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Direct Percutaneous Access Technique for Transaxillary Transcatheter Aortic Valve Implantation

"The Hamburg Sankt Georg Approach"

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Objectives This study questioned whether transaxillary transcatheter aortic valve implantation (TAVI) is feasible as a true percutaneous approach using percutaneous closure devices.

Background Transaxillary TAVI is gaining increasing acceptance as an alternative to the transfemoral route; however, the access has always been done via surgical cutdown so far.

Methods Between August 2010 and September 2011, a total of 24 high-risk patients with severe aortic valvular stenosis underwent a percutaneous TAVI procedure by direct puncture of the axillary artery without surgical cutdown. For safety reasons and as a target for the puncture, a wire was advanced via the ipsilateral brachial artery. Moreover, a balloon was placed into the subclavian artery via the femoral artery for temporary vessel blockade before percutaneous vessel closure. Vascular closure was performed using either the ProStar XL system (Abbott Vascular Devices, Redwood City, California) or 2 ProGlide systems (Abbott Vascular Devices).

Results The true percutaneous approach was successfully completed in all patients (14 left and 8 right axillary artery cases). Overall mortality at 30 days was 8.3%. Acute vascular closure device success was achieved in 17 patients (71%). Vascular closure device success rate was 100% for the ProGlide device and 37% for the ProStar device, respectively. Seven patients (29%) with failing closure devices were treated by endovascular stent graft implantation without the need for surgical repair. For the last 12 treated patients, direct closure was achieved in 11 patients.

Conclusions Direct puncture of the axillary artery for TAVI is feasible and safe if a wire is placed into the subclavian artery via the ipsilateral brachial artery. (J Am Coll Cardiol Intv 2012;5:477–86) © 2012 by the American College of Cardiology Foundation

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In 2002, transcatheter aortic valve implantation (TAVI) was successfully introduced as a new treatment option for aortic valvular stenosis (1). Since then, rapidly rising implantation numbers (>25,000) have proven the feasibility and safety of this technology. Nowadays, TAVI may be considered as a better alternative to surgical aortic valve replacement in high-risk patients. When TAVI was in its infancy, it was still necessary to surgically expose the arterial access vessels under general anesthesia to accommodate

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the large introducers of the first-generation devices (1–4). Currently, 2 Conformité Européenne (CE)-marked devices for transfemoral TAVI—Sapien XT bioprosthesis (Edwards Lifesciences, Irvine, California) and Medtronic CoreValve System (Medtronic, Minneapolis, Minnesota)—are approved for TAVI via sheathes with an 18- or 19-F diameter. The Sapien prosthesis can also be implanted via a transapical approach (5). The major goal of creating lower-profile devices was to obtain a true percutaneous access in conjunction with local anesthesia (an advantage over the transapical access with its need for general anesthesia) and the use of vascular closure devices, thereby reducing the high vascular complication rates and improving patient outcomes (6,7). In this regard, the recently published PARTNER (Placement of Aortic Transcatheter Valve) A and B studies demonstrated major vascular complications in 11% and 16.2%, respectively. The total number of in-hospital deaths in both randomized treatment arms was increased 3-fold (36% vs. 10.3%) in patients with vascular complications compared with those without vascular complications (8,9). Over the last 3 years, alternative access sites, such as the transaxillary (10,11) or the transaortic (12) approach, have been introduced. For the transaxillary approach, mainly the Medtronic CoreValve and only a few Sapien XT valves have been used in the past (10,11,13,14). All these alternative access sites have surgical exposure of the arterial vessels under general anesthesia in common. Safety and feasibility of the transaxillary approach using a surgical cutdown has been repeatedly demonstrated (10,11).

Abbreviations and Acronyms

PTA = percutaneous transluminal angioplasty

TAVI = transcatheter aortic valve implantation

VARC = Valve Academic Research Consortium

The present paper describes for the first time, to our knowledge, a new access site technique for direct percutaneous puncture of the axillary artery in a series of 24 consecutive patients for TAVI, not suitable for the transfemoral approach. Puncture technique, site visualization, and closure technique in addition to several treatment options for the management of vascular complications are outlined in the following text.

Methods

Between August 2010 and September 2011, a total of 24 patients with severe aortic stenosis underwent percutaneous transaxillary TAVI (self-expandable devices) at our institution (12.1% of 385 TAVI procedures). All patients had symptomatic severe aortic valvular stenosis with an increased operative risk (logistic EuroSCORE >20% or a Society of Thoracic Surgeons [STS] score >10%—or other risk factors for surgical aortic valve replacement, such as porcelain aorta, cirrhosis of the liver, previous radiation treatment of the chest), and all patients were identified as not suitable for the transfemoral approach because of severe peripheral artery disease (severe calcification, significant stenosis/occlusions, or severe vessel tortuosity) as assessed by angiography or multislice computed tomography. Angiography of the subclavian arteries with a graduated pigtail catheter was performed to confirm a sufficient access path for percutaneous transaxillary TAVI. Moreover, a precise evaluation of the aortic annulus (size, morphology, amount of calcification) was carried out via transesophageal echocardiography and angiography using a graduated pigtail catheter. An annulus size between 19 and 27 mm was accepted for implantation of a CoreValve prosthesis (26 or 29 mm, Edwards Lifesciences). Transaxillary TAVI was performed using vascular closure devices with the intention to start and finish TAVI solely by a percutaneous technique without surgical exposure of the access vessel.

Procedure. Before the procedure, all patients received a clopidogrel loading dose of 300 mg and aspirin 100 mg that was followed by 75 mg of clopidogrel for 3 months and 100 mg of aspirin indefinitely. Intravenous cefazolin was used as antibiotic prophylaxis. In 15 of 24 patients, percutaneous transaxillary TAVI was performed under general anesthesia (62.5%). The decision regarding which side was used (right or left axillary artery) was made with preference to the artery with the least degree of calcification and kinking. Moreover, patent left internal mammary artery grafts were considered as a relative contraindication for TAVI from the left axillary artery. Thus, 7 of 8 patients with left internal mammary artery grafts were treated via the right axillary artery.

For safety reasons, a 6-F sheath (23 cm, Easy Glide, Smiths Medical, Grasbrunn, Germany) was placed into the ipsilateral brachial artery. Retrograde dye injection (5 to 10 ml) through the sheath was used to visualize the axillary artery (Fig. 1A). Using fluoroscopy and a regular J-wire as a landmark, the axillary artery was punctured below the clavicula at a spot significantly lateral to the rib cage to avoid a pneumothorax and to have the possibility for manual