Transcutaneous aortic valve implantation using the axillary/subclavian access with patent left internal thoracic artery to left anterior descending artery: Feasibility and early clinical outcomes

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Objective: Both retrograde femoral and subclavian artery catheterization techniques have been described as the most common methods for the implantation of the Medtronic CoreValve percutaneous aortic valve (Medtronic Inc, Minneapolis, Minn). The subclavian artery has been shown to be a safe and effective alternative access route in patients with unfavorable femoral access. Of the patients who are identified as candidates for subclavian artery access, a subset possess a patent left internal thoracic artery to left anterior descending artery. This patent left internal thoracic artery presents an additional anatomic and clinical variable that must be taken into consideration to ensure procedural safety and efficacy. We describe the Medtronic CoreValve percutaneous aortic valve implantation using the subclavian arterial approach in patients with a patent left internal thoracic artery and report our study’s findings.

Methods: The CoreValve percutaneous aortic valve is a self-expandable nitinol-based frame with a porcine pericardial valve. The subclavian access was created by a small infraclavicular surgical incision to expose the artery. Rapid ventricular pacing was used to reduce cardiac output to perform the balloon aortic valvuloplasty via a 12F sheath inserted into the subclavian artery. An 18F sheath was then inserted into the artery down into the ascending aorta and used for introduction of the delivery catheter and implantation of the percutaneous aortic valve.

Results: With the use of this method, 19 patients (76±13 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 have received implants. Subclavian artery or left internal thoracic artery injury did not occur in any patient. Two deaths occurred. One patient died of right coronary artery occlusion during the procedure, and one patient died 48 hours after the procedure as the result of a tamponade after the temporary pacemaker wire ablation.

Conclusions: This initial experience suggests that subclavian transarterial aortic valve implantation in patients with a patent left internal thoracic artery to left anterior descending artery is feasible and safe with satisfactory short-term outcomes. (J Thorac Cardiovasc Surg 2012;144:1416-20)
Abbreviations and Acronyms
CABG = coronary artery bypass grafting
LAD = left anterior descending
LITA = left internal thoracic artery
TAVI = transcatheter aortic valve implantation

surgical access points when used in patients with severe respiratory dysfunction or a calcified ascending aorta. Moreover, a number of complications have been reported after the introduction of a percutaneous valve holder through the apex of the left ventricle.9,10 In addition, although feasible, redo sternotomy in patients with patent grafts remains a risky procedure.

In centers where the heart team approach of TAVI is effective, using the axillary or subclavian artery, because of its safety, effectiveness, and less-invasive nature, became obvious as a second option after the femoral artery for introducing the device.11,12 However, patients undergoing coronary artery bypass grafting (CABG) remained challenging and potentially at higher risk of theoretic myocardial hypoperfusion. In this prospective study, we aimed to describe the implantation technique, procedural tips and tricks, and clinical outcome assessed up to 30 days after TAVI using axillary artery access in patients who have a patent left internal thoracic artery (LITA) to left anterior descending (LAD) artery. This prospective study, performed between January 2010 and June 2011, was performed on 19 consecutive patients recruited for this study.

MATERIALS AND METHODS

Patients
A prospective, single-arm study was performed. Patients with severe symptomatic aortic stenosis were referred for a percutaneous procedure because of multiple comorbidities and excessive surgical risk. All patients had a surgical history of CABG with a documented patent LITA to LAD. Our objective was to evaluate the feasibility, safety, and clinical outcomes of TAVI via subclavian or axillary artery access of the 18F Medtronic CoreValve System (Medtronic Inc, Minneapolis, Minn) in this category of patients. The cases were selected following the guidelines of the European Society of Cardiology. A heart team of senior interventional cardiologists, cardiac surgeons, and anesthetists formally reviewed patients with a consensus that patients did not have a reasonable surgical option. Patient preference alone for TAVI was not an acceptable reason for inclusion. Informed consent was obtained. All patients underwent transthoracic echocardiography, iliofemoral, and coronary angiography. Whole-body computed tomography angiography and Doppler echocardiography were used to assess left subclavian, axillary, and LITA diameters and patency. Short segments of calcified or focal stenosis of subclavian or axillary arteries were not considered an exclusion criterion.

Prosthetic Valve System
The Medtronic CoreValve System consists of porcine pericardium cut into a trileaflet pattern mounted within 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. Because the aortic annulus is not circular, a computed tomography scan was also used to measure the minimum and maximum diameter. An annulus diameter of 20 to 23 mm was considered appropriate for a 26-mm diameter prosthesis and 23 to 27 mm for a 29-mm prosthesis. Both prostheses require an 18F introducer sheath. An axillary arterial diameter of 7 mm or greater was considered adequate for implantation.

Patients were premedicated with a loading dose of clindamycin and aspirin and received an intravenous injection of 1 g cefazolin immediately before the procedure. The latter was performed in a catheterization laboratory with operating room sterility precautions. A femoral access was used, and a 6F pigtail catheter was inserted for control angiograms during valve implantation, as well as a vein access for the temporary pacemaker lead used for rapid pacing during valvuloplasty. Heparin 50 U/kg was administered intravenously on completion of vascular access.

The proximal subclavian artery (segment 2) was exposed through a small infraclavicular incision. In those patients, unlike in routine subclavian prosthesis implantations, we did not use 5-0 Prolene continuous purse-string sutures to achieve controlled and careful closure of the artery at the end of the procedure. A 6F sheath was inserted, through a 1-cm contra-incision made 2 cm outside of the main incision, in the middle of the exposed segment of the artery, using a percutaneous technique. The contra-incision allows for an excellent stabilization of the 18F sheath and the valve catheter throughout the procedure without achieving a purse-string suture. The native valve was crossed using a conventional technique that includes use of a straight wire. After hemodynamic transvalvular gradient and end-diastolic ventricular pressure measurement, a manually preshaped stiff wire was placed into the ventricular cavity. A 12F sheath was then inserted into the subclavian access under fluoroscopy. Balloon valvuloplasty was inserted, and valvuloplasty was performed using a 22-mm balloon (Nucleus; NuMED Inc, Hopkinton, NY) for the 26-mm Medtronic CoreValve prosthesis or 25-mm balloon for the 29-mm prosthesis. After balloon deflation, the rapid pacing was stopped and the balloon catheter was withdrawn. We then achieved progressive artery dilatation using increased dilator diameters (14F, 16F, and 18F). This step allowed assessing any myocardial perfusion impairment potentially reflected by electrocardiogram monitoring. The 18F sheath was then carefully inserted, 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. The valve was then advanced and deployed using repeated fluoroscopic controls. The prosthesis was positioned so that it protruded less than 80 mm out of the calcified native valve leaflets into the left ventricular cavity. During prosthesis implantation, no rapid pacing was used and effort was made to maintain blood pressure above 100 mm Hg throughout the procedure, except during valvuloplasty and a short period of time during valve deployment. A coordinated approach was used wherein 1 operator maintained ideal valve positioning by pulling slowly on the catheter during valve release, while the second operator turned the release knob to deliver the valve. Aortic root angiographies were performed to assess valve position during implantation. After full release of the valve, the stiff wire position was maintained into 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 repaired. To achieve optimal artery repair, no purse string was used (Figure 1). Indeed, we preferred direct reparation at the end of the procedure. Two clamps were placed above and below the site of arterial puncture. This will temporarily interrupt the blood flow, but not at the level of the LITA. We preferred to repair the artery using interrupted 5-0 Prolene sutures to prevent vascular constriction and artery thrombosis. The clamps...
were then removed, and the artery patency was tested by palpation and by achieving direct angiographic control of the subclavian artery. Papaverine could have been used in case of vascular spasm. No patch reparation was required in our patients.

Patients were then transferred to the intensive care unit for 24 to 48 hours of observation. They 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 19 consecutive patients between January 2010 and June 2011. Complete follow-up was performed in all patients. Preoperative characteristics are shown in Table 1. All enrolled patients had severe symptomatic aortic stenosis with a mean transvalvular gradient of 42 ± 15 mm Hg. The pre-procedural mean aortic valve area was 0.55 ± 0.35 cm². The procedure was performed under general anesthesia. The use of transesophageal echocardiographic guidance was not systematic and left to the discretion of the operators. Percutaneous placement of the 18F sheath was successful in all cases. No vascular complication requiring surgical repair was observed. In 1 patient, the repositioning attempt resulted in a valve position that was too high because of initially low valve implantation. The valve was partially pulled out from the aortic root and positioned in the upper part of the ascending aorta; a second valve was successfully implanted using the same arterial access.

Prosthesis implantations were uneventful in this series. There was 1 intraprocedural death due to right coronary artery occlusion documented by angiography during the procedure. Despite previous CABG surgery, the patient had severe symptomatic coronary artery disease that has required a recent angioplasty on the right coronary artery 2 months before the TAVI. A severe intra-stent restenosis occurred, causing an acute myocardial hypoperfusion. Two days after the procedure, another patient died of a tamponade that occurred on temporary pacemaker wire ablation. Intraoperative and postoperative details are shown in Tables 2 and 3.

Valve Function

Paravalvular leak, as assessed immediately after the procedure by angiography and echocardiography controls, was trivial (grade 0–1) in most of the cases (n = 15). 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 3 patients, moderate paravalvular leak occurred immediately after valve implantation and appeared to be caused by an insufficiently expanded frame. Additional valvuloplasty, during the same procedure, using the same diameter balloon, under rapid pacing, reduced severe paravalvular

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**TABLE 1. Baseline characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
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<tbody>
<tr>
<td>Age, y, mean ± SD</td>
<td>76 ± 13 y</td>
</tr>
<tr>
<td>Angina, n (%)</td>
<td>0%</td>
</tr>
<tr>
<td>Heart failure, n (%)</td>
<td>26%</td>
</tr>
<tr>
<td>NYHA III–IV failure class</td>
<td>40%</td>
</tr>
<tr>
<td>Syncope, n (%)</td>
<td>13.3%</td>
</tr>
<tr>
<td>Male gender, n (%)</td>
<td>46.2%</td>
</tr>
<tr>
<td>Diabetes mellitus, n (%)</td>
<td>20%</td>
</tr>
<tr>
<td>Coronary heart disease, n (%)</td>
<td>53.3%</td>
</tr>
<tr>
<td>Prior angioplasty, n (%)</td>
<td>20%</td>
</tr>
<tr>
<td>Renal dysfunction,* n (%)</td>
<td>6.6%</td>
</tr>
<tr>
<td>Logistic euroSCORE predicted mortality, mean ± SD, %</td>
<td>25 ± 13</td>
</tr>
<tr>
<td>Left ventricle ejection fraction %</td>
<td>49 ± 10</td>
</tr>
</tbody>
</table>

*euroSCORE, European System for Cardiac Operative Risk Evaluation; NYHA, New York Heart Association; SD, standard deviation. *Estimated glomerular filtration rate > 60 mL/min.

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**TABLE 2. Procedural outcome**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful valvuloplasty</td>
<td>100%</td>
</tr>
<tr>
<td>Successful prosthesis implantation</td>
<td>100%</td>
</tr>
<tr>
<td>Death, intraprocedure</td>
<td>1</td>
</tr>
<tr>
<td>Stroke, minor</td>
<td>0</td>
</tr>
<tr>
<td>Cardiac perforation</td>
<td>1</td>
</tr>
<tr>
<td>Ventricular fibrillation</td>
<td>0</td>
</tr>
<tr>
<td>Emergent cardiac surgery</td>
<td>0</td>
</tr>
<tr>
<td>Transfusion rate ≤ 2 units</td>
<td>41%</td>
</tr>
<tr>
<td>Hospital stay (d)</td>
<td>9.4</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>0%</td>
</tr>
</tbody>
</table>

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**FIGURE 1.** Angiographic control showing flow persistence in the subclavian and internal thoracic artery (continuous blue arrow) despite the presence of the 18F sheath in the subclavian artery (discontinued blue arrow).
insufficiency to trivial in these 3 patients without apparent damage to the valve leaflets, as assessed by the absence of a central leak during the echocardiographic control. At 30 days and on the last day of follow-up, the mean paravalvular leak remained unchanged.

DISCUSSION

The scope of heart valve disease that might benefit from percutaneous valve therapy is in motion. TAVI represents a less-invasive alternative heart surgery for treatment of severe aortic stenosis in elderly and high-risk patients. However, major concerns remain mainly related to the access route and to the betterment of prosthesis implantation. In patients with iliofemoral arteriopathy, transfemoral access may turn out to be an unfeasible or too high-risk procedure. When a transarterial route is not accessible, transapical or transaortic approaches may be interesting alternatives in some patients. However, those alternatives are intrinsically more invasive because they require a thoracotomy with left ventricular puncture or partial sternotomy, and therefore may not be suitable in fragile patients, especially in those with severe respiratory or ventricular dysfunction or a calcified ascending aorta. In addition, although feasible, these alternatives are also risky in case of previous cardiac surgery. It has been shown that TAVI using the subclavian or axillary approach is feasible and safe, as well as familiar to some cardiovascular surgeons. In comparison with the transfemoral approach, positioning the valve and controlling its release proved to be considerably easier and offered greater movement precision. The short distance between the subclavian artery and the aortic annulus might explain the increased control of the 18F sheath and delivery catheter. The subclavian and proximal axillary arteries are usually of good size and only moderately diseased even in the most elderly population groups. The vessels can be approached through an infra- or a supraclavicular incision. The supraclavicular incision may be preferred especially in patients with pacemakers implanted in the infraclavicular area to avoid risk of infective endocarditis.

However, in patients with a medical history of CABG with a patent LITA, this route could be challenging. Thus, only experienced teams should consider this access route. Indeed, some technical conditions associated with this procedure, described above, should be respected (eg, progressive artery predilation, maintaining high blood pressure, interrupted sutures). Indeed, a risk of LITA damage during the procedure and a theoretic impairment of myocardial perfusion through the LAD should be kept in mind. Of note, in this series, the right subclavian artery was not used. Currently, in our centers we perform percutaneous femoral, direct aortic, carotid, subclavian, and transapical approaches to achieve valve implantations. On the basis of screening results, we always prefer the less-invasive approach in patients. Although the direct aortic approach is feasible in this subset of patients with previous CABG surgery and patent arterial and venous grafts, there is a risk of graft lesion and the subclavian, less-invasive approach may be effective and thus should be considered for implantation.

This prospective study reports a real-life experience of selected high-risk patients with degenerative aortic valve stenosis who were treated with TAVI by the same surgeon (TM) using left subclavian access. The results of this series of 19 patients, in accordance with similar recently published articles, confirm the feasibility of the procedure. 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 valve positioning and reducing procedure time. From an anesthetic point of view, maintaining blood pressure greater than 100 mm Hg is recommended throughout the procedure. This could have been observed in our patients except during valvuloplasty and a short period of time during valve deployment. Electrocardiogram monitoring confirmed the good myocardial tolerance throughout the procedure. In addition, angiographic controls showed no impairment of LITA flow despite the 18F sheath in the subclavian artery (Figure 1). Moreover, direct subclavian vascular repair was easily performed and surgical control of the access point allowed (Figure 2) for limited risk of immediate or delayed vascular complications as observed with the percutaneous transfemoral access.
Our series shows that patients with a history of CABG and patent LITAs are eligible for the subclavian approach. Nevertheless, this access route should be considered carefully because of the potential risk of subclavian dissection, which may compromise graft patency. We recommend a minimum 7.5-mm artery diameter to ensure a safe approach as demonstrated by our findings.

We preferred to calculate the transfusion rate to provide a reliable indication of major bleeding consequences on patients. In our series, transfusion rate was acceptable in a population exposed to preoperative anemia (41% of patients, ≤ 2 units), although no bleeding complications occurred throughout the study. Although stroke is a known risk of routine balloon valvuloplasty, none of our patients experienced an ischemic cerebrovascular event. 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 prostheses and the annulus causing incomplete sealing. Three patients required iterative balloon valvuloplasty inside the prostheses, each during the same procedure and using the same valvuloplasty balloon diameter, to reduce paravalvular leaks responsible for aortic regurgitation greater than grade 2. In this study, hospital stay duration was acceptable and comparable to previous reported experience. Confirmation of the efficacy and safety of this technique will require a larger population. This report shows that the outcome of TAVI using the subclavian route in patients with a patent LITA compares favorably with our experience of transfemoral and transaxillary (without a patent LITA) implantations and provides improved valve implantation accuracy that results in lower average grades of paravalvular leakage and complications.

**CONCLUSIONS**

The current application of TAVI is limited to patients who are high-risk candidates for surgical valve replacement. Among this population, a number of patients do not meet the criteria for transfemoral implantation because of the lack of suitable arterial access. The transaxillary or subclavian approach in these patients represents a feasible, safe, and technically interesting alternative, even in patients with a patent LITA to LAD.

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**References**