Transcatheter Aortic Valve Implantation by the Left Axillary Approach: A Single-Center Experience

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Background. Transcatheter aortic valve implantation (TAVI) is an accepted alternative treatment for severe symptomatic aortic stenosis in high-risk and inoperable patients. Femoral or transapical accesses are commonly used. We report our initial clinical experience with TAVI using the left-axillary artery approach.

Methods. A single-center, retrospective study of patients undergoing transaxillary TAVI between January 2010 and December 2012 was performed. Procedural success was defined as successful device implantation with reduction in the mean aortic gradient and without need for conversion to open-heart surgery. Short-term echocardiographic follow-up was obtained in all patients.

Results. A total of 18 consecutive patients with severe aortic stenosis who were not candidates for surgical replacement underwent transaxillary TAVI. Mean age was 81.1 ± 7.3 years and 14 patients (78%) were male. Median logistic European System for Cardiac Operative Risk Evaluation was 8.5% (range, 1.5% to 54.1%). Procedural success was obtained in 17 out of 18 patients (94%). There was no in-hospital or 30-day mortality. One major bleeding complication in the form of an upper gastrointestinal bleeding was observed. No stroke or major vascular complication was reported. Postoperative implantation of a permanent pacemaker was performed in 7 patients (39%). At a mean follow-up of 326 ± 213 days, mean aortic gradient was 10.8 ± 4.8 mm Hg. Mean aortic valve area was 1.7 ± 0.4 cm² and aortic insufficiency grade was mild or less in all but 1 patient, who showed moderate regurgitation.

Conclusions. The transaxillary approach for TAVI is associated with high procedural success and low rates of stroke, vascular, or bleeding complications. This approach is an appealing alternative to the commonly used transfemoral and transapical TAVI.


Transcatheter aortic valve implantation (TAVI) has emerged as a promising alternative to standard surgical aortic valve replacement (AVR) in patients with severe symptomatic aortic stenosis (AS) who are deemed inoperable or who present a high surgical risk [1, 2]. The presence of a safe remote access route to the heart is a critical determinant of success with catheter-based treatment of valvular heart disease. Several approaches have been described for TAVI. The 2 most commonly used are the transfemoral [3] and transapical [4] techniques. However, the former is associated with high rates of vascular complications in patients with severe peripheral vascular disease (PVD) [5–7] while the latter involves a minithoracotomy that may complicate the postoperative course in patients with severe associated lung disease. These limitations have led to the development of alternative routes for TAVI. In recent years, the axillary artery has gained popularity as a safe alternative vascular access site in patients for whom both the transfemoral and transapical routes are contraindicated [8]. However, despite several potential advantages over the other approaches, the transaxillary (TAx) route for TAVI has yet to gain widespread acceptance in the medical community.

There are currently 2 commercially available devices for TAVI, the Edwards-SAPIEN valve (Edwards Lifesciences, Irvine, CA) and the CoreValve Revalving System (Medtronic CV, Santa Rosa, CA), both of which have been successfully implanted through the axillary artery. However, only the CoreValve has received the CE mark certification for this approach [8].

The purpose of this study is to report our initial clinical experience with the transcatheter implantation of the CoreValve prosthesis using the left axillary artery approach.

Material and Methods
This retrospective single-center study examined TAVI procedures carried out between January 2010 and December 2012 at the Montreal Heart Institute, focusing
All patients provided written informed consent for the procedure and the retrospective analysis was approved by the institution’s ethics committee.

Procedural and clinical outcomes are reported according to the updated Valve Academic Research Consortium (VARC-2) definitions [10]. Procedural success was defined as successful device implantation with reduction in the mean aortic gradient without need for conversion to open heart surgery. Unless otherwise specified, continuous variables are presented as mean ± standard deviation. Improvements of mean aortic valve gradient and aortic valve area were assessed using the Wilcoxon signed rank test.

**Surgical Technique**

The Medtronic CoreValve prosthesis was used in all patients. The CoreValve Revalving System includes 3 components: a self-expanding nitinol support frame with a trileaflet porcine pericardial tissue valve, an 18F catheter delivery system, and a disposable loading system [5, 11]. Each procedure was performed by a multidisciplinary team composed of interventional cardiologists, cardiac anesthesiologists, and a cardiac surgeon. Valve implantation was carried out under general anesthesia. A 5F pigtail is first inserted percutaneously into the femoral artery and advanced to the level of the noncoronary sinus for aortic angiography. The left axillary artery is then exposed through a small infraclavicular incision and secured with nylon tapes.

After systemic heparinization, the axillary artery is retracted with vessel loops, punctured and dilated. After direct insertion of a 6F sheath, a stiff wire is positioned in the ascending aorta and an 18F sheath is then inserted through the left axillary artery. The rest of the procedure is carried out in a standard fashion [7, 12]. Briefly, the native valve is crossed retrogradely and dilated using balloon valvuloplasty. The loaded prosthesis is then introduced through the 18F sheath and positioned across the aortic valve using angiographic and fluoroscopic guidance. When correct placement has been confirmed, the valve is deployed. At this point, the patency of the coronary arteries and degree of aortic insufficiency are assessed using aortic angiography. The valve is also examined for the presence of any paravalvular leak. The axillary artery is closed with paradoxal interrupted 5/0 polypropylene sutures to avoid any stenosis and a wound suction device (HemoVac) is left in place to avoid compression of the brachial plexus by an eventual hematoma. An angiogram of the left axillary artery is performed at the end of each procedure.

**Results**

Between January 2010 and December 2012, 174 TAVI procedures were performed at our institution. Of these, 100 (57%) were performed through a transfemoral approach, 55 (32%) through a transapical approach, 18 (10%) through a TAx approach, and 2 (1%) through a direct transarterial approach. This report focuses on the TAx implantations.
Patient baseline characteristics are presented in Table 1. Median preoperative New York Heart Association functional class was III/IV. Significant PVD and chronic obstructive pulmonary disease were present in 14 (78%) and 9 (50%) patients, respectively. Median logistic European System for Cardiac Operative Risk Evaluation was 8.5% (range, 1.5% to 54.1%).

Median prosthesis size was 29 mm (range, 26 to 31 mm). Procedural success was obtained in 17 out of 18 patients (94%). In 1 case, valve deployment proved impossible due to severe leaflet calcification and failure to expand the prosthesis. The CoreValve was successfully removed prior to full deployment and the patient underwent elective surgical AVR in a subsequent hospitalization. In 2 further cases, the prosthesis had to be withdrawn and repositioned after an unsuccessful first attempt. In all other patients, the valve was correctly positioned and successfully deployed. After the procedure, AI grade was mild or less in all but 1 patient, who showed moderate AI.

There was no in-hospital or 30-day mortality. Mean hospital length of stay was 12.3 ± 4.8 days. One patient (6%) was rehospitalized 19 days after the procedure for the treatment of new onset atrial fibrillation and repair of a left femoral pseudoaneurysm. There were 2 periprocedural myocardial infarctions, both of which occurred in the setting of atrial fibrillation. During the postoperative period, 1 patient (6%) suffered from acute kidney injury, as defined in the Valve Academic Research Consortium consensus report [10]. This patient had preoperative chronic renal failure. There was no stroke or transient ischemic attacks. No life-threatening bleeding was reported. One major bleeding complication in the form of an upper gastrointestinal bleeding and 2 minor bleeding events in the form of a left inguinal hematoma were documented. Eight patients (44%) received at least 1 blood transfusion. There was no major vascular complication.

One minor vascular complication (6%) was documented in the form of a small, localized subclavian artery dissection that did not impinge on the vessel’s patency and therefore did not require any additional intervention. At the end of each surgical vessel repair, angiography was performed and no postprocedural subclavian stenosis was observed.

Early postoperative implantation of a permanent pacemaker (PPM) was performed in 7 patients (39%). Of these, 5 (71%) had a preoperative condition predisposing them to need for PPM, such as atrial fibrillation, first degree atrioventricular block, right bundle branch block, or a combination of these.

All patients underwent a transthoracic echocardiography prior to discharge. Compared with baseline, mean aortic gradient decreased from 50.5 ± 18.7 to 14.0 ± 10.1 mm Hg ($p < 0.001$), peak aortic gradient decreased from 77.9 ± 28.4 to 25.3 ± 18.3 mm Hg ($p = 0.002$), and aortic valve area increased from 0.8 ± 0.3 to 1.9 ± 0.5 cm$^2$ ($p < 0.001$). Mean left ventricular ejection fraction was slightly increased but this difference was not statistically significant ($p = 0.11$). One patient (6%) was discharged with moderate centro-prosthetic aortic insufficiency; all others left the hospital with mild or less aortic insufficiency.

At 1-year follow-up there were 2 further deaths (11%), including 1 cardiac death. There were no neurologic events and no vascular complications. No brachial plexus injury was reported. All patients in whom procedural success was achieved were free from reintervention. One patient (6%) who had a preoperative history of coronary artery disease with previous percutaneous coronary intervention suffered from an acute myocardial infarction. New onset atrial fibrillation was diagnosed in 2 patients (11%), 1 of which received a PPM.

A follow-up echocardiogram was obtained in all patients, at a mean follow-up time of 326 ± 213 days. Evolution of aortic valve mean and peak gradients are illustrated in Figure 1. At last follow-up, mean and peak aortic gradients were 10.8 ± 4.8 and 20.1 ± 9.2 mm Hg, respectively. Mean aortic valve area was 1.7 ± 0.4 cm$^2$ and aortic insufficiency grade was mild or less in all but 1 patient, who showed moderate regurgitation.

**Table 1. Baseline Characteristics of Patients Undergoing Transcatheter Aortic Valve Implantation by the Transaxillary Approach (n = 18)**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>81.1 ± 7.3</td>
</tr>
<tr>
<td>Male</td>
<td>14 (78)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>15 (83)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>8 (44)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>13 (72)</td>
</tr>
<tr>
<td>Morbid obesity, BMI ≥ 35 kg/m²</td>
<td>3 (17)</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>13 (72)</td>
</tr>
<tr>
<td>vascular disease</td>
<td>14 (78)</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease</td>
<td>9 (50)</td>
</tr>
<tr>
<td>Pulmonary hypertension (PAPs &gt; 30 mm Hg)</td>
<td>6 (33)</td>
</tr>
<tr>
<td>Chronic renal failure</td>
<td>7 (39)</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>5 (28)</td>
</tr>
<tr>
<td>Permanent pacemaker</td>
<td>3 (17)</td>
</tr>
<tr>
<td>History of acute myocardial infarction</td>
<td>4 (22)</td>
</tr>
<tr>
<td>History of stroke/TIA</td>
<td>2 (11)</td>
</tr>
<tr>
<td>History of abdominal aortic aneurys</td>
<td>6 (33)</td>
</tr>
<tr>
<td>Previous CABG</td>
<td>1 (6)</td>
</tr>
<tr>
<td>Previous PCI</td>
<td>5 (28)</td>
</tr>
<tr>
<td>Previous aortic balloon valvuloplasty</td>
<td>4 (22)</td>
</tr>
<tr>
<td>NYHA functional class III-IV</td>
<td>14 (78)</td>
</tr>
<tr>
<td>LVEF ≤ 0.4 on echocardiogram</td>
<td>3 (17)</td>
</tr>
<tr>
<td>Logistic EuroSCORE (%)</td>
<td>13.7 ± 13.8</td>
</tr>
</tbody>
</table>

Continuous variables are presented as mean ± standard deviation; Dichotomous variables are presented as number (%).

BMI = body mass index; CABG = coronary artery bypass graft; EuroSCORE = European System for Cardiac Operative Risk Evaluation; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; PAPs = systolic pulmonary artery pressure; PCI = percutaneous coronary intervention; TIA = transient ischemic attack.

**Comment**

In western countries, AS is the most prevalent form of valvular heart disease in adults [13] and AVR is the standard treatment for these patients [14]. However, the
operative risk of AVR increases with age and multiple comorbidities [15], so that up to one third of patients with severe AS are denied surgery [16].

Transcatheter aortic valve implantation is rapidly gaining popularity as an alternative treatment for inoperable or high-risk surgical patients with significant aortic stenosis. Presently the access route of choice is transfemoral as vascular access can be achieved by percutaneous puncture of the femoral artery or through a small surgical cutdown. However, the transfemoral approach is contraindicated in patients with small, tortuous or atheromatous ilio-femoral vessels, as it is associated with a high rate of procedural failure and vascular complications in these cases [5–7]. In those patients with significant PVD, other alternatives include the transaxillary, transapical, and transaortic approach.

The TAx approach has several potential advantages over the other implantation routes. Compared with the transfemoral technique, the shorter distance between the delivery sheath and the aortic annulus provides better control of the device and allows more precise positioning of the prosthesis as well as its recapture, if needed. Although TAx TAVI can also be performed through the right axillary artery, the left axillary artery was used in all patients as it provides a better angle for the advancement of the sheath toward the aortic root. This favorable angle, coupled with the superior control afforded by the position of the sheath close to the aortic valve, allowed easy positioning of the prosthesis in all patients. The only case of procedural failure was due to severe aortic valve calcification, which prevented complete expansion of the device. Due to the close proximity of the sheath, the valve was easily recaptured without any complication and the patient underwent successful open AVR 3-months afterward. In 2 further cases, the close proximity of the vascular access site to the aortic valve allowed recapture and repositioning of the prosthesis.

The TAx approach does pose certain technical challenges. The nature of a subclavian access results in wire bias toward the lesser curvature of the aorta, making coaxial placement of the device challenging. A few strategies may improve the coaxial approach of the TAVI. First, forward pressure on the wire to push it toward the greater curve is often successful but may result in upward movement of the device. Therefore, measures must be taken to ensure appropriate correction of device position. In addition, adding a bend to the portion of the stiff wire in the ascending aorta prior to placement can aid to direct the trajectory of the wire to a more coaxial position.

Surgical access of the axillary artery is frequently performed by cardiac surgeons as it is routinely cannulated for cardiopulmonary bypass during ascending aorta and aortic arch replacement [17]. In our series, no major access site vascular complication occurred. There was only 1 minor vascular complication; a small, localized dissection without clinical consequences. In comparison with the transapical and transaortic approaches, the axillary route is less invasive and permits early patient mobilization due to less postoperative pain. This is particularly important in the setting of severe associated lung disease as chest pain can lead to nonobstructive atelectasis in these patients. Furthermore, an apical access route is relatively contraindicated in patients with depressed left ventricular function, a small left ventricular cavity, or an apical thrombus [18].

The TAx approach also allows for less catheter manipulation than the transfemoral route in the descending thoracic aorta and in the distal aortic arch, which may reduce the risk of embolic events secondary to displacement of atherosclerotic material. Furthermore, the fact that the prosthesis is advanced through the ascending aorta protected by the sheath may reduce the risk of atheromatous emboli. This theoretic advantage seems to be confirmed in our experience as there were no neurologic complications in this series, a result consistent with those of previous reports, as demonstrated in a recently published systematic review of the literature by Caceres and colleagues [8], who highlighted the relatively low risk of stroke for this population of patients with severe PVD.

Paravalvular leak is a common problem after TAVI and although mild regurgitation is usually tolerated, moderate to severe insufficiency often warrants additional manipulation such as balloon dilatation or valve-in-valve implantation. In our series, there were no moderate or
severe paravalvular leaks. No postimplantation balloon dilatation was required and no valve-in-valve implantation was performed. These findings are in accordance with Laborde [19] who presented the cumulative data on TAx TAVI on behalf of the CoreValve Percutaneous Aortic Valve Replacement registry participants. They concluded that there was a higher rate of valve-in-valve implantation after transfemoral TAVI compared with TAx TAVI (4.3% vs. 0.0%, respectively), likely due to a superior control of the device through the axillary artery.

Postoperative need for PPM is a common complication after TAVI [8]. The mechanism leading to conduction abnormalities after catheter-based treatment of AS is thought to be different from the temporary conduction delay secondary to tissue edema after standard open AVR. Conduction tissue injury after TAVI is speculated to be caused by radial compression of the conduction system by the prosthesis [20]. In some cases, this may be related to incorrect positioning of the device. It is therefore reasonable to speculate that the superior control granted by the TAx approach could lead to better positioning of the implant and lower rates of conduction abnormalities. However, our results do not support this hypothesis. Early postoperative implantation of a PPM was performed in 39% of our patients. This high rate is consistent with those reported in previous case series in which the rate of PPM ranged from 18.5% to 37.5% [8, 19, 21]. These results are probably not related to the access route but rather to the use of the CoreValve prosthesis, which has been identified as a significant independent predictor of PPM implantation after TAVI [20, 22]. This is probably due to factors related to the design of the valve such as its self-expanding nature, its noncircular shape, and its longer stent frame [23]. Furthermore, the high rate of postoperative PPM implantation in this series must be interpreted in light of the fact that 71% of these interventions were performed on patients who had preoperative conduction abnormalities such as atioventricular block and right bundle branch block. Preexisting conduction system disease has been identified as an independent predictor of PPM need after TAVI [23].

All patients in this series were discharged in good health and there was no early mortality. At 1-year follow-up there were 2 deaths, neither of which was valve related. No neurologic or vascular complication was reported after hospital discharge. Echocardiographic follow-up showed good and durable results with a sustained decrease in transaortic gradients and freedom from severe paravalvular leak in all patients.

Study Limitations
This study has several limitations. First, the study design was retrospective and the data was not initially collected for research purposes. Second, the external validity of this study is somewhat limited by the fact that all cases were performed in a single tertiary center. Furthermore, there was a single surgical operator for all cases. Finally, echocardiographic studies were performed in a nonblinded fashion, which might have resulted in an observation bias.

Conclusions
Transcatheter aortic valve replacement using the left axillary artery is a safe, reproducible, and efficient procedure. It is an appealing alternative to the commonly used transfemoral approach in patients with severe iliofemoral disease and to the transapical approach in patients with severe associated lung disease. However, well-powered comparative studies are needed to assess the superiority of the TAx approach over the transfemoral and transapical access routes.

References
14. ACC/AHA 2006 guidelines for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force
ABTS Requirements for the 10-Year Milestone for Maintenance of Certification

Diplomates of the American Board of Thoracic Surgery (ABTS) who plan to participate in the 10-Year Milestone for the Maintenance of Certification (MOC) process as Certified-Active must hold an unrestricted medical license in the locale of their practice and privileges in a hospital accredited by the JCAHO (or other organization recognized by the ABTS). In addition, a valid ABTS certificate is an absolute requirement for entrance into the MOC process. If your certificate has expired, the only pathway for renewal of a certificate is to take and pass the Part I (written) and the Part II (oral) certifying examinations.

The CME requirements are 150 Category I credits over a five-year period. At least half of these CME hours need to be in the broad area of thoracic surgery. Category II credits are not accepted. Interested individuals should refer to the Board’s website (www.abts.org) for a complete description of acceptable CME credits.

Diplomates will be required to take and pass a secured exam after their application has been approved. Taking SESATS in lieu of the secured exam is not an option. The secured exam is administered over a two-week period in September of every year at Pearson Vue Testing Centers, which are located nationwide. Diplomates will have the opportunity to select the day and location of their exam. For the dates of the next MOC exam, visit the Board’s website at www.abts.org.

Starting on July 1, 2014, the ABTS will require its Diplomates to participate in an outcomes database as fulfillment of Part IV (Performance in Practice) for the 10-year Milestone of Maintenance of Certification (MOC). For a list of approved outcomes databases or for more information on how to have a database approved by the Board, visit the Board’s website at www.abts.org. Participation in the Professional Portfolio will no longer be accepted as fulfillment of MOC Part IV after July 1, 2014.

Diplomates may apply for MOC in the year their certificate expires or, if they wish to do so, they may apply up to two years before it expires. However, the new certificate will be dated 10 years from the date of expiration of their original certificate or most recent MOC certificate. In other words, going through the MOC process early does not alter the 10-year validation. Diplomates certified prior to 1976 (the year that time-limited certificates were initiated) are also required to participate in MOC if they wish to maintain valid certificates.

The deadline for submitting an application for 10-year Milestone of MOC is March 15 of every year. Information outlining the rules, requirements, and dates for MOC in thoracic surgery is available on the Board’s website at www.abts.org. For additional information, please contact the American Board of Thoracic Surgery, 633 N St. Clair St, Ste 2320, Chicago, IL 60611; telephone (312) 202-5900; fax (312) 202-5960; e-mail: info@abts.org.