortic stenosis. However, the surgical procedure has an operative mortality rate that ranges from 10% to 50% when performed in high-risk patients with comorbid conditions.<sup>7,8</sup> Percutaneous aortic balloon valvuloplasty is still used as an alternative, with satisfying short-term results but high restenosis rates in the majority of patients at 6 months.<sup>9,10</sup> As a result of this treatment dilemma in elderly, high risk patients, transcatheter aortic



**Figure 5.** A: maximal balloon inflation for valve delivery, pushing aside the calcific leaflets; B: prosthetic heart valve delivery via the left subclavian artery; C: the prosthetic valve in position in the mid part of the native aortic valve. Simultaneous pressure recordings in the ascending aorta and left ventricle before (D) and after (E) aortic valvuloplasty are shown.

valve implantation has emerged as a new, less invasive treatment modality. The safety and the technical feasibility of PAVI have been demonstrated in case reports and in larger groups of patients for both of the types of aortic valvular prosthesis that are currently approved for use.

The CoreValve prosthesis is a trileaflet porcine pericardial valve, which is mounted in a self-expanding stent. The lower portion of the prosthesis has a high radial force to expand against the calcified leaflets, providing secure anchoring. The middle portion carries the valve and is constrained to avoid the coronary arteries, while the upper portion has a low radial force to orient the system. The device is deployed via a delivery system, the sizes of which have been gradually reduced over time to allow easier deployment. The first-in-man studies were done on high-risk patients, utilising 25 F and 21 F delivery systems, which required a surgical cutdown under general anaesthesia and showed the feasibility of this procedure.<sup>11</sup> Subsequent publications referred to a population treated with the current third-generation (18 F) system, which is deployed percutaneously under mild sedation.<sup>12,13</sup> The Medtronic CoreValve is manufactured in two sizes, with the smaller prosthesis generally used for aortic annulus sizes  $\leq 23$  mm. The larger valve fits annulus sizes up to 27 mm in diameter. The device is available for trans-arterial introduction, for which the femoral arteries are usually preferred because of the 18 F profile of the catheter.

The Medtronic CoreValve design provides several advantages: 1) the self-expanding nature of the stent, which may minimise the occurrence of paravalvular leaks; 2) the lower crossing profile; 3) the feasibility of implantation without requiring rapid pacing and cardiac arrest; 4) self-alignment features; 5) tight anchoring in the ascending aorta, avoiding valve migration or dislodgement; and 6) the ability for device retrieval after partial implantation of the prosthesis.<sup>11-13</sup>

In addition, the Medtronic CoreValve prosthesis offers the unique advantage of subclavian access with a cutdown procedure, as an alternative access site for patients with severely diseased peripheral vessels not suitable for valve implantation. In this way transapical implantation can be avoided, since the reported prognosis of this approach is worse. The left subclavian artery is usually chosen, because the angle of implantation by the way of the right subclavian artery is unfavourable. In this approach, the diameter

of the vessel must be at least 6 mm, with no severe calcifications or irregular plaques, so that it can be dilated by the introduction sheath.<sup>14,15</sup>

To date, more than 1500 patients around the world have undergone PAVI using the 18 F CoreValve Revalving System, with high procedural success rates (97%), and resulting in a marked reduction of aortic transvalvular gradients with the aortic regurgitation grade remaining  $\leq$  grade 2.<sup>13</sup> The mortality rates were lower than predicted by risk algorithms, with a procedural mortality of 1.5% and 30-day mortality of 8%.<sup>13</sup> The overall vascular access site complication rate is approximately 1.7%, with the most preferred access site being the femoral artery. There are only a few case reports describing the technique of subclavian approach, with no reported complications, and relatively few cases included in larger series without any specific information according to the type of access route.<sup>14-16</sup>

Although the feasibility of the Medtronic CoreValve procedure has already been demonstrated, randomised controlled trials with rigorous follow up are needed to show whether this technique is superior to conventional surgery. Moreover, there is a definite need for further progress in implantation technique, device positioning, as well as the device itself. The most critical deficiencies to be overcome include exact valve positioning, the risk of coronary artery obstruction, disorder of mitral valve function, and the risk of paravalvular leak. The suitability of the device for patients who have a large sized annulus ( $>27$  mm) or predominant aortic regurgitation, or for patients who are good candidates for surgical aortic valve replacement, will need to be further elucidated. However, according to the recent published recommendations, PAVI should only be considered for patients with high-grade, symptomatic aortic stenosis who would be at high operative risk and not for 'good surgical candidates'.<sup>17,18</sup>

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