The trans-subclavian retrograde approach for transcatheter aortic valve replacement: Single-center experience

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Objective: Aortic valve disease is the most common acquired valvular heart disease in adults. With the increasing elderly population, the proportion of patients with symptomatic aortic stenosis who are unsuitable for conventional surgery is increasing. Transcatheter aortic valve implantation has rapidly gained credibility as a valuable alternative to surgery to treat these patients; however, they often have severe iliac-femoral arteriopathy, which renders the transfemoral approach unusable. We report our experience with the trans-subclavian approach for transcatheter aortic valve implantation using the CoreValve (Medtronic CV Luxembourg S.a.r.l.) in 6 patients.

Methods: In May 2008 to September 2009, 6 patients (mean age of 82 ± 5 years), with symptomatic aortic stenosis and no reasonable surgical option because of excessive risk, were excluded from percutaneous femoral CoreValve implantation because of iliac-femoral arteriopathy. These patients underwent transcatheter aortic valve implantation via the axillary artery. Procedures were performed by a combined team of cardiologists, cardiac surgeons, and anesthetists in the catheterization laboratory. The CoreValve 18F delivery system was introduced via the left subclavian artery in 6 patients, 1 with a patent left internal thoracic to left anterior descending artery graft.

Results: Procedural success was obtained in all patients, and the mean aortic gradient decreased 5 mm Hg or less immediately after valve deployment. One patient required implantation of a permanent pacemaker. One patient required a subclavian covered stent implantation to treat a postimplant artery dissection associated with difficult surgical hemostasis. One patient was discharged in good condition but died of pneumonia 40 days after the procedure. All patients were asymptomatic on discharge, with good mid-term prosthesis performance.

Conclusions: Transcatheter aortic valve implantation via a surgical subclavian approach seems safe and feasible, offering a new option to treat select, inoperable, and high-risk patients with severe aortic stenosis and peripheral vasculopathy. (J Thorac Cardiovasc Surg 2010;140:911-5)

Supplemental material is available online.

Aortic stenosis (AS) is the most frequent form of valvular heart disease in adults in western countries,[1] and aortic valve replacement is the standard treatment for these patients.[2] However, the mortality rate associated with aortic valve replacement increases substantially with age, the presence of left ventricular dysfunction, or multiple comorbidities.[3] In recent years, transfemoral[4,5] or transapical[6] transcatheter aortic valve implantation (TAVI) has rapidly gained credibility as a valuable alternative to treat this group of patients who are not considered for surgery because of significant comorbidities.[7,8] The 2 devices currently clinically available are the Edwards-Sapien stainless-steel, balloon-expandable bovine bioprosthesis (Edwards Lifesciences, Irvine, Calif) and the CoreValve nitinol porcine self-expanding bioprosthesis (Medtronic CV Luxembourg S.a.r.l.). The transfemoral approach is the preferred method for both devices, but with a 24F or 18F introducer, respectively, the presence of small, tortuous, heavily calcified femoral and iliac arteries contraindicates this approach. To prevent vascular complications in this group of patients, a transapical approach with the Ascendra transapical catheter and the Edwards-Sapien valve (Edwards Lifesciences) was preferred, but there is only experimental experience with this approach using the CoreValve. This approach seems demanding because it requires direct left ventricle apex surgical exposure and a dedicated operating room. We report our experience with retrograde CoreValve implantation through the axillary artery in 6 high-risk surgical candidates with severe AS and heavily calcified and atherosclerotic femoral and iliac arteries.

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Disclosures: None.

Received for publication Nov 13, 2009; revisions received Dec 28, 2009; accepted for publication Jan 22, 2010.

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0022-5223/$36.00

doi:10.1016/j.jtcvs.2010.01.027

Abbreviations and Acronyms
AS = aortic stenosis
TAVI = transcatheter aortic valve implantation

MATERIALS AND METHODS

From May 2008 to September 2009, 120 patients with severe, symptomatic AS and no reasonable surgical option because of excessive risk were evaluated for TAVI. The patient screening protocol included transthoracic echocardiography, complete left-sided heart catheterization, and coronary angiography, with angiography of the iliac and femoral arteries, and chest and aortic-iliac-femoral computed tomography scans. Acceptance for the procedure required consensus by a team composed of a cardiac surgeon, an interventional cardiologist, the referring cardiologist, and a cardiac anesthesiologist. All patients provide written informed consent, and all procedures were approved by the local ethics committee. Forty-five patients were eligible for CoreValve percutaneous femoral implantation, whereas 6 patients (5 male) with a mean age of 82 ± 5 years were excluded because of small size, calcification, iliac-femoral arteriopathy, or excessive tortuosity. These patients underwent CoreValve implantation via the left axillary artery. All patients underwent supra-aortic vessel angiography and computed tomography to assess the left subclavian artery size, course, and calcification (Figure E1). Two patients had previously undergone coronary artery bypass grafting, and 1 patient had a patent left internal thoracic to left anterior descending artery graft. Two patients had severe left ventricular dysfunction, and 3 patients underwent a bridge procedure of balloon aortic valvuloplasty. The patients' characteristics are shown in Table 1.

The CoreValve ReValving System consists of 3 unique components: a self-expanding support frame with a trileaflet porcine pericardial tissue valve, an 18F catheter delivery system, and a disposable loading system, as previously described.[9-11]

Operative Technique

The procedure was performed in the cardiac catheterization laboratory by a team of interventional cardiologists, cardiac surgeons, and a cardiac anesthesiologist. All procedures were performed under general anesthesia. The best femoral artery was accessed by a single wall puncture under fluoroscopic and angiographic guidance to allow homodynamic monitoring and landmark aortic angiography through a 5F pigtail. A temporary pacing lead was advanced in the right ventricle through the right femoral vein in the patients without a permanent pacemaker to treat possible post-TAVI atrioventricular block. Heparin was administered to maintain an activated clotting time greater than 250 seconds throughout the procedure. The axillary artery was surgically isolated through a subclavicular incision of 3 to 5 cm just below the clavicle (Figure E2). Arterial cannulation was performed using the Seldinger technique through a purse-string suture. The left axillary artery was usually preferred because of the best angle of deployment. A 7F sheath was then inserted into the subclavian artery, and a 0.035 straight guidewire was placed in the left ventricle using a left Amplatz catheter (Amplatz Cook, Inc, Bloomington, Ind). A Cook 30-cm Check-Flo Performer 18F introducer (William Cook Europe, Bjaeverskov, Denmark) was inserted (Figure 1) over an Amplatz super stiff guidewire, and the native aortic valve was predilated with a 22- or 25-mm Nucleus balloon (NuMED Inc, Hopkinton, NY) without rapid pacing in all patients. The balloon design facilitates positive positioning while holding the balloon in the correct location, and initial inflation will hold the balloon in the desired position. A CoreValve prosthesis was then carefully introduced and retrogradely implanted under angiographic and fluoroscopic guidance over the stiff wire in the ascending aorta across the aortic valve (Figures 2, E3, and E4) with immediate improvement of the hemodynamic status in all patients. Immediately after CoreValve deployment, ascending aorta angiography was performed to assess the patency of the coronary arteries and coronary grafts, and the presence and location of the eventual paravalvular leak (Figure 3). After the procedure, heparin was neutralized by protamine, and the subclavian artery was restored by direct suture.

Statistical Analysis

Incidence rates of events are reported by giving the number of patients experiencing the event followed by the corresponding percentage. Continuous data are reported by giving the mean ± standard deviation or median and the range of values observed.

RESULTS

According to definitions by Piazza and colleagues,[12] procedural success was defined by the combination of 3 different end points: adequate technical placement, normal bioprosthesis performance, and operative outcome. Adequate technical placement was the correct positioning of the

TABLE 1. Baseline patient characteristics at implant

Patient	Gender	Age, y	Comorbidity	AoVArea cm^2	MAoG mm Hg	Peak Ao Δ mm Hg	LVEF%	EuroSCORE Additive	EuroSCORE Logistic	Society of Thoracic Surgeons Mortality	Society of Thoracic Surgeons Morbidity
1	M	78	Vasculopathy, porcelain aorta, previous PCI	0.8	51	90	69	8	10	6.3%	28.9%
2	F	85	Vasculopathy, thrombocythemia	0.8	51	93	67	11	20	8.7%	29.9%
3	M	74	Vasculopathy, AMI, bladder neoplasm, IDDM, previous CABG and PCI	1	52	81	58	12	27	11%	41.9%
4	M	86	Vasculopathy; IDDM, CRI, previous PCI	0.9	47	80	30	15	53	14.6%	42.7%
5	M	85	Vasculopathy, stroke	0.9	62	104	49	13	39	5.2%	30%
6	M	85	Vasculopathy, IDDM, AMI, previous CABG	1.1	47	82	26	16	59	13.7%	45.5%

Ao, Aorta; *AMI,* acute myocardial infarction; *IDDM,* insulin-dependent diabetes mellitus; *CRI,* chronic renal insufficiency; *AoV,* aortic valve area; *MAoG,* mean aortic gradient; *Peak Ao Δ mm Hg,* echo peak transvalvular aortic pressure gradient; *LVEF,* left ventricular ejection fraction; *PCI,* percutaneous coronary intervention; *CABG,* coronary artery bypass grafting.

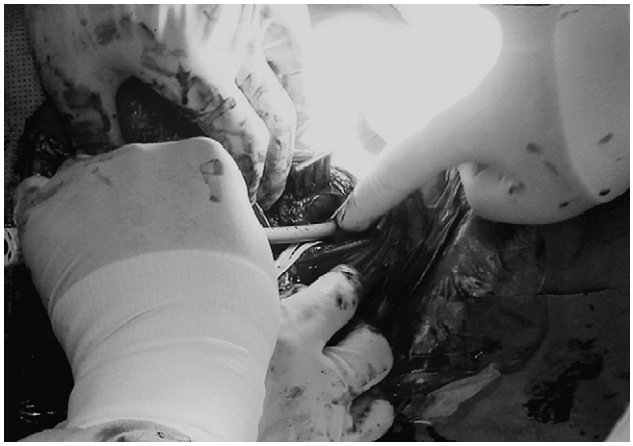

FIGURE 1. After subclavian exposure, the 18F introducer is inserted over an Amplatz (Amplatz Cook, Inc, Bloomington, Ind) super stiff guidewire.

CoreValve in the aortic root. Good valve performance was evidenced by a reduction in mean transaortic gradient to less than 20 mm Hg and aortic regurgitation grade of 2 or less, as evaluated by aortic angiogram or echocardiogram. Operative outcome was represented by any event occurring during the procedure and within the subsequent 24 hours. Any events occurring within 30 days from the procedure were considered procedure related.[12] Events collected were death, neurologic event, myocardial infarction, ventricular perforation, cardiac tamponade, aortic dissection, vascular access complication, infections, and contrast-induced nephropathy. The CoreValve was inserted through the left subclavian artery in 6 patients. In patient 6, the procedure was performed through the left subclavian artery with a patent left internal thoracic artery graft on the descending anterior coronary artery. Aortic valvuloplasty was performed to predilate the native valve in all patients. The mean duration of the procedure was 147 $\pm$ 63 minutes (range, 105–270 minutes), with a mean fluoroscopy time of 28 $\pm$ 14 minutes and a mean contrast medium amount of 186 $\pm$ 84 mL. Procedural success was obtained in all cases. Mean aortic gradient decreased 5 mm Hg or less immediately after valve deployment in all patients. Two patients had grade 1 to 2 aortic insufficiency (Table 2). In patient 6, post-deployment valve dilation was performed to improve CoreValve strut expansion to reduce paraprosthetic leak. After removal of the 18F sheath and surgical closure of the axillary artery, the radial pulse disappeared in patient 4. The surgeon had also some difficulty in obtaining an adequate hemostasis at the puncture site. An immediate angiography at this level revealed a long dissection with a flow-limiting stenosis at the puncture site, which was treated with Gore Viabahn 8$\times$50 mm (WL Gore and Associates Inc, Flagstaff, Ariz) covered polytetrafluoroethylene stent implantation. At 8 months follow-up, the left radial pulse is normal in this patient. All patients were extubated after the end of the procedure in the catheterization laboratory. Post-implant complete atrioventricular block developed in patient 5, who required permanent pacemaker implantation via the right subclavian vein. All patients were asymptomatic on discharge with

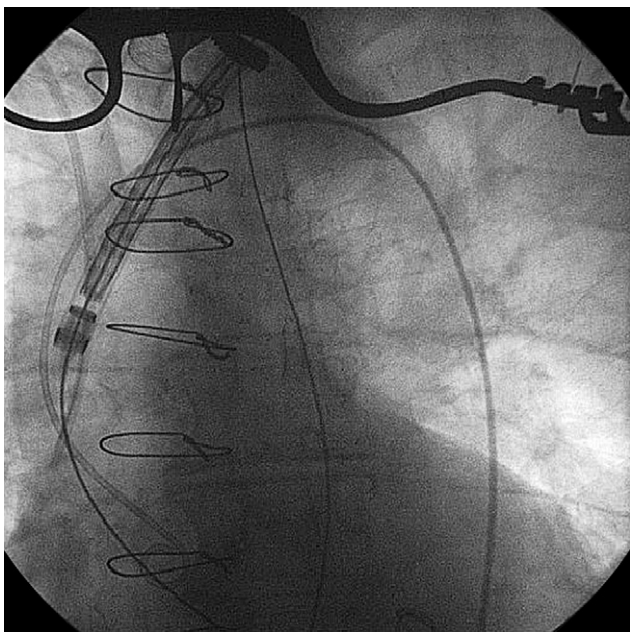

FIGURE 2. CoreValve (Medtronic CV Luxembourg S.a.r.l.) delivery catheter and prosthesis are advanced in place. Notice the short distance from the subclavian access to the aortic annulus requiring weaker forces of tension and torsion.

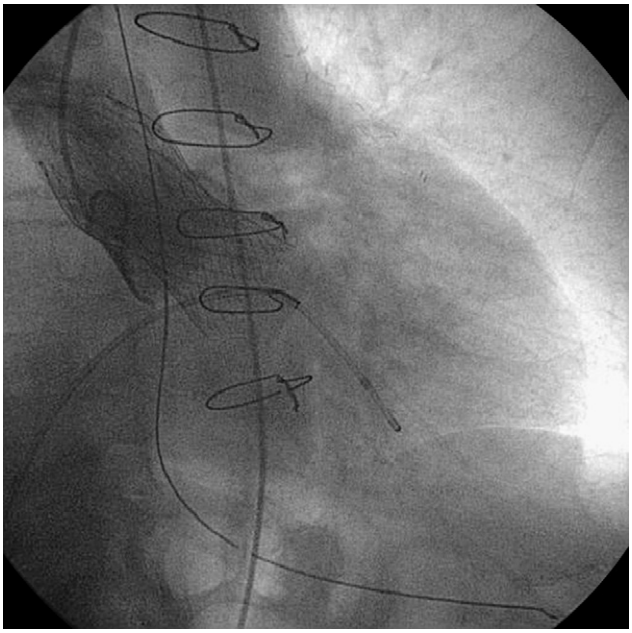

FIGURE 3. Immediately after CoreValve deployment, ascending aorta angiography was performed to assess the correct positioning of the device, periprosthesis regurgitation, and patency of the coronary arteries.

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TABLE 2. Procedural details and complications

Patient	Valve size (mm)	Implant time (min)	DAP Gycm^2	P-t-P Ao gradient (mm Hg)	Aortic insufficiency	Complications
1	29	110	213	4	1+	—
2	26	105	50	5	1+	—
3	29	115	105	5	1+	—
4	29	270	240	2	1+	Subclavian stent
5	29	160	313	4	1–2+	PM implant
6	29	125	212	4	1–2+	ARF

DAP, Radiation dose/area product; *P-t-P Ao,* hemodynamic peak-to-peak trans-aortic gradient; *PM,* pacemaker; *ARF,* acute renal failure (creatinine clearance < 30 mL/min).

good prosthesis function as assessed by echocardiography after a mean hospitalization of 13 days (range 7–22 days) with a dual antiplatelet regimen of aspirin 100 mg and clopidogrel 75 mg daily for 3 months, after which 100 mg of aspirin daily was prescribed indefinitely. Regular clinical and echocardiography follow-up were performed after discharge in all patients at 1, 3, 6, and 12 months and if clinically necessary. At discharge the average of mean transvalvular aortic pressure gradient was 9 ± 4 mm Hg. During follow-up, all patients experienced functional class improvement after CoreValve implant at a mean time of 341 ± 166 days (range 41–470 days). Five patients are asymptomatic and have returned to normal life activities, limited only by their previous medical conditions. One patient was rehospitalized after discharge and died of pneumonia 41 days after the procedure. Two patients required femoral artery percutaneous transluminal angioplasty, and 1 patient underwent iliac-femoral bypass surgery. One patient experienced lower-extremity cholesterinic embolism that was successfully medically treated (Table E1). Echocardiographic controls, at 1 year, showed stable and good prosthesis performance, with an average mean transvalvular aortic pressure gradient of 9 ± 4 mm Hg, and mild aortic insufficiency caused by trivial paravalvular leak in 3 patients (Table E2).

DISCUSSION

TAVI has emerged as an alternative therapy to treat patients with symptomatic AS who are not considered for surgery because of high-risk surgical features.[7,8] In the last 5 years, approximately 10,000 patients have been treated worldwide for severe AS using a TAVI technique.[13] Several technical approaches were applied, including antegrade approaches via the femoral vein and transseptal puncture, retrograde approaches via the femoral arteries, and the transapical approach via a minithoracotomy.[4-6] The choice for the best approach depends on a patient's morbidity and tortuosity; the presence of excessive femoral, iliac, or aortic atherosclerosis; and the size and type of the device used.

The antegrade transvenous approach[14] theoretically seems more suitable to introduce the large delivery system, reducing the risk of vascular complications. However, transseptal puncture makes this approach challenging, and passage of large-diameter catheters through the mitral valve may damage the mitral valve apparatus; thus, this approach has been abandoned.[5]

After reducing the size of the delivery catheters, the preferred access site for TAVI is the retrograde approach via the femoral arteries; however, actual selection criteria of patients of advanced age with porcelain aorta or previous cardiac surgery, select a cohort of patients at high risk for peripheral artery disease, and non-permissive retrograde transfemoral arterial approach. This condition may be overcome by a transapical approach widely and successfully performed using the Edwards-Sapien valve.[6,15] This approach allows the introduction of delivery systems directly through the apex of the left ventricle without sheath diameter limitation. This approach is more invasive and requires an anterolateral minithoracotomy in a hybrid operating room.[15] Moreover, transapical valve implantation has some technical limitations, as in the case of severe septal hypertrophy in combination with the angled position of the left ventricular outflow tract in relation to the aortic root and unique potential complications, such as significant incidence of perivalvular leak, myocardial perforation, and mitral or aortic trauma that may occur from misdirected stiff catheters.[16,17] In this scenario, as recently reported by other authors, a trans-subclavian retrograde approach could represent an intriguing alternative for TAVI in high-risk patients with associated severe iliac-femoral arteriopathy.[18-20] The axillary artery is easily accessible after surgical cutdown, and its size allows the introduction of 18F sheaths. The CoreValve Extended Evaluation Registry has reported data for approximately 74 patients in whom subclavian access was used with 100% procedural success.[21] Our experience confirms the possibility of performing CoreValve implantation through the left subclavian artery in a patient with a patent internal thoracic graft to the left anterior descending artery. In this case, as suggested by Fraccaro and colleagues,[19] it may be safer to completely introduce the sheath only to implant the valve and then slightly retrieve the sheath to minimize the risk of thoracic flow obstruction. Some operators have experience with right subclavian access.[18] This access is feasible even if correct positioning of the valve is made difficult by the fact that the stiff wire used to deliver the valve is pushed against the left aspect of the aorta. In case of aortic annuli with a significant inclination on the sagittal plane (>30 degrees; Jean-Claude Laborde, personal communication, March 2009), correct CoreValve implantation is difficult

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because of the difference in height of the 2 opposite parts of the annulus. In the trans-subclavian approach, the proximity between the aortic annulus and the sheath of the valve provides more direct access to the implantation site, easier manipulation of the device, and correct positioning of the CoreValve (particularly during the stepwise retraction of the outer sheath that allows deployment of the self-expanding prosthesis) than the transfemoral approach, because no bending of the aorta and pelvic arteries hinders the control of the device.

The axillary approach also has the advantage of overcoming challenging aorto-ileo-femoral vascular disease, without the invasiveness of the transapical technique, and avoids the risk of dislodging atherosclerotic plaque during valve passage through the aorta, which may cause particulate embolization and subsequent stroke. None of our patients had neurologic events. As with the transapical approach, procedural times are longer than in percutaneous transfemoral implantation.[15,19] In our experience, the subclavian procedural length (mean implant time 147 minutes) was longer than the percutaneous transfemoral implantation (mean implant time 111 minutes), but was comparable to the time necessary for an implant requiring femoral artery surgical cut-down, although the trans-subclavian approach enables a more rapid mobilization of the patients. Except for subclavian dissection in 1 patient, no other vascular problem occurred in our series; no other patients experienced bleeding or difficult surgical hemostasis despite double-antiplatelet therapy.

No surgical wound infections occurred, and all patients were discharged in good health conditions and stable hemodynamic compensation 2 weeks after valve implant. During follow-up, all patients had improved New York Heart Association functional class and functional capacity, and echocardiograms showed good valve performance at 16 months.

In our series, 2 patients required permanent pacemaker implantation after TAVI. Permanent pacemaker requirement after CoreValve implantation is reported to be 33% in-hospital and 40% within 1 year. The cause is that the native aortic valve remains in situ and is compressed by the CoreValve stent frame against the surrounding structures adjacent to the left ventricular outflow and aortic annulus, including the atrioventricular node and its left bundle branch.[22]

CONCLUSIONS

Our experience, characterized by a multidisciplinary contribution necessary to offer the safest conditions and care for patients, confirms the safety and feasibility of the subclavian approach with the immediate hemodynamic success of the treatment.

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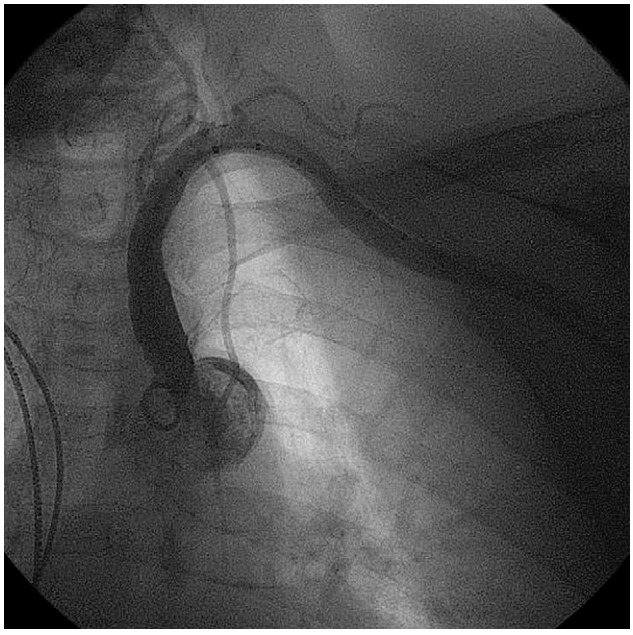

FIGURE E1. Supra -aortic vessel angiography to assess left subclavian artery size, course, and calcification.

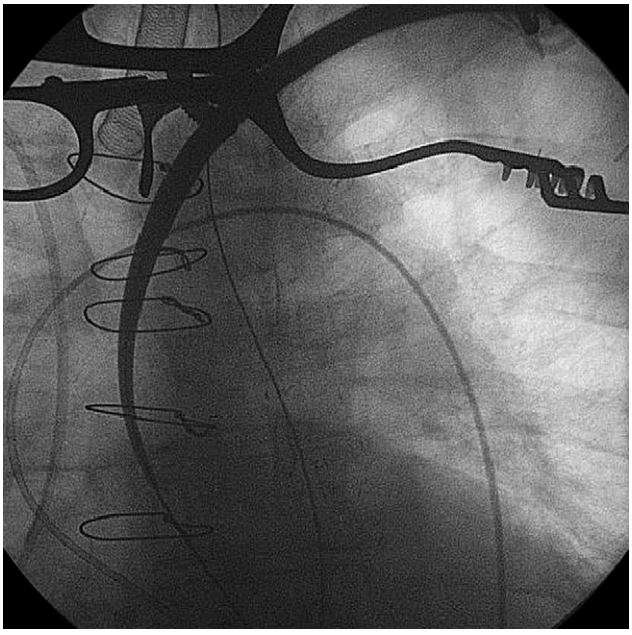

FIGURE E3. The CoreValve revalving system 18F introducer was carefully advanced to the ascending aorta.

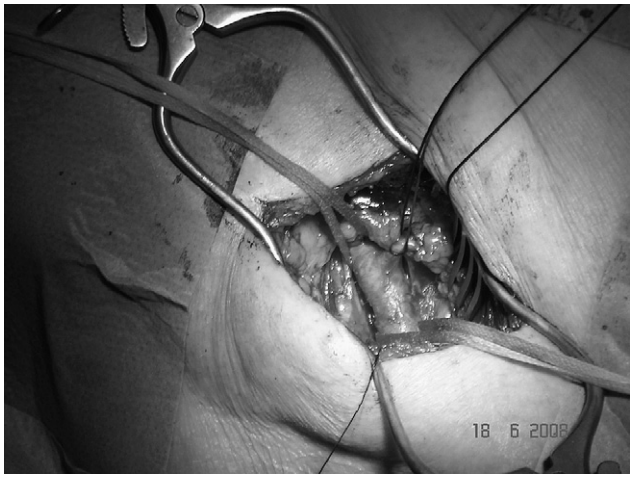

FIGURE E2. Subclavian exposure after incision of cutaneous and subcutaneous tissue.

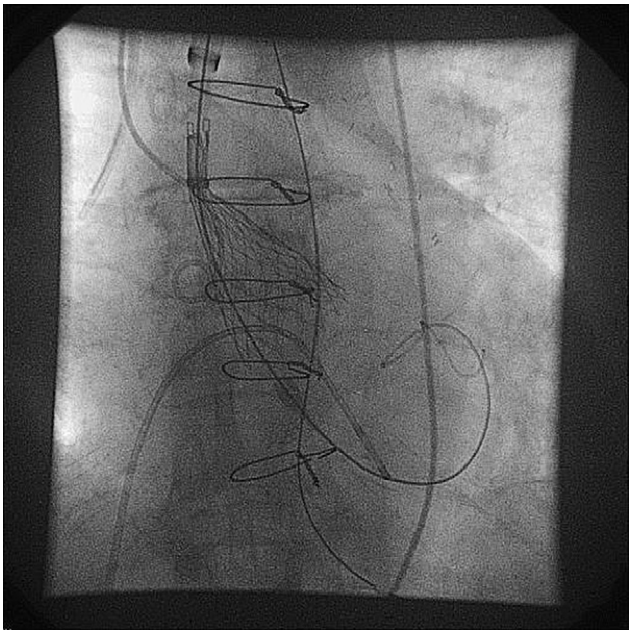

FIGURE E4. After careful checking of the CoreValve's position, the valve was released.

TABLE E1. Patients' clinical follow-up

Patient	NYHA class	Events	Outcome	Follow-up (mo)
1	I	AF, PM	Alive	16
2	I	PTA and iliac-femoral bypass of femoral artery	Alive	15
3	I	PTA of femoral artery	Alive	15
4	II	HF episode	Alive	12
5	NA	Pneumonia	Death	1
6	I	Cholesterinic embolism	Alive	9

NYHA, New York Heart Association; *AF,* atrial fibrillation; *PM,* pacemaker; *PTA,* percutaneous transluminal angioplasty; *HF,* heart failure.

TABLE E2. Patients' echocardiographic follow-up

	1 mo			6 mo			1 y		
Patient	MAoG mm Hg	LVEF%	AoI	MAoG mm Hg	LVEF%	AoI	MAoG mm Hg	LVEF%	AoI
1	10	63	1+	6	50	1+	8	50	1+
2	6	65	0	6	51	0	13	54	0
3	9	58	1+	11	63	1+	9	64	1+
4	4	35	1+	5	37	1+	4	38	1+
5	16	50	2	—	—	—	—	—	—
6	11	49	1–2+	6	53	—	—	—	—

MAoG, Mean aortic gradient; *AoI,* aortic insufficiency; *LVEF,* left ventricular ejection fraction.