Access Path Angle in Transapical Aortic Valve Replacement: Risk Factor for Paravalvular Leakage

Borek Foldyna, MD, Martin Hänsig, MD, Christian Lücke, MD, David Holzhey, MD, Claudia Andres, MD, Matthias Grothoff, MD, Axel Linke, MD, Friedrich Wilhelm Mohr, PhD, MD, Matthias Gutberlet, PhD, MD, and Lukas Lehmkuhl, MD

Department of Interventional and Diagnostic Radiology, Clinic of Cardiac Surgery, and Department of Cardiology, University of Leipzig—Heart Center, Leipzig, Germany

Background. **The aim of this study was to analyze the angle between the left ventricular (LV) long axis and the LV outflow tract (αLV-LVOT) on cardiac computed tomography and to describe its effect on the occurrence of paravalvular leakage (PL), fluoroscopy time, and postoperative creatine kinase-MB levels in transapical transcatheter aortic valve replacement (TA-TAVR).**

Methods. **High-risk patients with severe aortic stenosis scheduled for TA-TAVR using an Edwards SAPIEN (Edwards Lifesciences, Irvine, CA) prosthesis were retrospectively included. The αLV-LVOT was measured during systole and diastole as far as retrospectively gated data sets were available. The αLV-LVOT was correlated with the occurrence of PL, total fluoroscopy time, and postoperative creatine kinase-MB levels. Interobserver variability was assessed in all cases.**

Results. **The study included 81 patients (57 women [70.4%], 24 men [29.6%]) with an average age of 81.9 ± 5.8 years. The mean αLV-LVOTs were 61.8 ± 9.9 degrees during systole and 61.1 ± 10.0 degrees during diastole. There was a minimal, nonsignificant change in the αLV-LVOT between systole and diastole of 0.2 ± 4.1 degrees (p = 0.7). PL was found in 39 patients: grade 0 in 42 (51.9%), grade I in 30 (37.0%), and grade II in 9 (11.1%). Patients with a clinically significant PL (grade ≥ II) showed a significantly greater mean αLV-LVOT than patients with grade I or without PL (mean difference, 13.8 ± 3.2 degrees; p < 0.001). No significant correlation was found between the αLV-LVOT and total fluoroscopy time (r = –0.17, p = 0.16) and postoperative creatine kinase-MB levels (r = –0.1, p = 0.44).**

Conclusions. **During TA-TAVR, greater αLV-LVOTs were associated with significantly higher grades of PL. Thus, the αLV-LVOT might influence the selection of the transapical implantation path and could have a significant effect on designs for future stents or novel delivery devices.**

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Transapical (TA) transcatheter aortic valve replacement (TA-TAVR) has proven to be a viable treatment option for elderly, high-risk patients with severe aortic stenosis. Recent studies have shown that TA-TAVR has a comparable 1-year outcome to surgical aortic valve replacement [1, 2]. TA-TAVR leads to a significantly lower all-cause mortality during 1-year follow-up compared with standard medical therapy [3].

Although TA-TAVR has become a routine procedure in numerous medical centers around the globe, paravalvular leakage (PL) remains one of the most common post-interventional complications next to vascular complications, conduction defects, acute kidney injury, and stroke [4, 5]. In particular, intermediate and severe aortic regurgitation appears to have a significant effect on short-term and long-term patient outcomes after surgical aortic valve replacement [6] and in patients treated by TA-TAVR [5, 7]. The presence of mild aortic regurgitation after TA-TAVR is associated with increased late mortality [5]. Abdel-Wahab and colleagues (2012) [7] and Grube and colleagues (2007) [8] found that intermediate and severe PL occurs in up to 17% of patients treated by TA-TAVR, and both studies showed a significant association between clinically significant aortic regurgitation and increased in-hospital mortality. Aortic regurgitation has been used in recent studies as a collective term to describe both paravalvular and transvalvular leakage.

Currently, the Edwards SAPIEN valve (Edwards Lifesciences, Irvine, CA) is the most commonly used prosthesis for the TA approach in Europe and is usually implanted using the fixed, straight, inflexible Ascendra introducer sheath set (Edwards Lifesciences).

Known risk factors for the occurrence of postoperative PL include valvular calcification, which can potentially lead to suboptimal valve deployment [9], and an inappropriately small prosthesis, which results in suboptimal adhesion of the prosthesis to the aortic annulus [10, 11]. Another potential risk factor could be the angle between the left ventricle (LV) long axis and the longitudinal axis of the LV outflow tract (αLV-LVOT) because a greater

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Address correspondence to Dr Foldyna, Department of Interventional and Diagnostic Radiology, University of Leipzig—Heart Center, Struempellstrasse 39, 04289 Leipzig, Germany; e-mail: borek.foldyna@herzzentrum-leipzig.de.

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Abbreviations and Acronyms

αLV-LVOT	=	angle between the left ventricular long axis and the axis of the left ventricular outflow tract
Ao	=	aorta
AS	=	aortic stenosis
AUC	=	area under curve
AVA	=	aortic valve area
CK	=	creatine kinase
CT	=	computed tomography
ECG	=	electrocardiogram
ED	=	effective diameter
LA	=	left atrium
LV	=	left ventricle
LVEF	=	left ventricular ejection fraction
LVOT	=	left ventricular outflow tract
NYHA	=	New York Heart Association
PAOD	=	peripheral arterial occlusive disease
PL	=	paravalvular leakage
SD	=	standard deviation
STS	=	The Society of Thoracic Surgeons
TA	=	transapical
TA-TAVR	=	transapical transcatheter aortic valve replacement
TEE	=	transesophageal echocardiography

angle could restrict the positioning of the prosthesis. The αLV-LVOT could also have a comparable effect on the occurrence of PL similar to the effect the angle between the LVOT and the ascending aorta has in patients undergoing retrograde transcatheter implantation of the CoreValve prosthesis (Medtronic, Minneapolis, MN), as described by Sherif and colleagues [12].

Computed tomography (CT) has become a standard preoperative imaging modality for three-dimensional assessment of the aortic root and the access path [4]. CT imaging provides accurate dimensions of the aortic root, including the aortic annulus and the ascending aorta, which are important for prosthesis sizing. It also provides information on the suitability of the peripheral access vessels and on extracardial comorbidities. Initial data indicate that CT-based sizing of the prosthesis, compared with echocardiographic sizing, may lead to better results with reduced rate of PL [13, 14].

This study used CT to examine the αLV-LVOT as a possible risk factor for the occurrence of postprocedural complications. Our hypothesis was that a greater angle would lead to a higher rate of PL, prolonged fluoroscopy time, and myocardial damage resulting in elevated postoperative creatine kinase (CK)-MB levels.

Material and Methods

Study Design

This retrospective study included 81 consecutive high-risk patients who had been scheduled for TA-TAVR between February 2007 and May 2010 due to severe symptomatic aortic stenosis. The inclusion criteria were a successful implantation using the Edwards SAPIEN prosthesis, a preoperative electrocardiogram (ECG)-triggered cardiac CT as part of the preoperative planning, and a complete postprocedural hemodynamic assessment using direct aortography and transesophageal echocardiography. Further inclusion criteria were assessment of the postoperative CK-MB levels and available documentation of the total fluoroscopy time. The exclusion criteria were incomplete or unavailable imaging data, the use of an implantation path other than TA, or an implanted prosthesis other than an Edwards SAPIEN.

Image Data Acquisition

CT scans were performed on a 64-row CT (Philips Medical Systems, Cleveland, OH) using a retrospectively ECG-gated technique or on a 128-row dual-source CT (Siemens Healthcare, Erlangen, Germany) using a prospectively ECG-gated technique according to the standard protocol in our facility. The retrospective ECG-gated scan mode provided images during all cardiac phases, and prospective triggering was set to capture the aortic root during late diastole according to the ECG. In total, 100 mL (iodine: 370 mg/mL) or 70 mL (iodine: 400 mg/mL) nonionic iodinated contrast medium were applied before scanning with the 64-row or 128-row CT scanner, respectively.

Image Data Analysis

The CT image analysis, including the αLV-LVOT measurement, was completed on SyngoVia V.11 (Siemens Healthcare), a commercially available medical three-dimensional workstation. All measurements were performed by 2 blinded, experienced radiologists (B.F. and C.L.).

Assessment of the αLV-LVOT

The αLV-LVOT describes the deviation from an ideal 180-degree access path and was defined as a direct spatial angle between the LV long axis and the longitudinal axis of the LVOT (Fig 1). The LV long axis was defined as connecting the LV apex and the midpoint of the mitral valve. The LVOT longitudinal axis was defined as the axis orthogonal to the plane of the aortic annulus.

The spatial position of each axis was expressed using left anterior oblique/right anterior oblique and cranial/caudal values of the planes orthogonal to their respective axes. Vector analysis was used to calculate the αLV-LVOT as the smallest cutting angle between the 2 planes.

In all of the retrospectively ECG-gated data sets, the αLV-LVOT measurements were performed separately during systole and diastole to capture possible dynamic changes during the cardiac cycle. Systole and diastole were determined visually using the functional analysis tool of the workstation. The cardiac phase with an open aortic valve, a closed mitral valve, and minimal filling of the LV was defined as systole, and the cardiac phase with a closed aortic valve, an open mitral valve, and maximal filling of the LV was defined as diastole.

An area-derived effective diameter of the aortic annulus was also measured in all patients in the diastolic phase.