

## EDITORIAL COMMENT

# Getting Safely In and Out of a Transcatheter Aortic Valve Implantation Procedure

## Vascular Complications According to the Valvular Academic Research Consortium Criteria\*

Nicolo Piazza, MD,† Patrick W. Serruys, MD, PhD,‡  
Ruediger Lange, MD, PhD†

*Munich, Germany; and Rotterdam, the Netherlands*

The occurrence of vascular complications associated with transcatheter aortic valve implantation (TAVI) is not surprising given the use of large-bore catheters and imperfect vascular closure devices. Vascular complications have been reported in 2% to 30% of patients undergoing TAVI. The conflicting reports are mainly due to heterogeneous endpoint definitions (1).

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Published in January 2011, the aims of the Valvular Academic Research Consortium (VARC) were to arrive at a consensus: 1) on the most appropriate clinical endpoints reflecting device and patient effectiveness and safety; and 2) to standardize the definition of endpoints for valve-related clinical trials (2). This multidisciplinary endeavor brought together interventional cardiologists, cardiac surgeons, noninvasive cardiologists, regulatory bodies, professional societies, and industry with the hope to facilitate the reporting, communication, and evaluation of this new catheter-based therapy. The goal of VARC was not to establish “utopian-like” definitions but to arrive at a consensual agreement based on state-of-the-art practices and materials.

In this issue of *JACC: Cardiovascular Interventions*, Hayashida et al. (3) investigated the incidence, predictors, and impact of VARC-related vascular complications in 127 patients undergoing transfemoral implantation with the

Edwards Sapien (n = 99) (Edwards Lifesciences, Irvine, California) or CoreValve devices (n = 28) (Medtronic Inc., Minneapolis, Minnesota). Vascular complications were observed in 27.6% of patients (major: 17.4%, minor: 10.2%). Major but not minor vascular events were associated with increased mortality. Furthermore, an outer Sheath diameter to Femoral Artery minimal luminal diameter Ratio (SFAR) ratio  $\geq 1.05$  (i.e., outer sheath diameter to femoral artery minimal luminal diameter) identified patients at higher risk for major vascular events and 30-day mortality.

The investigators should be acknowledged for their detailed description of vascular complications according to the VARC definitions. Having said that, we can now begin to understand that most major vascular events were due to interventions on the femoral or iliac artery (angioplasty, stenting, or surgery) and the need for blood transfusions  $\geq 4$  U. Complications occurred with near-equal frequency in the femoral and iliac artery, with rare involvement of the aorta. Whereas dissections were the cause of most femoral injuries, ruptures played a bigger role in the iliac artery. The VARC definitions provide greater transparency and a better understanding of where things may go wrong. This is especially important during the adoption phase of a new catheter-based therapy.

Recently, Gurvitch et al. (4) reported a VARC vascular event rate of 17.4% (10% major, 7.4% minor) in a series of 205 patients implanted with the transfemoral Edwards Sapien device. In that study, the majority (84%) of major vascular complications were attributed to blood transfusions  $\geq 4$  U. Despite the use of apparently similar definitions, these 2 series report rather disparate vascular complication rates. In both of these studies, retrospective adjudication of outcomes may have led to reporting bias. By contrast, the differences in vascular event rates may be the result of individual clinical practice patterns (e.g., patient selection, vascular access and closure techniques, imaging modalities).

Similar to clinical endpoint reporting, it is clear that significant heterogeneity exists across hospitals with respect to “best” TAVI clinical practices. This can be appreciated in the pre-procedural, procedural, and post-procedural management of patients. Patient selection and procedural factors such as operator experience, techniques, and selection of device systems may thus influence the occurrence of vascular complications. In their report, Hayashida et al. (3) do not provide any details about vascular access criteria (e.g., minimum acceptable femoral artery diameter, calcification, and tortuosity thresholds). Angiography, as it appears, is their primary screening modality for vascular access. The authors reported that 58 of 127 (46%) patients did not have a pre-procedural multislice computed tomography (MSCT). We believe that MSCT is superior to angiography for evaluating the minimal luminal diameter across the vasculature, severity of calcification, and degree of tortuosity. A few rhetorical questions come to mind: Did MSCT

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From the †German Heart Center Munich, Cardiovascular Surgery Department, Munich, Germany; and the ‡Erasmus Medical University Center, Interventional Cardiology Department, Rotterdam, the Netherlands. Drs. Piazza and Lange are consultants for Medtronic. Dr. Serruys has no relationships relevant to the contents of this paper to disclose.

play a role in vascular access evaluation in those 69 patients with MSCT? What was the vascular complication rate in those 58 patients without MSCT? In these latter patients, could vascular complications have been mitigated if MSCT were available?

The investigators identified an SFAR ratio  $\geq 1.05$  (i.e., outer sheath diameter to femoral artery minimal luminal diameter) as a predictor of VARC major vascular complications as well as 30-day mortality. The SFAR ratio increased to 1.10 in the absence of calcium and decreased to 1.00 in the presence of calcium. This would imply an increase in the manufacturer's recommended femoral artery minimal lumen diameter that is acceptable for TAVI. These findings would need to be confirmed by others. Whether the same SFAR cutoff criteria would apply to MSCT is unclear. These findings are thought-provoking and should be considered in future recommendations for TAVI guidance.

The learning curve associated with TAVI is multifaceted, dynamic, and difficult to describe. It may involve a change in patient-selection criteria, operator skills, or device selection. To evaluate the impact of a learning curve, the first one-half of the series ( $n = 67$ ) was compared with the latter one-half. It must be noted, however, that 28 of 67 (42%) patients from the first one-half underwent surgical cut-down of the femoral artery. Furthermore, these patients were more likely treated with the 22- and 24-F sheaths as opposed to the 18- and 19-F. The "learning curve" that the investigators describe, therefore, needs to be put into context. Part of the VARC definition for minor vascular complications includes closure device failure requiring interventional or surgical correction but not associated with death, blood transfusion  $\geq 4$  U, or irreversible end organ damage. In the present report, the majority of minor vascular complications were due to Prostar (Abbott Vascular, Abbott Park, Illinois) failures (11 of 13, 85%). We humbly believe that surgical cut-downs for transfemoral TAVI procedures are being underutilized. In selected patients, this can be performed rather quickly with a small 3- to 4-cm incision that provides direct visualization and tactile feel of calcium-free areas for puncture and that might mitigate vascular closure device failures. Ultrasound-guided puncture is another alternative that can help localize calcium-free areas of the femoral artery.

Providing a specific proposal for an algorithm on how to evaluate peripheral access for patients undergoing TAVI can be a challenging task given the lack of evidence-based medicine in this field and various success rates using different endpoint definitions in the midst of heterogeneous practice patterns. Nonetheless, peripheral vessel contrast angiography and/or MSCT scan should be obtained in every patient before TAVI, keeping in mind that MSCT scan provides greater information about vessel calcification, tortuosity, and minimal luminal diameter. In cases where femoral access is unsuitable, transsubclavian/axillary artery, transapical, and transaortic access routes should be further evaluated.

Vascular complications remain to be a problem with TAVI—herein reported in nearly one-third of patients. Improvements in patient selection, operator experience, selected techniques, and device iterations should diminish the risk of vascular complications in the future. Getting in and out of a TAVI procedure is not always easy.

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**Reprint requests and correspondence:** Dr. Nicolo Piazza, German Heart Center Munich, Cardiovascular Surgery Department Lazarette Strasse 36, 80636 Munich, Germany. E-mail: nicolopiazza@mac.com.

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