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Alternative approaches for trans-catheter self-expanding aortic bioprosthetic valves implantation: single-center experience☆

Giuseppe Bruschi*, Federico De Marco, Pasquale Fratto, Jacopo Oreglia, Paola Colombo, Luca Botta, Silvio Klugmann, Luigi Martinelli

Cardiology & Cardiac Surgery Department, Niguarda Ca' Granda Hospital, Milan, Italy

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Abstract

Objective: Trans-catheter aortic valve implantation has emerged and rapidly gained credibility as a valuable alternative to treat patients with severe aortic stenosis and no surgical option; however, these patients are often affected also by severe iliac—femoral arteriopathy, rendering the transfemoral approach unemployable. From May 2008, 92 patients with severe, symptomatic aortic stenosis and no reasonable surgical option because of excessive risk underwent trans-catheter aortic valve implantation at our center. Eighty patients (34 male) with mean age 82 ± 8 years were eligible for CoreValve percutaneous femoral implantation. Twelve patients, mean age 81 ± 8 years, were excluded from percutaneous femoral CoreValve implantation because of iliac—femoral arteriopathy. **Methods:** These 12 patients underwent trans-catheter aortic valve implantation through the left axillary artery in six cases, the other six directly from the ascending aorta through a right anterior mini-thoracotomy. Procedures were performed by a combined team of cardiologists, cardiac surgeons, and anesthetists. **Results:** Procedural success was obtained in 11 cases; all these patients were discharged in asymptomatic status, with midterm good prosthesis performance. Three patients required the implantation of a permanent pacemaker. One patient needed a subclavian covered stent implantation to treat a post-implant artery dissection. One patient of the direct aortic access group was converted to the femoral approach due to an extremely fragile aortic wall, but died in the intensive care unit of abdominal aortic aneurysm rupture. All discharged patients improved their New York Heart Association (NYHA) functional class and functional capacity, and echocardiograms evidenced good valve performance at 2 years. **Conclusions:** Trans-catheter aortic valve implantation with surgical subclavian or direct aortic approach seems safe and feasible, offering a new attractive option to treat selected high-risk patients with severe aortic stenosis and peripheral vasculopathy, and has emerged as a valuable alternative route to trans-apical procedures.

Keywords: Aortic stenosis; Trans-catheter valve replacement; Axillary artery; Aortic valve

1. Introduction

Severe aortic stenosis (AS) is the most frequent form of valvular heart disease in adults in Western countries, especially in elderly patients [1]; aortic valve replacement (AVR) is the standard treatment for these patients [2]. However, the mortality rate associated with AVR increases substantially with age, the presence of left-ventricular (LV) dysfunction, or multiple co-morbidities that are common in elderly patients [3]. In these cohorts of high risk for surgery, symptomatic AS patients' trans-catheter aortic valve implantation (TAVI), transfemoral [4,5] or trans-apical [6] has emerged, and is rapidly gained credibility, as a valuable alternative to conventional AVR. Since the first-in-man procedure in 2002 [4], several improvements have been achieved on TAVI device technologies, procedural management, and access, leading to incremental success rates [7—9]. Presently, the two TAVI devices under post-marketing surveillance in Europe are the balloon-expandable Edwards SAPIEN prosthesis (Edwards Lifesciences, CA, USA) and the self-expandable CoreValve Revalving prosthesis (Medtronic Inc., MN, USA). Both devices can be delivered in most of the screened patients using the transfemoral approach. Because of the large device size of current-generation systems, the transfemoral approach requires favorable ileo—femoral arterial anatomy; this approach is contraindicated in patients with excessive atherosclerosis, calcifications, or tortuosity of ileo—femoral arteries, and should be considered cautiously in patients with an aneurysm of the thoracic or abdominal aorta. To treat these patients, a trans-apical approach with the Ascendra trans-apical catheter and the Edwards-SAPIEN valve should be preferred. However, this approach appears

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* Corresponding author. Address: Cardiology & Cardiac Surgery Department, Niguarda Ca' Granda Hospital, Piazza dell'Ospedale Maggiore 3, 20162 Milan, Italy. Tel.: +39 02 6444 2565; fax: +39 02 6444 2566.

E-mail address: giuseppe.bruschi@fastwebnet.it (G. Bruschi).

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demanding, as it requires direct left-ventricle-apex surgical exposure, which can be structurally friable in elderly patients and in case of severe hypertrophy. Moreover, the trans-apical approach requires a dedicated antegrade delivery system.

2. Materials and methods

From May 2008 to July 2010, 160 patients with severe, symptomatic AS and no reasonable surgical option because of excessive risk were evaluated for TAVI at our center. The patient screening protocol included transthoracic echocardiogram, complete left-heart catheterization, and coronary angiography, with angiography of the iliac and femoral arteries and chest and aortic–iliac–femoral computed tomography scan (CT). Acceptance for the procedure required consensus by a team composed of a cardiac surgeon, an interventional cardiologist, the referring cardiologist, and a cardiac anesthesiologist. Written informed consent was obtained in all patients and the local ethics committee approved the procedures.

Eighty patients (34 male), mean age 82 ± 8 years, were eligible for CoreValve percutaneous femoral implantation. All patients had severe symptomatic AS (mean transvalvular pressure gradient 54.3 ± 11.1 mmHg, mean aortic valve area 0.7 ± 0.2 cm [2]). The mean predicted mortality by logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation) was 27.8 ± 17.1% and by Society of Thoracic Surgeons (STS) score 15.5%. A total of 26 patients (33%) underwent previous cardiac operation; porcelain aorta was the reason for TAVI in 10% of patients. Peripheral vasculopathy was present in 34 patients (42%), 35 patients (43%) had concomitant coronary artery disease, 20 patients (25%) suffered from severe chronic obstructive pulmonary disease and 13 patients (16%) had severe pulmonary hypertension.

Twelve patients (eight male), mean age 81 ± 8 years, were excluded from the transfemoral approach because of iliac–femoral arteriopathy, small size, excessive tortuosity, calcification, or abdominal aorta aneurysm and underwent CoreValve implantation through the left axillary artery in six cases or directly to the ascending aorta through a right mini-thoracotomy. Two patients had previously undergone coronary artery bypass grafting (CABG) surgery and one had a patent left internal mammary to left anterior descending artery (LAD) graft. Two patients had severe LV dysfunction and three patients underwent a bridge procedure of balloon aortic valvuloplasty. Patients' characteristics are reported on Table 1 All the patients underwent supra-aortic vessels' angiography and CT scan to assess left subclavian artery size, course, and calcification (Fig. 1). Patients were not eligible for the subclavian approach in case of vessel diameter <6 mm, heavy calcifications, excessive tortuosity, or tight subclavian stenosis not amenable to percutaneous balloon angioplasty, and therefore underwent direct aortic access. The presence of a patent left internal mammary artery graft to a coronary artery was not considered a contraindication to the subclavian approach, provided the subclavian artery was larger than 7 mm and free from atherosclerotic disease.

The current 3rd-generation CoreValve Revalving system was used in all patients. The CoreValve System consists of three unique components: a self-expanding support frame with a trileaflet porcine pericardial tissue valve; an 18-Fr catheter delivery system, and a disposable loading system; details have been described previously [8,10,11]. The procedures were performed by the cardiovascular team composed by interventional cardiologists, cardiac surgeons with expertise in hybrid procedures, and cardiac anesthesiologists. The patients were under general anesthesia and mechanical ventilation.

2.1. Operative technique

All patients received acetylsalicylic acid 100 mg before the procedure and lifelong thereafter. A 300-mg loading dose of clopidogrel was administered the day before the procedure, followed by 75 mg daily for 3–6 months. In

Table 1. Baseline patient's characteristics at implant.

Pt	Access	Sex	Age	Comorbidity	AoVArea cm^2	MAoG mmHg	Peak Ao Δ mmHg	LV EF %	EuroSCORE		STS	
									Additive	Logistic	Mortality	Morbidity
1	S	M	78	Vasc; porcelain Ao. previous PCI	0.8	51	90	69	8	10	6.3%	28.9%
2	S	F	85	Vasc; thrombocythemia	0.8	51	93	67	11	20	8.7%	29.9%
3	S	M	74	Vasc; AMI; Bl. Neo; IDDM; previous CABG and PCI	1	52	81	58	12	27	11%	41.9%
4	S	M	86	Vasc; IDDM; CRI; previous PCI	0.9	47	80	30	15	53	14.6%	42.7%
5	S	M	85	Vasc; stroke	0.9	62	104	49	13	39	6.2%	31%
6	S	M	85	Vasc; IDDM; AMI; previous CABG; PHT	1.1	47	82	26	16	59	15.7%	49.1%
7	A	F	83	Vasc; CRI; PHT	0.5	74	130	67	12	31	12.1%	43.2%
8	A	F	60	Vasc; obesity	0.5	82	137	61	5	5	5.1%	29.1%
9	A	F	85	Vasc; lymphoma; COPD	0.6	50	83	60	12	26	14.9%	47.3%
10	A	M	85	Vasc; IDDM; COPD	0.6	45	78	63	11	22	12.7%	46.0%
11	A	M	82	Vasc; COPD; CRI	0.7	60	106	44	14	51	14.8%	48.7%
12	A	M	87	Vasc; CRI	0.8	55	95	55	14	46	7.4%	39.4%

Pt: patient; S: subclavian; A: direct aortic; F: female; M: male; Vac: vasculopathy; Ao: aorta; AMI: previous acute myocardial infarction; Bl. Neo: bladder neoplasm; IDDM: insulin-dependent diabetes mellitus; CRI: chronic renal insufficiency AoV: aortic valve area; MAoG: mean aortic gradient – echocardiography; Peak Ao Δ mmHg: echo peak transvalvular aortic pressure gradient; LV EF: left-ventricular ejection fraction; PCI: percutaneous coronary intervention. PHT: pulmonary hypertension. COPD: chronic bronchopneumopathy.

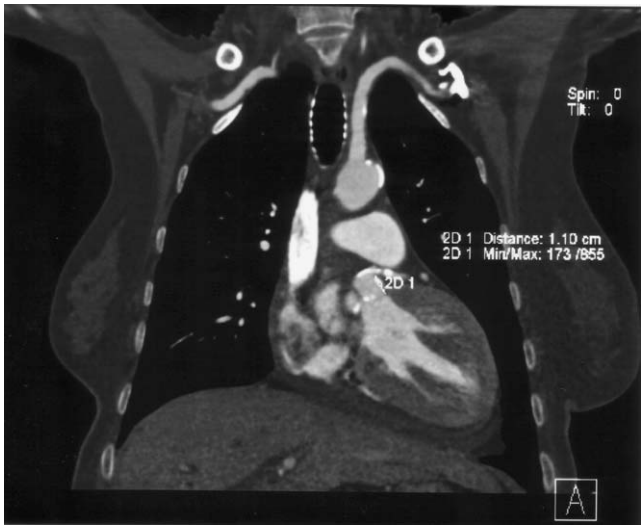

Fig. 1. Computed tomographic angiography performed in order to detect size, course, and calcification of left subclavian artery, aortic arch, and ascending aorta.

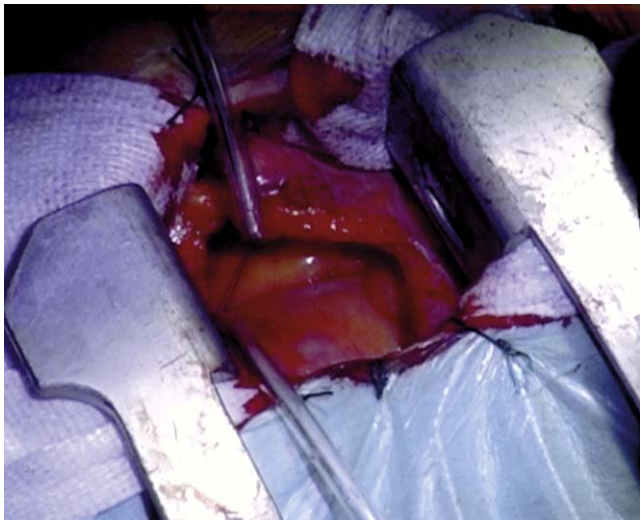

Fig. 2. Standard double purse string suture in the anterior-lateral wall of the ascending aorta for arterial cannulation.

patients treated by the subclavian or the direct aortic approach, clopidogrel was started the day of the procedure. Standard antibiotic prophylaxis was started before the procedure and continued for 5 days. During the intervention, unfractioned heparin 100 UI kg^{-1} was administered to achieve an activated clotting time of 200—250 s for the duration of the procedure.

A temporary pacing lead was advanced in the right ventricle through the right femoral vein or the jugular vein, in the patients without permanent pacemaker, to treat possible post-TAVI atrioventricular block.

2.1.1. Transfemoral approach

The best femoral artery was used for 18 Fr insertion, after contrast injection from the contralateral femoral artery, in a crossover fashion, to allow midline puncture of the vessel; the common femoral artery was then punctured and cannulated under fluoroscopic guidance using a pigtail, as a landmark. A Prostar XL 10-Fr-suture-mediated closure device (Abbott Vascular Devices Laboratories, Redwood City, CA, USA) was placed in the femoral artery (preclosure technique) in all patients. Controlateral access was used to allow homodynamic monitoring and landmark aortic angiography through a 5-F pigtail, as previously described [8,10].

2.1.2. Subclavian approach

The axillary artery was surgically isolated through a subclavicular incision of 3—5 cm. 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 7-F sheath was then inserted into the subclavian artery.

2.1.3. Direct aortic approach

A 5.0-cm incision was made at the level of the second right anterior intercostal space with a right-internal-thoracic-artery-sparing procedure. A soft-tissue retractor and a small rib retractor were used to access the pericardium. An angiography of the basal ascending aorta was performed to measure the distance between the aortic annulus and the entry site in the ascending aorta. Aortic cannulation was performed with the Seldinger technique through a double purse-string suture (Fig. 2). A 6-F sheath was then inserted into the ascending aorta. Using a left Amplatz catheter, a 0.035 straight-tipped guide wire was placed in the left ventricle, then a Cook 30-cm Check-Flo Performer 18-Fr introducer (William Cook Europe, Bjaeverskov, Denmark) was inserted (Fig. 3) over an Amplatz super stiff guide wire (Amplatz Cook, Inc., Bloomington, IN, USA) and the native aortic valve was predilated with a 22 or 25 mm Nucleus balloon (NuMED, Inc. Hopkinton, NY, USA) without rapid pacing in all patients. A CoreValve prosthesis was then carefully introduced and retrogradely implanted under angiographic and fluoroscopic guidance (Fig. 4) over the stiff wire across the aortic valve 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, presence, and location of eventual paravalvular leak. After the procedure, heparin was neutralized by protamine. The subclavian artery was restored by direct suture or thoracotomy, and closed by standard fashion.

2.2. 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 and/or median and the range of values observed.

3. Results

According to Piazza and colleagues' definitions [9], procedural success was defined by the combination of three different end points: adequate technical placement, normal

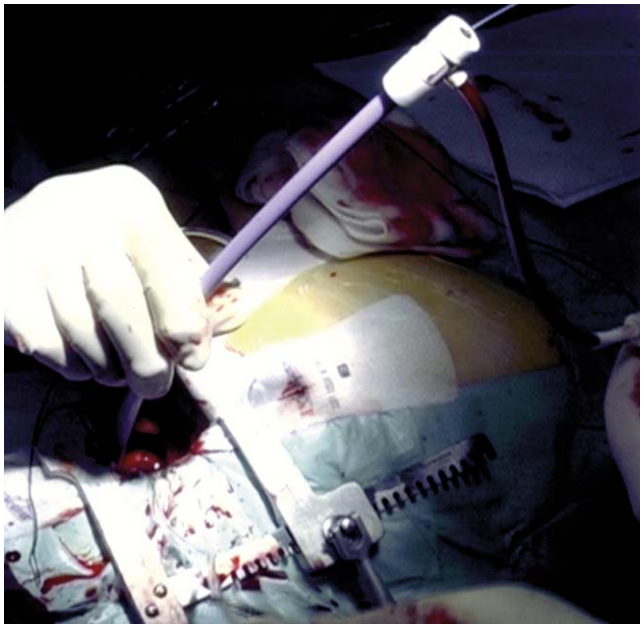

Fig. 3. 18-Fr introducer inserted over an Amplatz super stiff guide wire.

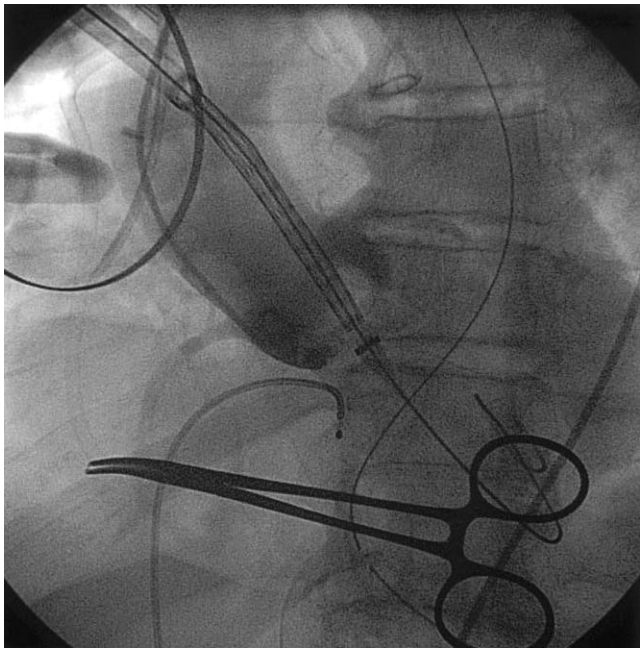

Fig. 4. CoreValve implantation under angiographic and fluoroscopic guidance, notice the direct access to the aortic annulus from the aortic cannulation.

bioprosthesis performance, and operative outcome. Adequate technical placement was the correct positioning of the CoreValve in the aortic root, good valve performance was evidenced by a reduction in mean trans-aortic gradient to less than 20 mmHg and aortic regurgitation grade $\leq$2, as evaluated by aortic angiogram or echocardiogram, and operative outcome was represented by any event occurring during the procedure and within the subsequent 24 h. Events occurring within 30 days from the procedure were considered as procedure-related events [9]; events collected were death, neurologic event, myocardial infarction, ventricular perforation, cardiac tamponade, aortic dissection, vascular access complication, infections, and contrast-induced nephropathy.

3.1. Transfemoral group

The mean procedural time was 108 $\pm$ 35 min. Mean aortic gradient dropped immediately after valve deployment in all patients, and procedural success was obtained in 95% of patients: two patients had grade >2 aortic insufficiency and three patients underwent two valves' implantation. Intra-procedural death occurred in one patient for aortic annulus rupture. Major access site complications were observed in 12 patients (15%); three of them required femoral surgical patch repair. No stroke and myocardial infarction were observed. Nineteen patients (24%) developed post-implant complete atrioventricular block, requiring permanent pacemaker implantation. Two patients died during the hospitalization of cardiac cause, leading to a 30-days' mortality of 3.7% (3/80 patients). Seventy-seven patients have been discharged after a mean hospitalization of 13 days (range 7–27 days). The mean transvalvular aortic pressure gradient at discharge was 9 mmHg. During a mean follow-up of 13 $\pm$ 11 months (range 1–34 months), all subjects experienced functional class improvement and returned to a normal life, limited only by their previous medical conditions. Two patients underwent pacemaker implantation. Three patients died during follow-up: one of neoplasm, one of respiratory insufficiency, and one of cardiac cause. All patients underwent regular echocardiographic follow-up controls that evidenced normal prosthesis performance with an average mean transvalvular aortic pressure gradient of 10.3 $\pm$ 4 mmHg at 18 months; none had more >2 grade aortic insufficiency due to paravalvular leak.

3.2. Subclavian group

The CoreValve was inserted through the left subclavian artery in all six patients. Mean duration of the procedure was 147 $\pm$ 63 min (range 105–270 min). Procedural success were obtained in all cases, the mean aortic gradient dropped immediately $\leq$5 mmHg after valve deployment in all patients, and two patients had grade 1–2 aortic insufficiency (Table 2). In one patient, the procedure was performed through the left subclavian artery with a patent left internal mammary artery graft on the descending anterior coronary artery.

In one patient (patient 4), after 18-F sheath removal and surgical closure of the axillary artery, the radial pulse disappeared. Angiography, performed by the femoral artery, revealed a long dissection with a flow-limiting stenosis at the puncture site, which was treated with Gore Viabahn 8 mm $\times$ 50 mm (W.L. Gore & Associates, Inc. Flagstaff, AZ, USA) covered polytetrafluoroethylene (PTFE) stent implantation. All patients were extubated after the end of the procedure in the catheterization laboratory. One patient developed post-implant complete atrioventricular block requiring permanent pacemaker implantation, via the right subclavian vein.

All six patients have been discharged from hospital asymptomatic, with good prosthesis function, as assessed

Table 2. Procedural details and complications.

Pt	Valve size (mm)	Implant time (min)	DAP Gy cm^2	P-t-P Ao gradient (mmHg)	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
7	26	120	167	3	0	PM implant
8	26	240	198	1	0	PM implant
9	29	480	212	1	1	Ao and RV bleeding. Sternotomy; death
10	29	130	150	1	0	–
11	29	160	265	2	2	–
12	26	180	346	1	0	–

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). Ao: aortic; RV: right ventricle.

by echocardiograph after a mean hospitalization of 12 days (range 7–18 days). One patient was re-admitted 11 days after discharged for livedo reticularis in both feet, eosinophilia (9.1%), and slight worsening of his renal function. The lower extremities cholesterinic embolism, caused by passage through the abdominal aorta of the 5 F diagnostic pigtail catheter used for contrast injections during the procedure, was successfully medically treated. One patient died 41 days after the procedure of a pneumonia. During a mean follow-up of 20 $\pm$ 9 months, all subjects experienced functional class improvement, all are asymptomatic and returned to a normal life, limited only by their previous medical conditions. Two patients required femoral artery percutaneous transluminal angioplasty (PTA) and one underwent iliac–femoral bypass surgery during follow-up. All patients underwent regular echocardiographic follow-up controls that evidenced normal prosthesis performance with an average mean transvalvular aortic pressure gradient of 8 $\pm$ 4 mmHg at 1 year. All patients after the first months had only mild aortic insufficiency due to trivial paravalvular leak (Table 3).

3.3. Direct aortic access group

Procedural success was obtained in five cases. One patient, an 85-year-old female with a non-Hodgkin's lymphoma treated with CHOP (cyclophosphamide, adriamycin, vincristine, and prednisone) chemotherapy, had an extremely fragile aortic wall. After the 18-Fr introducer insertion, bleeding from ascending aorta was noticed; at the same time, clinical and echocardiographic signs of cardiac tamponade were evident. We decided to perform a median sternotomy and right ventricle (RV) laceration was evident. RV direct patch suture was performed. When new ascending aorta purse-string sutures were performed, bleeding from ascending aorta was evident, requiring prolong hemostasis. Despite the presence of the abdominal aorta aneurysm, considering the extremely fragile aortic wall, we decided to perform a femoral-approach TAVI. Successful CoreValve implantation was performed. After 18-Fr introducer sheath removal and simultaneously knotting and closure of the Prostar sutures, extravasation occurred. A PTA balloon was than inflated twice for 10 min, but extravasation continued to be evident at contrast injection from the crossover sheath; hence, a covered-stent Gore-Viabhan 7 cm $\times$ 10 cm was successfully placed. The patient was transferred to the intensive care unit but died on the same day of abdominal aortic aneurysm rupture.

In all patients after valve deployment, the mean aortic gradient immediately dropped to $\leq$5 mmHg; two patients had grade 1 aortic insufficiency (Table 2). The mean duration of the procedure was 240 min. All patients, except the one who died, were extubated in the intensive care unit within the first 24 h. Two subjects developed post-procedure

Table 3. Patients clinical follow-up.

Pt	NYHA class	Events	Outcome	Follow-up (months)	6 months			18 months		
					MAoG mmHg	LV EF %	AoI	MAoG mmHg	LV EF %	AoI
1	I	AF. PM	Alive	27	6	50	1+	9	51	1+
2	I	PTA and I-F by pass	Alive	26	6	51	0	8	54	0
3	I	PTA of femoral A.	Alive	26	11	63	1+	8	57	1+
4	II	Episode HF	Alive	23	5	37	1+	5	40	1+
5	NA	Pneumonia	Death	1	–	–	–	–	–	–
6	I	Cholesterinic embolism	Alive	18	6	53	1+	7	50	1+
7	I	Thoracoscopic decortication	Alive	11	11	66	1+	–	–	–
8	II	–	Alive	11	19	61	0	–	–	–
9	NA	–	–	–	–	–	–	–	–	–
10	I	–	Alive	7	12	53	1+	–	–	–
11	I	–	Alive	5	–	–	–	–	–	–
12	I	–	Alive	1	–	–	–	–	–	–

NYHA: New York Heart Association; AF: atrial fibrillation; PM: pacemaker; PTA: percutaneous transluminal angioplasty; I–F: Iliac–femoral; A: artery; HF: heart failure; MAoG: mean aortic gradient; AoI: aortic insufficiency.

complete atrioventricular block requiring permanent pacemaker implantation. Five patients were discharged asymptomatic with good prosthesis function, as assessed by the echocardiograph after a mean hospitalization of 16 days (range 7—28 days). The mean transvalvular aortic pressure gradient at discharge was 12 mmHg. During a mean follow-up of 8 ± 4 months, all five patients experienced functional class improvement, and returned to a normal life, limited only by their previous medical conditions. One patient underwent right thoracoscopic decortication 35 days after the procedure. All patients underwent regular echocardiographic follow-up controls that evidenced normal prosthesis performance with an average mean transvalvular aortic pressure gradient of 9 ± 4 mmHg at 6 months, with only trivial paravalvular leak (Table 3).

4. Discussion

With the population aging, severe symptomatic AS is becoming a more prevalent public-health issue and is the most frequent form of valvular heart disease in Western countries [1]. Surgical AVR remains the mainstay of definitive treatment [2]. Although surgical therapy is effective, the mortality rate associated with AVR increases substantially with age, the presence of LV dysfunction, or multiple comorbidities that are common in frail elderly patients [3]. In these patients, TAVI, with its less invasive nature, is believed to offer a safer treatment solution. In the last 7 years, almost 12 000 patients had been treated worldwide for severe AS using a TAVI (www.bmctoday.net/citoday/2009/09). Several technical approaches have been applied until the first report of a successful percutaneous implantation of an aortic bioprosthesis in April 2002 was done via the femoral vein with an antegrade (transseptal) approach [4], followed by the retrograde approach via femoral arteries and by the most recently developed form of trans-catheter AVR, the trans-apical approach via a mini-thoracotomy [5,6]. The antegrade transvenous approach [4,12] theoretically appears more suitable in introducing the large delivery systems, reducing the risk of vascular complications. However, the technique was challenging because of the need for a transseptal puncture, the guide-wire interaction with the mitral valve and subvalvular apparatus, contributing to poorly tolerated acute mitral insufficiency; for these reasons, this approach has been abandoned [5,13]. Significant technical and prosthetic modifications followed to solve the previously encountered limitations. With CoreValve size reduction of delivery catheters from initial design 24-F system to new-generation devices that decreased the delivery sheath to 21- and 18-F subsequently, converting the procedure to a completely percutaneous one, and with Edwards introduction of a manually activated deflectable tip, which aids in the atraumatic passage across the aortic arch and in centering the guide wire through the aortic commissures, and modifications in the delivery sheath, the preferred access site for TAVI became the retrograde approach via the femoral arteries. However, considering the known overlap of etiology and risk factors for atherosclerotic vascular disease and AS and actual patients' selection criteria of advance age subjected to severe generalized atherosclerotic disease, porcelain aorta, or previous cardiac surgery, it is not surprising to over-select a cohort of patients with severe AS and concomitant severe peripheral vasculopathy. Because peripheral artery disease is associated with increased risk of peripheral complications, the femoral approach is contraindicated in patients with excessive atherosclerosis, calcifications, or tortuosity of femoral or iliac arteries, and should be considered cautiously in patients with an aneurysm of the thoracic or abdominal aorta. These conditions may be overcome by a trans-apical approach widely and successfully performed by using the Edwards-SAPIEN valve [6,14]. This approach allows the introduction of delivery systems directly through the apex of the left ventricle without theoretical sheath-diameter limitation. This approach requires a 5—8-cm sixth intercostal anterolateral thoracotomy. After the pericardium over the apex of the left ventricle is identified and opened, two paired orthogonal U-shaped sutures with pledgets are placed into the myocardium. An arterial needle puncture allowed placement of a 7F sheath through the apex into the LV cavity using a standard over-the-wire technique. The introduction of the valve catheter requires the Ascendra Trans-apical Delivery System (Edwards Lifesciences, CA, USA). Moreover, trans-apical valve implantation has some peculiar technical limitations, as in the case of severe septal hypertrophy in combination and with the angled position of the LV outflow tract in relation to the aortic root, calcifications of the apex, and previous LV patch surgery and calcified pericardium. Potential and unique complications include the occurrence of significant incidence of bleeding from the apical puncture site, myocardial tears requiring further surgical repair, and possible accidental damage of a coronary artery during apical repair, and mitral or aortic trauma that could occur from misdirected stiff catheters and long-term development of LV apical false aneurysm, arrhythmias, and echocardiographic hypokinesia or akinesia of the LV apex [6,15,16]. The analysis of the TRAVERCE (Trans-Apical surgical Delivery of the Cribier—Edwards Aortic Bioprothesis Clinical Feasibility) [17] data and data from large series of high-risk patients treated with the trans-apical approach [18] evidenced worse clinical outcomes associated with the trans-apical approach. This reflects the complexity of the technique and the importance of appropriate patient selection.

In this scenario, a new alternative to both the femoral and trans-apical access has been recently reported also by other authors: a trans-subclavian retrograde approach [19,20] and a direct aortic access [21,22]; both could represent an intriguing alternative for TAVI with the CoreValve system in high-risk aortic patients with associated severe iliac—femoral arteriopathy.

The axillary artery is easily accessible after surgical cut-down and if size is >6 mm, it allows the introduction of 18F sheaths. Up till today, the CoreValve Extended Evaluation Registry reported data about 150 patients for whom the subclavian access was used. The Italian Registry [23] reports data on 54 TAVI patients through the subclavian approach, with a procedural success of 100% and no 30-day mortality, showing that this approach is feasible and safe, with excellent procedural success, and low in-hospital complication rates, similar to the standard femoral approach in patients with severe peripheral vascular disease, which is a marker of worse

long-term outcome. In patients not eligible for the subclavian approach in case of vessel diameter <6 mm, heavy calcifications, excessive tortuosity, or tight subclavian stenosis not amenable to percutaneous balloon angioplasty, we opted for a direct aortic access through a right mini-thoracotomy, as routinely used for minimal invasive AVR with standard double purse-string suture in the anterior–lateral wall of the ascending aorta, for arterial cannulation [24]. Regarding the operative technique, the aortic cannulation is one of the most important features that can be performed directly through the thoracotomy instead of by the LV approach as in the transapical approach. The direct aortic approach technique provides a direct access to the aortic annulus, allowing an easier manipulation and delivery of the device, particularly during the stepwise retraction of the outer sheath, allowing a correct positioning of the CoreValve prosthesis, especially in cases where the implantation with other access may be difficult, such as in a very vertical valve, or horizontal ascending aorta, or where the native valve is at the upper limit of the size and you have to be very precise. The direct aortic approach and the axillary one have also the advantage of overcoming challenging aorto–ileo–femoral vascular disease, and avoiding the risk of dislodging atherosclerotic plaque during valve passage through the aorta that may cause particulate embolization and subsequent stroke; none of our patients experienced any neurological event. Our experience confirms the possibility to perform CoreValve implantation through the left subclavian artery also in patients with a patent internal mammary graft to a coronary artery; otherwise, we believe that a direct aortic approach should be preferred in these group of patients to avoid the risk of impairing flow in the left internal mammary artery. No patient experienced surgical wound infections and all patients were discharged in good health conditions and stable hemodynamic compensation within 3 weeks after valve implant. During follow-up period, all patients improved their NYHA functional class and functional capacity, and echocardiograms evidence good valve performance at 2 years. We did not observe any difference between the three groups of patients in terms of patient recovery and short- and long-term follow-up. Our experience emphasized the fact that a multidisciplinary approach is necessary to offer the safest conditions and care for patients. Considering that the best access is the one that minimizes the risk to the procedure and offers the best recovery for the patient, TAVI, by subclavian or direct aortic retrograde approach, is safe and feasible in high-risk patients with symptomatic AS and co-existing peripheral vasculopathy. Direct trans-aortic deployment of TAVI is a viable alternative to the standard trans-apical technique and may overcome the inherent shortcomings associated with the implantation of the self-expanding CoreValve aortic prosthesis; both these approaches will allow us to extend the current indications for TAVI and may increase the percentage of eligibility for TAVI.

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Alternative approaches for trans-catheter self-expanding aortic bioprosthetic valves implantation: single-center experience

Giuseppe Bruschi, Federico De Marco, Pasquale Fratto, Jacopo Oreglia, Paola Colombo, Luca Botta, Silvio Klugmann and Luigi Martinelli

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