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

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A new plug-based MANTA™ (Teleflex Inc., Morrisville, NC) vascular closure device was recently introduced. Although prospective studies of MANTA have reported promising results of 2% to 4% of major vascular complication (VC) in selected patients who underwent transfemoral-transcatheter aortic valve replacement (TF-TAVR) (1), major VC 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 to compare the incidence of access-site major VC and bleeding between the periods before and after introduction of 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 procedures, the activated clotting time was controlled to be below 250 seconds by protamine administration. Detailed descriptions of US-MANTA method are as follows: a scanning in a longitudinal view was used to identify the CFA with the MANTA toggle *in situ* (Figure 1A and B).

Step 1: An ultrasound-image was maintained, and the sheath was withdrawn up to pre-determined depth+1cm.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

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

Step 3: Pulling force was maintained under monitoring by the color code of the tension gauge (green code) until the collagen pad getting close to the vessel wall. Then, the blue tamper tube was advanced to further compact the collagen pad with keeping pulling force (Figure 1E).

Step 4: Hemostasis was confirmed in visual 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 (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).

In 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, significantly fewer 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 an 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 total study cohort (Figure 1F).

US-MANTA may enable more accurate hemostasis following TF-TAVR 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 US-MANTA strategy in the real-world setting.

REFERENCES

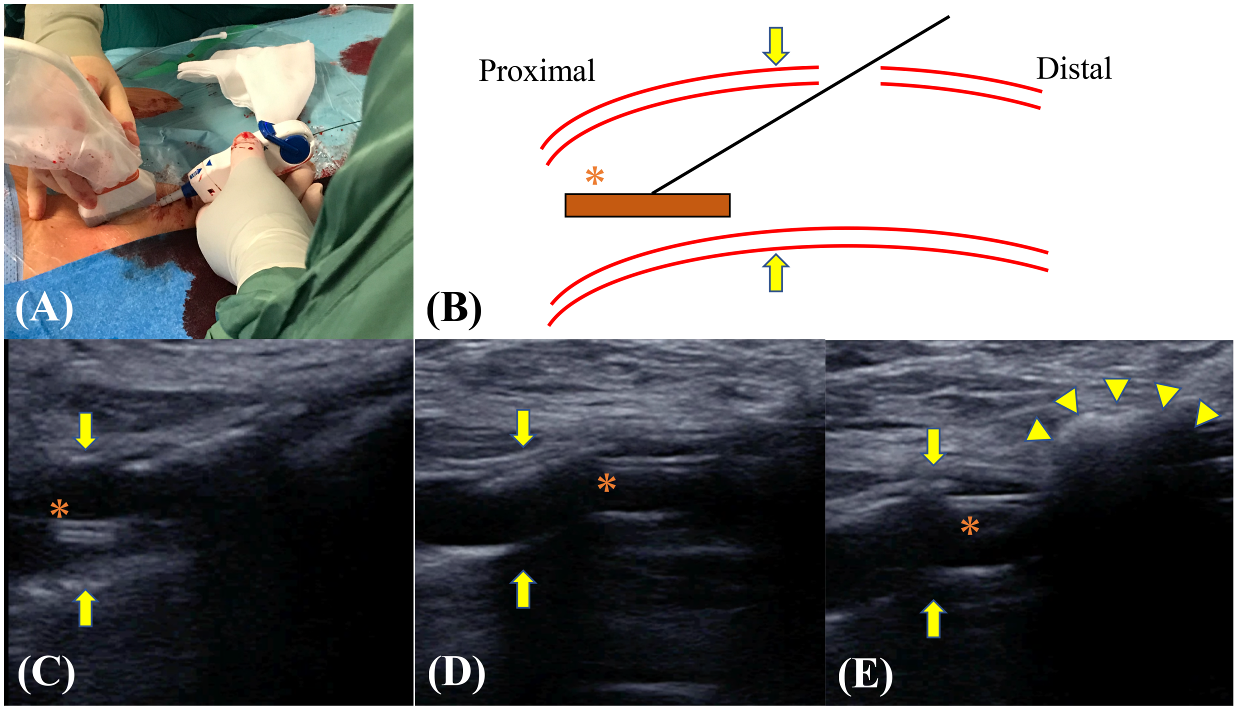
1. Wood DA, Krajcer Z, Sathananthan J, et al. Pivotal Clinical Study to Evaluate the Safety and Effectiveness of the MANTA Percutaneous Vascular Closure Device. Circ Cardiovasc Interv. 2019;12:e007258.
2. Moriyama N, Lindström L, Laine M. Propensity-matched comparison of vascular closure devices after transcatheter aortic valve replacement using MANTA versus ProGlide. EuroIntervention. 2019;14:e1558-e65.
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.

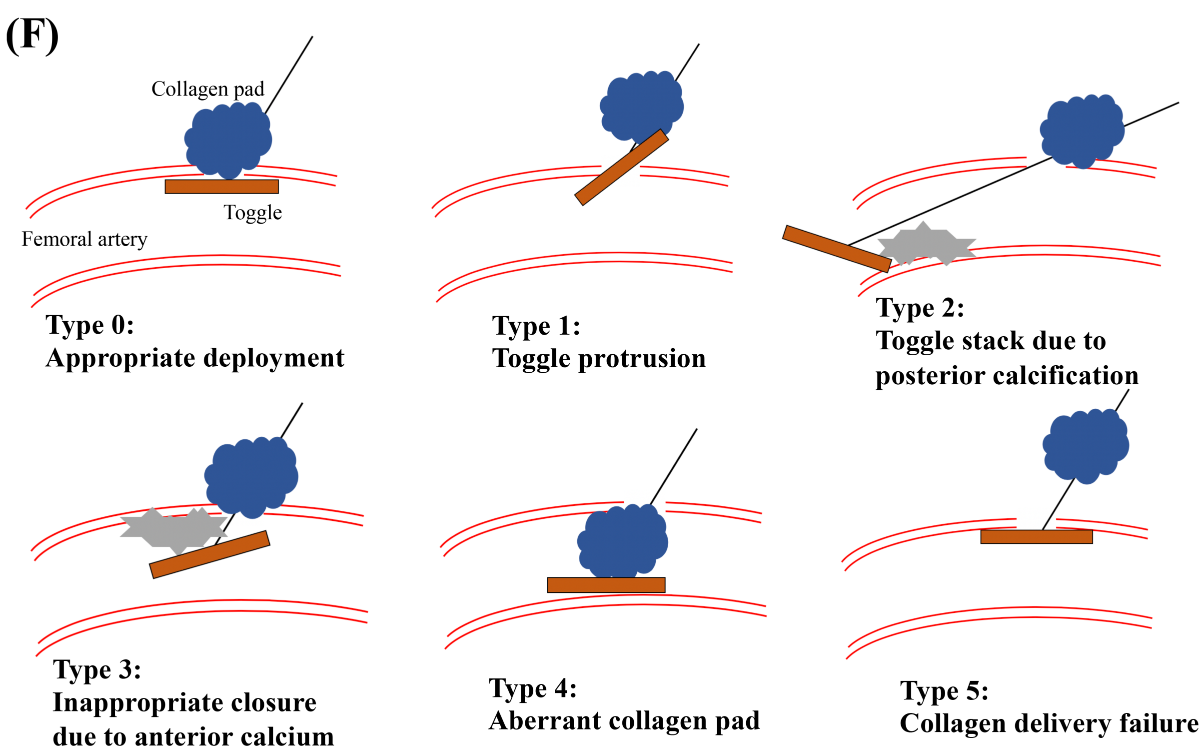
FIGURE LEGEND

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 (arrow head).

(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.


Proximal
Distal
(A)
(B)
(C)
(D)
(E)


(F)
Collagen pad
Toggle
Femoral artery
Type 0:
Appropriate deployment
Type 1:
Toggle protrusion
Type 2:
Toggle stack due to posterior calcification
Type 3:
Inappropriate closure due to anterior calcium
Type 4:
Aberrant collagen pad
Type 5:
Collagen delivery failure