1-year event-free survival in patients undergoing PMVR with the MitraClip system. The CHA_2DS_2-VASc score might serve as a simple tool for risk stratification in patients undergoing PMVR. Patients with high scores (≥7 points) may qualify for more careful monitoring because of the high rate of cardiovascular events.

Maximilian Spieker, MD
Clemens Metze, MD
Refik Kavsur, MD
Patrick Horn, MD
Christos Iliadis, MD
Vedat Tiyerili, MD
Roman Pfister, MD
Marc Ulrich Becher, MD
***Ralf Westenfeld, MD**

*Department of Cardiology, Pulmonology and Vascular Medicine
Heinrich-Heine University Düsseldorf
Moorenstraße 5
40225 Düsseldorf
Germany
E-mail: ralf.westenfeld@med.uni-duesseldorf.de

https://doi.org/10.1016/j.jcin.2019.08.045

Please note: The authors have reported that they have no relationships relevant to the contents of this paper to disclose.

REFERENCES

1. Buccheri S, Capodanno D, Barbanti M, et al. A risk model for prediction of 1-year mortality in patients undergoing MitraClip implantation. Am J Cardiol 2017;119:1443–9.

2. Yoshihisa A, Watanabe S, Kanno Y, et al. The CHA_2DS_2-VASc score as a predictor of high mortality in hospitalized heart failure patients. ESC Heart Fail 2016;3:261–9.

3. Kirchhof P, Benussi S, Kotecha D, et al. 2016 ESC guidelines for the management of atrial fibrillation developed in collaboration with EACTS. Eur Heart J 2016;37:2893–962.

RESEARCH CORRESPONDENCE

The Efficacy of the Ultrasound-Navigated MANTA Deployment Following Transfemoral Transcatheter Aortic Valve Replacement

A new plug-based MANTA (Teleflex, Morrisville, North Carolina) vascular closure device was recently introduced. Although prospective studies of MANTA have reported promising results of a 2% to 4% rate of major vascular complications (VCs) in selected patients who underwent transfemoral transcatheter aortic valve replacement (1), the major VC rates ranges up to 9% using MANTA in unselected patients deemed to have calcified common femoral arteries (CFA) (2,3). Therefore, we recently developed an ultrasound-navigated method of MANTA deployment (US-MANTA) with the aim of exploring optimal usage and understanding failure mechanisms. We sought to assess the efficacy of the US-MANTA technique to compare the incidence of access-site major VCs and bleeding between the periods before and after introduction of the US-MANTA technique in the real-world setting.

Vascular access was established under ultrasound-navigated puncture, avoiding anterior wall calcification and bifurcation of CFA in all cases. At the end of the procedures, the activated clotting time was controlled to be below 250 s by protamine administration. Detailed descriptions of the US-MANTA method are as follows: scanning in a longitudinal view was used to identify the CFA with the MANTA toggle in situ (**Figures 1A and 1B**).

Step 1: The ultrasound image was maintained, and the sheath was withdrawn up to a pre-determined depth +1 cm. The toggle was released at this level and confirmed located adequately in the vessel as shown in **Figure 1C**. If the pre-determined deployment depth was not considered reliable, a new deployment depth was visually determined by confirming the toggle location inside the vessel.

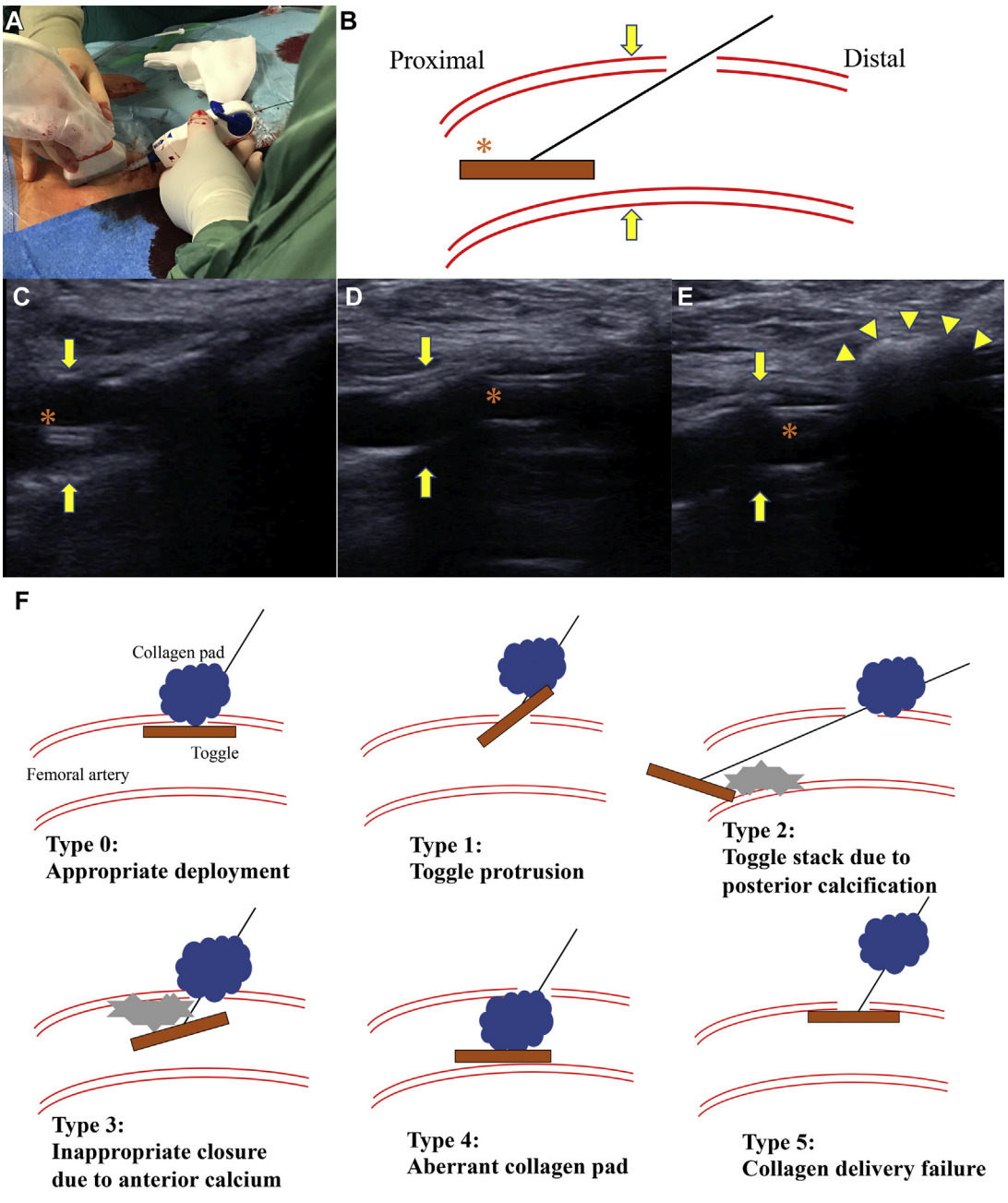
Step 2: The assembly was pulled back slowly while maintaining an ultrasound image centered on the toggle with a 45° or more angle between the skin surface and the MANTA sheath. It was confirmed that the toggle was attached with the vessel wall in parallel (**Figure 1D**). If toggle stacking due to posterior vessel wall calcification occurred, the MANTA was pushed forward and released from the calcification. The assembly was then pulled back again, rotating the device by 30° to 45°, avoiding stacking.

Step 3: Pulling force was maintained while monitoring the color code of the tension gauge (green code) until the collagen pad was getting close to the vessel wall. The blue tamper tube was then advanced to further compact the collagen pad while keeping a pulling force (**Figure 1E**).

Step 4: Hemostasis was confirmed by visual inspection and ultrasound scan. According to the situation, manual compression with gentle pressure was added.

In a retrospective, single-center study performed between September 2017 and May 2019, 246 consecutive patients with conventional MANTA deployment

FIGURE 1 Ultrasound-Navigated MANTA Method and Potential Failure Mechanisms



(A) A scanning in a longitudinal view is used to identify the common femoral artery with the MANTA. **(B)** Scheme of a longitudinal view (**asterisk**: toggle, **arrow**: vessel wall). **(C)** The toggle locating within a longitudinal view. **(D)** The toggle attaching vessel in parallel. **(E)** Arteriotomy sandwiched by the toggle and collagen pad **(arrowheads)**. **(F)** Schema of MANTA deployment failure. Type 0: appropriate MANTA deployment under ultrasound. All cases with type 1, 2, and 4 failure required unplanned surgical repairs. Cases with type 3 and 5 failure were associated with late pseudoaneurysm. In part of these cases, unplanned surgical or endovascular repairs were performed.

(C-MANTA) (1) and 153 consecutive patients with US-MANTA were evaluated. One-to-one propensity score matching resulted in 135 pairs with adequate balance of baseline characteristics with comparable sheath-to-femoral artery ratio (C-MANTA 1.03 ± 0.26 vs. US-MANTA 1.04 ± 0.21; $p = 0.36$) and moderate-to-severe calcification of CFA (C-MANTA 25.2% vs. US-MANTA 20.0%; $p = 0.38$).

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 12, NO. 24, 2019
DECEMBER 23, 2019:2558–70

In a matched series, access-site major VCs occurred significantly less frequently in patients with US-MANTA in comparison to those with C-MANTA (1.5% vs. 7.4%; p = 0.030), with significantly lower incidence of access-site life-threatening or major bleeding complication (1.5% vs. 8.9%; p = 0.008). Moreover, a significantly lower incidence of minor VCs (2.2% vs. 8.2%; p = 0.028) was observed in patients with US-MANTA. In multivariate analysis, US-MANTA (odds ratio: 0.29, 95% confidence interval: 0.08 to 0.80) was identified as the only independent predictor of less frequent access-site major VCs. Potential mechanisms of MANTA failure are also reported by surgical inspection and/or ultrasound imaging at the time of VCs in the total study cohort (**Figure 1F**).

US-MANTA may enable more accurate hemostasis following transfemoral transcatheter aortic valve replacement requiring a large-bore arteriotomy in unselected patients as compared with C-MANTA. Of note, this study is a single-center retrospective study, and large prospective trials are warranted to further investigate the efficacy of the US-MANTA strategy in the real-world setting.

Noriaki Moriyama, MD
Sebastian Dahlbacka, MD, PhD
Tommi Vähäsilta, MD, PhD
Tiina Vainikka, MD, PhD
Pekka Aho, MD, PhD
Juho Viikilä, MD
Olavi Lammintausta, MD
***Mika Laine, MD, PhD**

*Department of Cardiology
Heart and Lung Center
Helsinki University and
Helsinki University Central Hospital
Haartmaninkatu 4
00290 Helsinki
Finland
E-mail: Mika.Laine@hus.fi

https://doi.org/10.1016/j.jcin.2019.09.018

Please note: The authors have reported that they have no relationships relevant to the contents of this paper to disclose.

REFERENCES

1. Wood DA, Krajcer Z, Sathananthan J, et al. Pivotal clinical study to evaluate the safety and effectiveness of the MANTA percutaneous vascular closure device. Circ Cardiovasc Interv 2019;12:e007258.

2. Moriyama N, Lindström L, Laine M. Propensity-matched comparison of vascular closure devices after transcatheter aortic valve replacement using MANTA versus ProGlide. EuroIntervention 2019;14:e1558–65.

3. Biancari F, Romppanen H, Savontaus M, et al. MANTA versus ProGlide vascular closure devices in transfemoral transcatheter aortic valve implantation. Int J Cardiol 2018;263:29–31.

RESEARCH CORRESPONDENCE

Severe Mitral Stenosis in Patients With Severe Mitral Annular Calcification

An Area of Unmet Need

The clinical presentation and guidelines for treating patients with rheumatic mitral stenosis (MS) often overlap with those patients with MS due to severe mitral annular calcification (MAC) (1). Unfortunately, there is a paucity of effective transcatheter treatment strategies for patients presenting in this latter group. Percutaneous mitral balloon commissurotomy (PMBC) is not effective for this pathology, and early attempts at transcatheter mitral valve replacement using a transcatheter aortic valve placed in patients with severe MAC demonstrated a high rate of complications and poor overall results (2). The 2014 and 2017 American College of Cardiology (ACC)/American Heart Association (AHA) valve guidelines do not specifically address treatment options for those who have severe MS from severe MAC. MS progresses more rapidly in those patients with severe MAC, and given the aging population, the prevalence of MAC is likely to increase (3,4). Further, those patients with significant MS who undergo transcatheter aortic valve replacement benefit less than their counterparts without mitral disease (5). In this study, we aimed to characterize this population with MS due to MAC with respect to the only available rheumatic MS guidelines and their unmet need.

The Cleveland Clinic database for the years 2007 to 2017 was interrogated for patients with severe MAC with a mean transmitral gradient ≥10 mm Hg, and who had ≥2 echocardiograms over a ≥1-year period. MS severity was assessed by peak and mean transmitral gradients, mitral valve area (MVA) by pressure half-time (PHT) and planimetry. Mitral regurgitation (MR) was assessed qualitatively and by PISA, MR velocity, orifice area, regurgitant volume, and regurgitant fraction. Wilkins score, presence of left atrial clot, and New York Heart Association (NYHA) functional class were also evaluated. The most recent echocardiogram for a given patient was used for this analysis. Death was captured by both social security death index and the electronic health record.