The left axillary artery — a new approach for transcatheter aortic valve implantation

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Abstract

**Objective:** Transcatheter aortic valve implantation (TAVI) is an alternative treatment for aortic stenosis in selected cases, but requires appropriate vascular access. We report our initial clinical experience with a novel endovascular approach for TAVI. **Methods:** Between 1 April 2007 and 31 August 2008, 48 patients underwent TAVI at our institution. Of these, eight patients (17%) were deemed to be best served through direct surgical exposure of the left axillary artery rather than a trans-femoral or TA approach. **Results:** Procedural success was achieved in seven of eight cases. In one patient the axillary artery was too small to accept the 18 French sheath. In the remaining seven, the device was implanted without major complication and with only trivial paravalvular aortic regurgitation. The in-hospital mortality was 0%. The 30-day mortality was 12.5% (one patient). There was one localised dissection at the origin of the vertebral artery. There was one late pericardial effusion and a permanent pacemaker was implanted in five patients. **Conclusions:** TAVI can be performed through a left axillary artery approach. This is a technically simple procedure and, in this small initial clinical experience, was performed with encouraging results. It is a realistic option in patients in whom neither the trans-femoral nor trans-apical approaches are optimal.

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1. Introduction

Transcatheter aortic valve implantation (TAVI) is an emerging alternative therapy for patients who have severe symptomatic aortic stenosis but who are deemed to be at high risk from a conventional surgical aortic valve replacement (AVR) [1,2]. There is still much debate as to the precise patient population who are clinically suitable for TAVI [3,4]. In those patients who are deemed to be clinically suitable, a number of different access routes have been proposed for delivery of the catheter-based device. The first-in-man experience employed access through the femoral vein with a trans-septal puncture and antegrade delivery of the device across the diseased native aortic valve [5]. This was soon abandoned because of technical difficulties and a high complication rate and was replaced by a trans-arterial approach via the femoral artery, with retrograde delivery of the device across the aortic valve [4—8]. Trans-femoral access can be achieved by direct surgical cut-down and surgical closure, percutaneous puncture with surgical closure or percutaneous puncture with percutaneous closure of the femoral artery. Although there has been a reduction in the sheath size for the two commercially available devices, they remain a sizeable diameter: 18 French (Fr) for the CoreValve Re-Valving system (CoreValve Inc., Irvine, CA, USA) and 22 and 24 Fr for the Edwards Sapien Retroflex system (Edwards Lifesciences, Irvine, CA, USA) [1]. A combination of small size, tortuosity, calcification and atheromatous disease of the ilio-femoral vessels either precludes the trans-femoral approach in a significant number of patients, or can result in procedural failure or significant damage to the ilio-femoral vessels. The latter complication contributes significantly to the mortality and major morbidity associated with trans-femoral TAVI [4,8].

The trans-femoral approach is the only accepted access route for the CoreValve Re-Valving system. The Edwards SAPIEN valve can also be delivered through a trans-apical (TA) route using the Ascendra delivery system [9—11]. The TA approach involves a small antero-lateral thoracotomy with exposure of the apex of the left ventricle and cannulation of this site with a 26 Fr sheath. The valve is then delivered antegrade across the native aortic valve. Clearly, the TA route is an attractive option in those patients with problematic ilio-femoral arterial systems. However, it is not without its limitations. A small anterior thoracotomy can be a painful
incision and is relatively contraindicated in patients with significant respiratory dysfunction. The apex of the left ventricle can also be a fragile and unforgiving structure, particularly in the frail and elderly patient. There are a number of other relative contraindications to the TA approach, including a small left ventricular cavity (in terms of the size of the delivery system that needs to be positioned within the left ventricular cavity), a dilated right ventricle and apical left ventricular thrombus. Both trans-femoral and TA access routes therefore have their limitations, and there is a small but significant population of patients for whom neither is ideal. Therefore, there is a need to evaluate alternative access routes for TAVI.

The use of the axillary artery is familiar to the cardiac surgeons. It has been advocated for routine use in cannulation for cardiopulmonary bypass (CPB) during thoracic aortic surgery. Its use as an entry point to the vascular tree is therefore appealing in endovascular procedures.

The purpose of this article is to report our initial clinical experience of TAVI using a trans-axillary approach.

2. Materials and methods

Between 1 April 2007 and 31 August 2008, 160 patients were referred for consideration of TAVI. Following approval from the Ethical Committee, data were prospectively collected on all patients. The patients were assessed clinically and with echocardiography (trans-thoracic and trans-oesophageal), angiography and, in some cases, computed tomography (CT) and cardiac magnetic resonance (MR) to delineate the morphology of the aortic valve and root, cardiac function, the coronary and arterial vascular access anatomy. Each case was presented to a multidisciplinary team (MDT) panel involving surgeons, cardiologists (congenital, interventional, echo/MI and cardiac failure) anaesthetists and critical-care physicians. Patient suitability for the procedure was assessed against clinical and anatomical criteria, which have been defined previously [1]. Clinical suitability for TAVI was granted if the patient had severe symptomatic aortic stenosis and would benefit from an AVR, but where the MDT panel unanimously agreed that the anticipated operative mortality or clinical outcome associated with TAVI was better than could be expected following conventional AVR. Anatomical suitability was defined following detailed review of all imaging modalities against defined criteria [1].

In particular, the size of the aortic annulus and the geometry of the left ventricular outflow tract and the aortic root were evaluated to determine if any of the available devices were suitable. The next level of discussion focussed on the access route. During the first half of our experience, we had access only to devices designed for trans-femoral implantation. In this context, the left axillary artery was the only possible alternative route. In the second part of our experience, once we had access to the Edwards Ascendra system, we reserved the trans-axillary route for those patients where the trans-femoral and the TA access were contraindicated or suboptimal.

Informed consent was obtained for all patients. Forty-eight patients were accepted for TAVI. The CoreValve Re-valving system was used in 32 cases, the Edwards Sapien system in 12 patients and in four cases a balloon valvuloplasty alone was performed. The trans-femoral approach was chosen in 32 patients, the TA and the trans-axillary route in eight each.

The demographic characteristics of the population are presented in Table 1.

2.1. Operative technique — trans-axillary implantation

The CoreValve Re-valving system was used in all patients. All cases were performed under general anaesthesia. Central venous line, right radial artery line and a urinary catheter were inserted. The patients received continuous cardiac monitoring and trans-oesophageal echocardiography (TOE). The antibiotic prophylaxis followed the local protocol used for conventional surgery. Temporary trans-venous right ventricular and right atrial pacing wires were inserted through the right internal jugular vein. The patient was prepared and draped as per conventional surgery. An 8 Fr sheath was placed percutaneously into the femoral artery and a pigtail catheter positioned in the non-coronary sinus. The proximal left axillary artery was exposed through a small infra-clavicular incision and encircled with nylon tapes.

Following the administration of heparin (3000—5000 I.U.), a 5 Fr sheath was inserted in the vessel and a stiff wire was positioned in the apex of the left ventricle crossing the aortic valve retrogradely. The axillary artery was then clamped and a transverse arteriotomy performed. The 18 Fr sheath was inserted directly in the vessel and delivered around the aortic arch into the distal ascending aorta. In all cases the sheath diameter was either slightly larger or perfectly matched the
axillary artery diameter, and there was no need to snare the vessels.

The subsequent technique used for the implantation of the core-valve prosthesis has been well described [4, 5]. Briefly, the native valve was dilated using a balloon valvuloplasty during rapid ventricular pacing. The loaded valve/stent was then introduced through the 18 Fr sheath and correct positioning achieved using both angiographic and echocardiographic guidance. The prosthesis was deployed, and the result was assessed with TOE and aortography. Fig. 1

3. Results

There was procedural success in seven out of eight cases. In one patient the axillary artery would not accept the 18 Fr sheath and a balloon valvuloplasty (only) was performed. The in-hospital mortality was 0% and the 30-day mortality was 12.5% (one of eight). The early death occurred in a 85-year-old male patient who had an uncomplicated procedure and was discharged on the 16th postoperative day. He developed an acute abdomen on the 29th postoperative day, rapidly deteriorated and died the following day. The post-mortem examination demonstrated the presence of mesenteric infarction due to severe atheromatous disease of the abdominal aorta and a critical stenosis of the superior mesenteric artery. All the other patients recovered well from the surgery. The median postoperative length of stay (LOS) was 11 days (range: 7–21 days) and all patients were discharged home. At the 6 weeks follow-up, the seven other patients remain well at a median follow-up of 7 months (range: 2–13 months).

3.1. Vascular access

Exposure of the axillary artery was simple and easy in all cases. We were able to successfully implant the prosthesis in all but one patient. This was an elderly frail lady (logistic EuroSCORE = 62.6%) whose femoral vessels were deemed too small to accept any of the currently available sheaths and who was deemed to be too frail to withstand a TA approach (as well as having a very small left ventricular cavity). Preoperatively the axillary artery was measured only 5 mm in diameter and therefore was below the acceptable size. We accepted the patient for trans-axillary TAVI in the hope that the vessel would have been larger than demonstrated at the angiogram and that we may be able to dilate it. At surgery we were not able to insert the 18 Fr sheath, and a valvuloplasty was carried out uneventfully whilst this very small artery was ligated. The arm remained warm and well perfused, and there were no adverse sequelae to the ligation of this small vessel. In all the successful implants, the small transverse incision in the axillary artery was repaired directly with simple interrupted sutures with good antegrade distal flow into the forearm. In one patient the post-procedural angiogram showed a small localised dissection at the origin of the vertebral artery. This was left alone, and there were no clinical sequelae.

3.2. Device positioning

In one case the device positioning proved difficult. Early during valve deployment, it was clear that the device had moved in a ventricular direction. This was deemed to be suboptimal. It was easy to re-capture the device into the sheath given the short distance involved and the stability of the system. The device was then successfully re-implanted. In all the other six cases, satisfactorily positioning of the valve was easily achieved. An additional balloon valvuloplasty was not required in any case. The aortogram performed soon after the device deployment showed absence of AR in two cases and only trace AR in five patients. Post-deployment balloon valvuloplasty was not required in any patient whereas it was undertaken in 11 of 25 (44%) of our trans-femoral CoreValve implants (in an attempt to reduce the degree of paravalvar regurgitation following this route of implantation).

3.3. Pericardial effusion

A single late pericardial effusion occurred in one case 3 days following TAVI, and this was successfully treated with a percutaneous drain inserted under fluoroscopic control.

3.4. Permanent pace maker

Cardiac rhythm problems were frequently experienced postoperatively. A permanent pacemaker implant was
performed in five patients. In two patients with severe left ventricular (LV) dysfunction and dyssynchrony pre-TAVI, it had been a management plan to insert a bi-ventricular device in the post-implant period. In three of the remaining five implants, new conduction abnormalities occurred during or after TAVI to a degree where we felt that a pacemaker insertion was indicated.

4. Discussion

In this article, we have described a technique for using the proximal left axillary artery as an access route for TAVI. The exposure of the axillary artery is familiar to cardiac surgeons and is easily carried out through a small infra-clavicular incision. Although the axillary and subclavian arteries may be diseased, they are often good-sized and good-quality vessels even in patients who have atheromatous disease or extensive calcification affecting their ilio-femoral arterial systems. We were able to successfully implant the prosthesis in all but one patient. This was a very small lady in whom essentially all three access routes were unsuitable and who underwent successful BAV through an axillary approach.

The axillary artery diameter was evaluated with an arteriogram and was just below the acceptable size (6 mm = 18 Fr). We hoped that we could dilate it but this was clearly not the case. The selection of this case was clearly outside the defined limits for the 18 Fr CoreValve sheath, but we felt this was an appropriate clinical decision with BAV as the back-up/bail-out option. In all the other patients, the transverse incision in the axillary artery was repaired directly with simple interrupted sutures with good antegrade distal flow into the forearm. In the aforementioned case, the artery was extremely small and electively was just ligated. The arm remained warm and well perfused, and there were no adverse sequelae. This highlights one of the potential advantages of the axillary route. Although damage to the intra-thoracic subclavian artery would be a major problem in a closed chest situation, injury to the extra-thoracic axillary or distal subclavian arteries does not carry the same inevitable consequence in terms of distal perfusion as an injury to the ilio-femoral system. In many elderly patients, this vessel, if damaged, could be ligated without undue consequence since the arm perfusion would be provided through the collateral circulation between the thyro-cervical trunk of the subclavian artery and the sub-scapular artery [12] (in contrast to the situation with injury to the common femoral or external iliac vessel). However, we believe that the presence of a patent left internal mammary artery (LIMA) graft is an absolute contra-indication to the use of this approach.

The infra-clavicular incision is well tolerated and, in our experience, has caused very little discomfort, let alone pain, whilst allowing for very early mobilisation. This is in accordance with the experience reported by Strauch et al. [13] who employed axillary artery cannulation for CPB. The use of a side graft has been reported to reduce the morbidity associated with an axillary cannulation [14]. We directly cannulated the vessel because our sheath travels into the vascular system much further than a CPB inflow cannula would, and we felt that there was no advantage in adding a side graft.

During trans-femoral TAVI, the sheath introducer reaches the abdominal aorta only and the uncovered device is advanced through the concavity of the arch sometimes with difficulty. On the contrary, with the trans-axillary approach the sheath is advanced into the distal ascending aorta from the roof of the arch, that is, at a more favourable angle. Moreover, the device is advanced through the arch protected by the sheath. This may reduce the likelihood of injury or atheromatous emboli.

There were no neurological complications in this series. The position of the sheath close to the aortic valve also affords excellent stability of the device and delivery system and facilitates positioning and delivery of the implant. However, even with this enhanced degree of control, positioning of the implant can be problematic. We experienced this in one case. The close proximity of the sheath allowed relatively easy re-capture of the partially deployed device into the sheath, re-mounting of the device and then delivery into an optimal position.

One of the recognised problems associated with TAVI is paravalvar aortic regurgitation. At the present time, it is not clear how much of this paravalvar regurgitation is due to inherent deficiencies in the design of the implants, or due to the limited sizes available (and thus size mismatch between the device and patient) or due to suboptimal positioning of the devices. The recently reported post-CE mark surveillance data for trans-femoral CoreValve implantation confirms that paravalvar regurgitation remains a frequent occurrence [15]. In this registry, 21.2% of implants required further balloon dilatation because of initially unacceptable degrees of aortic regurgitation. This corroborates our findings where 44% of trans-femoral implants required post-implant dilatation because of an unacceptable degree of paravalvular AR. This is clearly a high rate and probably reflects our learning curve. However, over the same time period, there was trivial AR in all seven Tax implants without a need for post-implant dilatation. Our impression was that the extra control afforded by the trans-axillary approach made device delivery and positioning easier than with the trans-femoral route and achieved a satisfactory result without a need for additional balloon valvuloplasty. This has also been noted with the TA approach [16] albeit using a different device. These data presented in relation to paravalvar regurgitation are an interesting observation, which we believe warrants further discussion and study.

The trans-axillary route was used in 17% of all of our TAVI implants. For the first half of our programme, we only had access to the CoreValve Re-valving system, and during this period the trans-axillary route was our only alternative to a trans-femoral approach. Subsequently, we have had access to both the CoreValve system and the trans-femoral and TA Edwards systems. All eight patients had either very small or significantly diseased ilio-femoral vessels to a degree where we felt a trans-femoral approach would carry a significantly increased risk of vascular injury. Three of the four patients enrolled during the first half of the programme would not have been ideal for a TA approach because of severe respiratory disease or dysfunction, that is, there was one patient in this series where a TA approach would have been a reasonable alternative. Our current practice is that, once the patient has been deemed clinically suitable for TAVI,
anatomic suitability is assessed and the relative merits of the three (trans-femoral, trans-axillary and TA) access routes are debated. A further factor in this decision-making process has been the presence of significant LV dysfunction (ejection factor (EF) <25%). In two patients, this was a factor that we felt was a relative contraindication to a TA approach and was better managed with a retrograde trans-arterial approach.

Although we have reported the logistic EuroSCORE for these patients, the limitations of this scoring system in this patient population have been highlighted recently [17]. In this series we had three patients with a score <20 who had such severe respiratory disease/dysfunction that our anaesthesia/intensive care colleagues felt this would preclude them from conventional surgery.

Rhythm problems were frequently experienced in our TAVI population, so we electively inserted dual-chamber temporary wires in all patients at the time of surgery. We prefer to use a right jugular sheath, because it is potentially cleaner than the femoral ones and we kept them for a period of up to 48–72 h during which the patients were encouraged to mobilise from bed to chair. When rhythm disturbances persisted, patients were implanted with a permanent system. The permanent pacemaker insertion rate has been high compared to conventional AVR. In two cases the implant was planned prior to the TAVI procedure as the preferred form of management in the presence of dys synchrony. For the other cases, we speculated that either the balloon valvuloplasty or the radial force produced by the stent holding the valve could be the cause for the complete heart block (CHB). Contrary to the conventional setting, where CHB may disappear once oedema of the tissues has recovered, with TAVI the stent exerts a constant radial force applied to the LVOT and to the valve annulus that may indefinitely compress the conducting system. In our study, the median age of the population was 86.5 years and this possibly contributed as well to the phenomenon.

The postoperative median LOS in our population was 11 days, which is longer than expected following conventional AVR in a population of elderly patients. However, all our cases had a number of co-morbidities that required medical optimisation prior to the discharge in the community. We believe that it is essential to have the support of the MDT not only at the time of the assessment but also as a backup for the successful treatment of complex medical problems not always commonly seen in a surgical population.

Major vascular injury remains a complication of TAVI and remains a significant clinical problem with the trans-femoral approach [3,8]. Less major vascular complications are also not uncommon. We are unable to define what the incidence of major vascular injury will be with the axillary approach from this small experience.

TAVI through a left axillary approach is an attractive option in patients where both trans-femoral and TA approaches are suboptimal. It is a relatively simple technique and, in this small series, we were able to implant the prostheses successfully without any major procedural complications.

Device control and prosthesis positioning may be facilitated by the extra stability afforded by the close proximity of the sheath to the native aortic valve. This increased control may influence the degree of paravalvular regurgitation. We believe it should be an active option in all patients who are being considered for TAVI.

References


Appendix A. Conference discussion

Dr. V. Falk (Leipzig, Germany): There are a couple of questions I would like to ask you. First of all, it is very well known that patients with peripheral artery disease often present with some degree of atheromatous disease of the aortic arch; in addition, they may have subclavian artery stenosis. From the data you presented and also in the paper, it was not clear what your routine procedure is to identify patients with peripheral artery disease. Do you perform preoperative CT scans or angiography on all these patients to determine if a patient is a suitable candidate for a transcatheter approach using the subclavian artery? The second question relates to the results of the trans-apical approach. Some series have reported very little problems with the trans-apical approach, and favour this approach especially in patients with peripheral artery disease. I wonder what the reasons were in your series to preclude patients from a trans-apical approach. Especially since I believe that the number of patients that were not amenable for a trans-apical approach seemed rather high.

It would be interesting to get a better understanding of why you think this approach would reduce aortic regurgitation over a standard trans-femoral route, because essentially the valve is the same, and it is a little bit difficult to understand how the assumed increase in stability would decrease the degree of aortic regurgitation.

Dr. De Robertis: Regarding the first question about peripheral artery disease. Yes, at our centre we assess the patient for clinical and anatomical suitability. When we assess anatomical suitability, we look at the geometry of the annulus and the root, but also we screen the patient to decide which access we will use. So for each patient we discuss the three different options, the trans-apical, trans-femoral, or trans-axillary, and we investigate and interrogate the anatomy using a CT scan or aortogram at the beginning of the experience.

Dr. Falk: So, excuse me, that was done in all patients? So before you decide on access, you do a CT-scan routinely on all these patients to determine access site?

Dr. De Robertis: Yes, we routinely investigate them with a CT-scan to assess the route we are going to use.

Regarding your second question: we do not preclude the trans-apical approach. At the moment of the assessment we discuss all the options equally. The subject of the paper is not our trans-apical experience. We agree that the trans-apical approach is a very nice alternative to the trans-femoral one. But if you are in a centre where you have access only to the CoreValve, then you are stuck with a trans-femoral route, and what we are proposing here is that perhaps the trans-axillary route is an interesting alternative for centres who only have access to the CoreValve device.

And for your third question, regarding the degree of aortic insufficiency, at the time of implantation using the trans-axillary route we had the feeling that there was superior control over the device which made the procedure slightly easier. When it comes to implanting this valve, there is very little margin for error: you can be too high and have problems with the coronary ostia and also too low and have more paravalvular leak. So it is quite important to have a stable device. And when you go trans-apically, for example, it is like having a valve on a stick a very short distance from the entry point to your landing zone, and therefore the control is very good and the results seem to be very good. But when you go trans-femoral, you have very long wires. Therefore, the degree of control is less and it is very hard to achieve a precise position and so we found it more difficult to have a good result.

These are very small numbers, so we can’t draw a final conclusion of which one is the best route to use. Perhaps in the future we should investigate randomized patients as to which route should be used. Perhaps the trans-femoral route is not the ideal one. I think it should be further investigated.

Dr. Falk: So given your results, you would actually assume that this could be a standard approach for this transcatheter valve placement?

Dr. De Robertis: I think it is. This is a small experience. You can look at it as a proof of concept, if you want. As I said, it is a nice alternative if you have a system that is meant to be only trans-femoral and you don’t have access to the trans-apical system, but I think that it should be equally considered along with the other two access routes.

Dr. P. Kappetein (Rotterdam, The Netherlands): Do you have a special preference for either the left side or the right side, and why?

Dr. De Robertis: Yes, we do have a preference for the left side, although in cases who have a patent LIMA graft, we think that it is a contraindication. Our preference is basically because of the anatomy. It is easier to go around the curvature of the left subclavian, and also when going through the left axillary artery you avoid having close proximity to the neck vessels.