Transcatheter aortic valve implantation using the axillary/subclavian access: Feasibility and early clinical outcomes

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Objective: Retrograde transfemoral artery catheterization is the most common way of implanting a percutaneous aortic valve. But in some cases, this access cannot be used and the subclavian artery access may represent an alternative to the femoral route, even offering certain advantages. This article describes prosthetic aortic valve implantation using the subclavian arterial approach and reports the findings.

Methods: The valve prosthesis is a self-expandable, nitinol-based device (CoreValve; Medtronic Inc. Minneapolis, Minn). The axillary or subclavian artery was exposed with a small incision. Rapid ventricular pacing was used to reduce cardiac output while a routine aortic balloon valvuloplasty was performed. Then, an 18F sheath was inserted into the axillary artery down into the ascending aorta. By using this method, a prosthesis was implanted in 17 patients (aged 71 ± 11 years) whose surgical risk was deemed excessive because of severe comorbidity and in whom transfemoral catheterization was considered unfeasible or at risk of severe complications.

Results: Subclavian arterial injury did not occur in any patient. The postprocedural aortic valve area increased from $0.6 \pm 0.3 \text{ cm}^2$ to $1.44 \pm 0.35 \text{ cm}^2$. A transient ischemic attack occurred in 1 patient. Two patients experienced transitory brachial plexus deficit. There were no intraprocedural deaths. Two deaths occurred in the 30-day follow-up period.

Conclusions: This initial experience suggests that subclavian transarterial aortic valve implantation, in selected high-risk patients, is feasible and safe with satisfactory short-term outcomes. (*J Thorac Cardiovasc Surg* 2011;141:487-91)

Supplemental material is available online.

Aortic valve stenosis is the most frequent adult heart valvular disease in the western world.¹ Patients are often high-risk candidates for open surgery using a heart-lung machine.² Although surgical valve replacement remains the “gold standard” treatment, many patients with severe aortic stenosis do not undergo surgery for the following reasons: patient refusal, excessive surgical risk, advanced age, or self-preference. Prognosis with medical management is poor, and the percutaneous approach as an alternative to surgery has been limited to palliative balloon valvuloplasty.³⁻⁵

Transcatheter aortic valve implantation (TAVI) has been under active investigation in many medical centers.⁶⁻¹²

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However, the technical complexity and associated risks of the antegrade approach limited its development.^{13,14} The retrograde femoral arterial approach is an adaptation of the original aortic valvuloplasty technique and is rapidly spreading worldwide with encouraging results.¹⁵ Patient selection requires a complete study of the different arterial access points, such as the aorta, aortoiliac, and femoral arteries. However, peripheral artery disease may render iliofemoral access difficult or even impossible in some cases. Retrograde femoral access difficulties, in elderly patients, relate to frequently diseased and tortuous femoral and iliac arteries. These obstacles greatly increase the risk of procedure failure or vascular injury with potentially lethal complications. This high vascular risk has led to the development of transapical or subclavian access techniques that have been recently described in the medical literature.¹⁶⁻¹⁸ Both techniques offer the advantage of avoiding access site problems and facilitating valve delivery. However, the transapical approach, requiring thoracotomy, is more invasive, making it a high-risk procedure in patients with severe respiratory dysfunction. Moreover, several complications resulting from the introduction of a percutaneous valve holder through the apex of the left ventricle have been reported.¹⁶

In centers where the medico-surgical approach of this new technique was effective, using the axillary or subclavian artery as a second choice after the femoral artery for

Abbreviation and Acronym

TAVI = transcatheter aortic valve implantation

introducing the device became obvious. In this prospective study, we describe the implantation technique, procedural success, and clinical outcome up to 30 days after TAVI using transaxillary or subclavian access in 17 consecutive patients who were purposely recruited. Procedures were performed in 4 different French centers between January and September of 2009.

MATERIALS AND METHODS**Patients**

A prospective, single-arm study was performed, including patients from 4 French centers (CHRU de Lille, $n = 7$; Lapitié Salpêtrière, $n = 5$; CHRU de Lyon, $n = 4$; and CHRU de Bordeaux, $n = 1$). Patients with severe symptomatic aortic stenosis were referred for a percutaneous procedure because of multiple comorbidities and excessive surgical risk. The cases were selected following the guidelines of the "French Sanitary High Authority." Our objective was to evaluate the feasibility, safety, and clinical outcomes of TAVI via subclavian or axillary artery access of the 18F CoreValve Revalving System (Medtronic Inc., Minneapolis, Minn). A heart team of senior interventional cardiologists, cardiac surgeons, and anesthesiologists formally reviewed patients with a consensus that patients did not have a reasonable surgical option. Patient preference alone for a percutaneous procedure was not considered as an acceptable reason for inclusion. Informed consent was obtained. The operating team always consisted of a cardiac surgeon, an interventional cardiologist, and, in some institutions, an interventional radiologist. All patients underwent transthoracic echocardiography and iliofemoral and coronary angiography. Angiographic computed tomography scan and echo Doppler were used to assess the diameter and patency of the right and left subclavian and axillary arteries when iliofemoral arterial access was considered at high risk of vascular complications. Short segments of calcified or focal stenosis were not considered exclusion criterion.

Prosthetic Valve System

The CoreValve Revalving System consists of porcine pericardium cut into a trileaflet pattern mounted on a nitinol frame. The diameter of the aortic annulus was measured using the transthoracic echocardiography parasternal long-axis view immediately below the insertion point of the valve leaflets. Moreover, because the aortic annulus is not circular, computed tomography scans were used to measure the shortest and longest diameters. Annulus diameters of 20 to 23 mm and 23 to 27 mm were considered appropriate for 26-mm and 29-mm diameter prostheses, respectively. Both valves require an 18F introducer sheath. An axillary arterial diameter of 6 mm was considered adequate for implantation.

Patients were premedicated with a loading dose of clopidogrel and aspirin, and intravenously injected with cefazolin 1 g immediately before the procedure. The procedure was performed in a catheterization laboratory with operating room-like sterility precautions. A femoral access was used, and a 5F pigtail catheter was inserted for control angiograms during valve implantation. Vein access for the temporary pacemaker lead was used for rapid pacing during valvuloplasty. Heparin (50 U/kg) was administered intravenously on completion of vascular access.

The proximal axillary artery was exposed through a small infra- or supraclavicular incision. Two 5-0 Prolene continuous purse sutures were placed on the anterior face of the artery. A 7F sheath was inserted in the middle of the purses using a percutaneous technique, and the native valve was crossed

using a conventional technique that includes a straight wire. After hemodynamic transvalvular gradient and telediastolic ventricular pressure measurement, a manually preshaped Stiff wire was placed in the ventricular cavity. The 18F sheath was then carefully inserted (Figure E1), and its progression was followed using fluoroscopic guidance. An aortic angiography was performed and displayed during the procedure to facilitate subsequent positioning of the sheath and prosthesis. The tip of the sheath was positioned in the upper part of the ascending aorta (Figure 1, A, B). Balloon valvuloplasty was performed using 22- and 25-mm balloons (Nucleus, NuMED Inc, Hopkinton, NY) for the 26- and 29-mm Medtronic CoreValve prostheses, respectively. After balloon deflation, rapid pacing was stopped and the balloon catheter was withdrawn. The valve was then advanced and deployed using repeated fluoroscopic controls. The prosthesis was positioned so that it protruded 4.0 to 8.0 mm out of the calcified native valve leaflets. During prosthesis implantation, no rapid pacing was used. A coordinated approach was used wherein one operator maintained ideal valve positioning by pulling slowly on the catheter during valve release, while the second operator turned the release knob that would deliver the valve. Aortic root angiographies were performed to assess valve position during implantation. After full release of the valve, a coaxial stiff wire position was maintained in the left ventricular cavity and a pigtail was advanced to measure the transvalvular gradient and then removed carefully. Aortic root angiography and echocardiography were performed to reassess valve competency, using standard criteria, and to evaluate the aortic regurgitation severity. After procedure completion, the subclavian arterial access site was surgically closed or repaired, when needed, after purse straining (Figure E2), and a control angiogram was performed. Patients were then transferred to the intensive care unit for 24 to 48 hours of observation. Patients continued taking aspirin indefinitely and clopidogrel for 6 months. Clinical follow-up and transthoracic echocardiograms were performed within 24 hours of the procedure and at 1 and 4 weeks after the device implantation.

RESULTS**Patient Outcome**

Valve implantation was attempted in 17 consecutive patients between January and September of 2009 in the above-mentioned centers. Complete follow-up was pursued to conclusion in all 17 patients. Preoperative characteristics are shown in Table 1. All patients enrolled had severe symptomatic aortic stenosis with a mean transvalvular gradient of 47 ± 13.3 mm Hg. The preprocedural mean aortic valve area was 0.6 ± 0.3 cm². The procedure was performed under general anesthesia (13 patients) or local anesthesia in combination with mild sedative-analgesic treatment. The use of transesophageal echocardiographic guidance was not systematic and was left to the discretion of the operators. Percutaneous placement of the 18F sheath was successful in all cases. All patients underwent planned open surgical access site closure. No vascular complications requiring surgical repair was observed. In one patient, because of initially low valve implantation, secondary migration occurred while trying to reposition the valve. The valve was positioned in the middle of the ascending aorta, and a second valve was successfully implanted using the same subclavian access.

Prosthesis implantations were uneventful in this small series. The 2 patients who had undergone operation via a supraclavicular incision presented minor and transitory neurologic arm deficit that recovered before patient discharge. One patient had a transient ischemic attack, and

FIGURE 1. Angiogram sheath views in the subclavian and axillary arteries (A) and ascending aorta (B).

1 patient had retrograde aortic dissection during guide wire insertion. The dissection had healed by the end of the procedure once the subclavian artery was repaired. There were no intraprocedural deaths. Intraoperative and postoperative details are shown in Tables 2 and 3.

Valve Function

Paravalvular leak, as assessed by angiography and echocardiography controls, was trivial (grade 0–1) in most cases (n = 14). There was no severe postprocedural aortic regurgitation (grade ≥ 3).

Valve function, as assessed by echocardiography within 24 hours after implantation, before discharge, and at 1 month, remained essentially unchanged (Table 4). In 2 patients, moderate paravalvular leak occurred immediately after valve implantation, which seemed to be caused by an insufficiently expanded frame. Additional valvuloplasty

after implantation, with a slightly oversized balloon under rapid pacing, reduced severe paravalvular insufficiency to trivial in both cases without apparent damage to the valve leaflets, the lack of which was assessed by the absence of a central leak during the echocardiographic control. At 30 days and the last day of follow-up, the mean paravalvular leak remained unchanged.

DISCUSSION

TAVI represents a less-invasive alternative to open surgery indicated in the treatment of aortic stenosis in elderly and high-risk patients.^{6,19} However, major concerns remain, mainly related to the access route and ways to optimize prosthesis implantation. In patients with iliofemoral arteriopathy, transfemoral access may turn out to be unfeasible or too high risk. The development of narrower sheaths may not be the only solution to ensure implantation success. When a transarterial route is not accessible, a transapical approach may be an interesting alternative in some patients.²⁰ However, because the approach requires thoracotomy and left ventricular puncture, it may not be suitable in fragile patients, especially in those with severe respiratory or ventricular dysfunction. The

TABLE 1. Baseline characteristics

Age, y, mean ± SD	71 ± 11 y
Angina, n (%)	0
Heart failure, n (%)	26
NYHA III and IV failure class	40
Syncope, n (%)	13.3
Male gender, n (%)	46.2
Diabetes mellitus, n (%)	20
Coronary heart disease, n (%)	53.3
Porcelain aorta, n (%)	0
Prior bypass graft surgery, n (%)	26.6
Prior angioplasty, n (%)	20
Renal dysfunction,* n (%)	6.6
Logistic euroSCORE predicted mortality, mean ± SD, %	34 ± 11
Left ventricle ejection fraction % mean	52 ± 14

NYHA, New York Heart Association; SD, standard deviation. *Estimated glomerular filtration rate > 60.

TABLE 2. Procedural outcome

Successful valvuloplasty	100%
Successful prosthesis implantation	100%
Death, intraprocedure	0
Stroke, minor	0
Cardiac perforation	0
Ventricular fibrillation	0
Emergency cardiac surgery	0
Transfusion rate ≤ 2 units	43%
Hospital stay (d)	9.4
Myocardial infarction	0%

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TABLE 3. Postprocedural outcome (follow-up of 30 days)

Death	2 patients
Thromboembolism	0%
Transient ischemic attack	1 patient
Myocardial infarction	0%
Aortic dissection	1 patient
Tamponade	0%
Conversion to surgery	0%
NYHA class I and II	100%
endocarditis	0%

Values are n (%) unless otherwise stated. NYHA, New York Heart Association.

axillary approach is safe, feasible, and familiar to cardiovascular surgeons. In comparison with the transfemoral approach, positioning the valve and controlling its release proved considerably easier and offered greater movement precision. The short distance between the subclavian artery and the aortic annulus might explain a sense of increased control of the delivery catheter and guide wire. The subclavian and proximal axillary arteries are of good size and usually only moderately diseased even in the oldest population groups. The vessels could be approached through an infra- or a supraclavicular incision, especially in patients with pacemakers implanted in the infraclavicular area to avoid infective endocarditis risk. We used this route in 2 patients with a history of pacemaker implantation. As in our routine practice for transfemoral implantation, we did not use transesophageal echocardiography control during valve positioning. We currently indicate a transesophageal echocardiography study in case of tamponade suspicion at the end of the procedure.

Although the left subclavian artery is the preferred access point, used in 15 of our 17 patients, the right subclavian artery²¹ has also been safely used in 2 patients. It is important to note that for a right subclavian approach, the angle between the aortic annulus plan and the horizontal line should not be greater than 20 to 25 degrees to achieve a safe implantation.

This study reports a real-life prospective study of selected high-risk patients with degenerative aortic valve stenosis who were treated with TAVI using subclavian or axillary access. The results of this prospective series of 17 patients, in accordance with similar recently published articles, confirm

the feasibility of the procedure.^{18,19,22} Optimal positioning of the prosthetic valve is mandatory to reduce risk of embolization, paravalvular insufficiency, and coronary obstruction. Because of the shorter distance between the arterial entry point and the implantation site, when compared with the femoral access, axillary or subclavian access provides better sheath and delivery catheter stability, increasing the accuracy of positioning the valve and reducing procedure time. Moreover, subclavian vascular repair was easily performed and surgical control of the access point allowed for limited risk of immediate or delayed vascular complications, as observed with the percutaneous transfemoral access.

This approach is also feasible in patients with coronary artery bypass grafting history with a patent left internal thoracic artery or right internal thoracic artery bypass. In our series, 2 patients with patent left and right internal thoracic arteries received implants using the right subclavian access. Nevertheless, this access route should be considered carefully in such situations because of the potential risk of subclavian dissection that may compromise graft patency;¹⁹ a minimum artery diameter of 6.5 to 7 mm should be required. The transfusion rate in our series, in a population with preoperative anemia, was high (43% of patients, ≤ 2 units), although no major bleeding complications occurred throughout the study. Unlike in other reports that have referred to major bleeding or access site bleeding rates,^{23,24} which are difficult to evaluate and compare, we preferred to calculate the transfusion rate allowing for a faithful reflection of bleeding complication rates.

Although stroke is a known risk of routine balloon valvuloplasty,^{25,26} none of our patients experienced an ischemic cerebrovascular event. However, 2 patients who underwent operation via supraclavicular access experienced transitory proximal neurologic deficits of the forearm secondary to plexus brachial damage.

Severe (grade > 2) paravalvular leak was not observed in our series. Paravalvular leaks altogether were uncommon and seemed to result from large calcifications positioned between the prosthesis and the annulus causing incomplete sealing. Two patients required iterative balloon valvuloplasty inside the prosthesis, all during the same procedure and using the same valvuloplasty balloon, to reduce paravalvular leaks responsible for aortic regurgitation greater than grade 2. In our study, the length of hospital stay was relatively long. This can easily be explained by the degree and severity of comorbidity of the study population at higher risk than the population of patients who are usually encountered in hospital practice. During follow-up, 2 patients died of noncardiovascular causes. Confirmation of the efficacy and safety of this technique will require a larger population. We believe the relative ease offered by the transaxillary route compares favorably with our experience of the transfemoral access, allowing more accuracy in

TABLE 4. Echocardiographic characteristics

	Baseline	Postprocedure	1 mo
Gradient mm Hg, mean	47 $\pm$ 13.3	7.9 $\pm$ 4.1	7.9 $\pm$ 4.1
Valve area,* cm ² , mean $\pm$ SD	0.6 $\pm$ 0.3	1.44 $\pm$ 0.35	1.44 $\pm$ 0.35
Annulus diameter, mm, mean $\pm$ SD	27.2 $\pm$ 5.5	NC	NC
Aortic valve insufficiency, grade ≤ 2	0%	20%	13.3%
Aortic paravalvular insufficiency, grade ≤ 2	NA	20%	20%

SD, Standard deviation; NC, not calculated; N/A, not applicable. *Derived from continuity equation.

implanting the valve and, as a result, lower average grades of paravalvular leak.

CONCLUSIONS

Percutaneous aortic valve implantation is an emergent technology with potential benefit in many patients. Current application of this procedure is limited to patients who are poor candidates for surgical valve replacement. Among this aging population, a number of patients do not meet the criteria for percutaneous transfemoral implantation because of the lack of suitable femoral arterial access. The transaxillary or subclavian approach in patients with difficult or unsuitable iliofemoral arteries represents a safe, feasible, and technically interesting alternative.

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FIGURE E1. Subclavian surgical access; 18F sheath insertion.

FIGURE E2. Surgical access closed.