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Ultrasound-Guided Versus Conventional MANTA Vascular Closure Device Deployment After Transcatheter Aortic Valve Implantation

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Despite the development of device technology and operators' experience, access site vascular complications (VCs) remain one of the major concerns after transcatheter aortic valve implantation (TAVI). MANTA (Teleflex, Wayne, Pennsylvania) is a large-bore vascular closure device (VCD) with promising incidence of VC. Previously, we demonstrated that the ultrasound-guided MANTA (US-MANTA) technique further improved the outcomes compared with conventional MANTA (C-MANTA) without ultrasound guidance. The present study was established to prove the effectiveness of the technique in a larger population. In this study, we included 1,150 patients (335 patients with C-MANTA and 815 with US-MANTA) who received MANTA after TAVI from April 2017 to September 2021. The primary endpoint was MANTA-related VC. Overall VC, VCD failure, and bleeding complications were also assessed based on the Valve Academic Research Consortium 3 criteria. MANTA-related VC occurred in 12.5% in the C-MANTA group and 6.8% in the US-MANTA group (p = 0.001). VCD failure rate were 7.5% and 3.9%, respectively (p = 0.012). Valve Academic Research Consortium 3 major and minor VC were more frequent in C-MANTA group (major: 7.8% vs 4.4%, p = 0.023; minor: 8.1% vs 4.4%, p = 0.022). Multivariate analysis revealed US-MANTA as the negative predictor of MANTA-related VC (odds ratio 0.57, 95% confidence interval 0.36 to 0.89, p = 0.013). However, subgroup analysis showed the efficacy of the US-MANTA technique was limited to the patients without severely calcified puncture site ($P_{interaction}$ = 0.048). In conclusion, the US-MANTA technique was an effective strategy to reduce VC after transfemoral TAVI compared with C-MANTA. **(Am J Cardiol 2022;180:116−123)**

Introduction

Transcatheter aortic valve implantation (TAVI) is an established treatment for severe aortic stenosis.[1,2] The vast majority of TAVI are performed through transfemoral approach. Despite the effort to reduce access site vascular complications (VCs) after TAVI, it remains one of the major concerns with a significant impact on clinical outcomes.[3,4] Recently, novel plug-based MANTA (Teleflex, Wayne, Pennsylvania) has been introduced. The efficacy of MANTA has been demonstrated by several studies,[5−9] whereas 2 studies did not show the differences between 2 types of VCDs in access site-related VC[10] and major VC.[11] In contrast, 1 randomized study and 1 retrospective study demonstrated significantly higher access site VC with MANTA in comparison with suture-based VCD.[12,13] In the MARVEL registry, several anatomic and baseline characteristics predicted VC with MANTA.[14] However, technical solutions to avoid VC have been scarcely proposed; our group reported that the ultrasound (US)-guided MANTA (US-MANTA) technique reduced VC after TAVI in a small retrospective study.[15] The present study aimed to extend the study's size and further compare the US-MANTA and conventional MANTA (C-MANTA) techniques without US.

Methods

This registry-based study included all consecutive patients who underwent transfemoral TAVI and received MANTA for a large-bore arteriotomy closure from April 2017 to September 2021 at Helsinki University Central Hospital (n = 1,182), and 32 patients were excluded (Figure 1). The baseline characteristics, clinical, and procedural data were prospectively collected as part of a dedicated institutional database. The study protocol conformed to the Declaration of Helsinki and was approved by the institutional review board. The data that support the findings of this study are available from the corresponding author on reasonable request.

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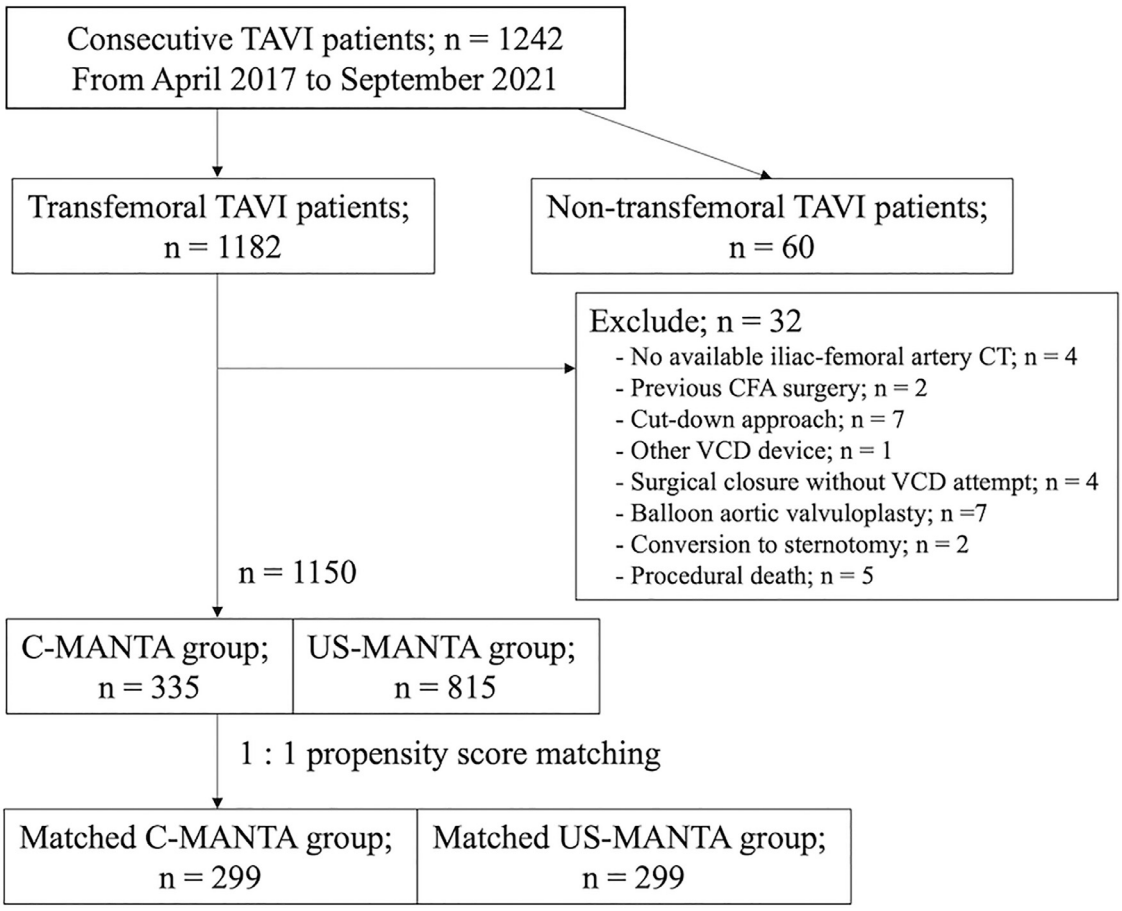

Figure 1. Study flow chart. C-MANTA = conventional MANTA; CFA = common femoral artery; CT = computed tomography; TAVI = Transcatheter aortic valve implantation; US-MANTA = ultrasound-guided MANTA; VCD = vascular closure device..

During the study period, our institution used MANTA as a VCD for transfemoral TAVI arteriotomy closure. For the first 335 consecutive cases, we used MANTA in the conventional method: an operator determines the distance of the subcutaneous track from skin level to the endoluminal arterial space using a dedicated dilator, and during the closure, the toggle is released at the predetermined deployment level. The rest of the patients received the US-MANTA technique, as previously reported.[15] The assistant operator scans the common femoral artery (CFA) to identify the position of the toggle in situ, with US in a longitudinal view. While the US image is maintained, the operator withdraws the MANTA to a predetermined depth + 1 cm. The toggle is released at this level, and the opening movement is confirmed in the image. If the predetermined deployment level is not considered reliable, a new deployment depth is visually determined by confirming the toggle location inside the vessel. The assembly was pulled back slowly with a 45° or more angle between the skin surface and the MANTA sheath while maintaining the toggle in the center of the US image. After confirming that the toggle is attached to the vessel wall in parallel, the operator maintains the pulling force while monitoring the color code of the tension gauge (green code) until the collagen pad gets close to the vessel wall. Although the MANTA is available in 2 sizes on the basis of the size of the large-bore device, only the 18-Fr device was used in this study.

All transfemoral TAVI procedures were planned after contrast-enhanced multidetector computed tomography (MDCT) and coronary angiography examinations. All patients were evaluated as eligible for transfemoral TAVI by a multidisciplinary heart team on the basis of the guidelines at the time. If eligible patients had previous femoral vascular closure within 30 days[16] or any previous surgical cutdown, the other femoral side was used. Pre-existing antiplatelet therapy was continued before and after the TAVI procedure. Direct oral anticoagulants were stopped for 24 hours before the procedure. Vitamin-K antagonists were continued, aiming at an international normalized ratio between 2 and 2.5 on the day of the procedure. Most transfemoral TAVI were performed under local anesthesia with conscious sedation. All femoral arterial access was punctured using US guidance in both US-MANTA and C-MANTA groups. Activated clotting time was controlled below 250 seconds by administrating protamine, and systolic blood pressure was lowered below 120 mmHg at the end of the procedure.

For the iliofemoral artery assessment, a 3-dimensional MDCT image was retrospectively reconstructed from raw DICOM data using 3mensio Structure Heart software (3mensio Medical Imaging BV, Bilthoven, The Netherlands). A curved multiplanar reconstruction centerline was generated to assess the cross-sectional image.[17] The following measurements were obtained in all patients on the side

of delivery sheath placement at the level of the CFA: minimum, mean, and maximum lumen diameter of the vessel at the minimum lumen diameter (MLD) level of the targeted CFA and degree of calcification based on MANTA femoral artery calcification score (MFACS).[14] CFA depth was determined as the distance between the skin and the center point of the CFA, as described previously.[18]

The primary endpoint of this study was MANTA-related VC at 30 days after TAVI. VC was defined based on the Valve Academic Research Consortium 3 (VARC-3) criteria,[19] and MANTA-related VC was defined as the access site-related VC that occurred because of MANTA usage. VC that was not related to MANTA (e.g., iliac artery rupture because of delivery sheath and aortic dissection) was classified as overall VC but not as MANTA-related VC. The institutional vascular surgeon and the heart team determined if the complication was related to the MANTA usage. MANTA-related VC was categorized into 4 categories (vascular injury, distal embolism, unplanned endovascular or surgical intervention, and VCD failure) based on the VARC-3 criteria.[19] Also, MANTA-related VC was classified based on the timing of the failure: VC that developed in the catheterization laboratory or operating room, in-hospital VC, and postdischarge VC. Based on the VARC-3 criteria, overall VC, VCD failure, and bleeding complications were also assessed. MANTA failures were classified based on the mechanism of the failure (Supplementary Figure 1).[15]

Categorical variables are presented as counts and percentages and were compared using the chi-square test or Fischer's exact test, if needed. Continuous variables are presented as the mean ± SD and were compared using the *t* test or Wilcoxon rank-sum test on the basis of their distributions. Logistic regression analysis, including baseline, MDCT, and procedural covariates, was used to obtain the odds ratio (OR) and 95% confidence interval (CI) for developing MANTA-related VC. Variables with a p value <0.05 in univariate analysis were included in the multivariate model. To balance the background between the US-MANTA group and C-MANTA group, the propensity score (PS) matching was modeled with the following variables; age, gender, Society of Thoracic Surgeons predicted risk of mortality (STS-PROM), hypertension, dyslipidemia, diabetes mellitus, atrial fibrillation, chronic kidney disease, chronic obstructive pulmonary disease, peripheral artery disease, previous coronary artery bypass graft surgery, previous percutaneous coronary intervention, previous stroke, hemoglobin level, left ventricular ejection fraction, dual antiplatelet therapy, and oral anticoagulant. Predefined subgroup analysis for MANTA-related overall VCs included gender, body mass index (BMI) (≤30 vs >30), CFA MLD (≤6.0 vs >6.0 mm), MFACS (<3 vs ≥3), CFA depth (≤33.8 vs >33.8 mm), and sheath to femoral artery ratio (SFAR) (≤1.05 vs >1.05). For the BMI, CFA diameter, and SFAR subgroups, thresholds were based on previous studies.[10,20] For the subgroup of CFA depth, the median value was used to divide the patients into 2 subgroups. A p <0.05 was considered statistically significant, and all statistical tests were 2-tailed statistical analyses that were performed using JMP version 14.2 (SAS Institute Inc., Cary, North Carolina).

Results

Between April 2016 and September 2021, 1,182 consecutive patients were treated with transfemoral TAVI and received MANTA for large-bore arteriotomy closure, and 32 patients were excluded from the analysis (Figure 1). In total, 1,150 patients were analyzed in this study. Baseline clinical characteristics of both groups are presented in Table 1. C-MANTA group had more women, higher STS score, more frequent chronic kidney disease, higher rate of previous percutaneous coronary intervention, previous peripheral artery disease, and previous stroke. Although there were significant differences in vitamin-K antagonist and direct oral anticoagulant use between the 2 groups, overall oral anticoagulant usage was not significantly different.

Table 2 shows anatomic and procedural characteristics. C-MANTA group had more frequent high SFA takeoff and larger effective sheath outer diameter, whereas the SFAR was not significantly different between the 2 groups. MFACS (0.97 vs 0.93, p = 0.57), MFACS ≥3 (11% vs 7.9%, p = 0.58), and the distribution of the CFA calcification were not different between the 2 groups. During the study period, 6 different types of transcatheter heart valve were used (Table 2).

MANTA-related VC occurred more frequently in the C-MANTA group (13% vs 6.8%, p = 0.001) (Table 3). In addition, both major and minor MANTA-related VC rates were higher in C-MANTA group (major: 6.6% vs 3.4%, p = 0.018; minor: 8.1% vs 4.4%, p = 0.022). Overall VARC-3 major complication (7.8% vs 4.4%, p = 0.023), minor complication (8.1% vs 4.4%, p = 0.022), major or life-threatening bleeding (11% vs 5.9%, p = 0.002), and MANTA failure (7.5% vs 3.9%, p = 0.012) occurred more frequently in the C-MANTA group. The 30-day all-cause mortality was not significantly different between the 2 groups. A detailed description of MANTA failure is presented in Supplementary Table 1. The incidence of each component of the types of VC was similar between the 2 groups. In addition, the incidence of the breakdowns of the vascular injury was not significantly different. In terms of the timing of MANTA-related VC, 48% and 44% (p = 0.70) of MANTA-related VC developed in the catheter laboratory or operating room, and 52% and 53% (p = 0.97) occurred during the hospitalization after the TAVI procedure. A total of 2 patients (2.1%) had postdischarge VC in the US-MANTA group. A total of 50% and 58% (p = 0.97) of MANTA-related VC ended up receiving surgical treatment, and 4.8% and 1.8% of patients (p = 0.50) had endovascular treatment. MANTA failure types were also classified (Supplementary Table 1). The most common failure mechanism was type 1, followed by type 5 in both groups. Multivariate analysis revealed US-guided and MFACS ≥3 as predictors of MANTA-related VC (Table 4).

PS matching resulted in the balanced baseline characteristics, except for previous coronary artery bypass graft surgery, baseline hemoglobin level, and creatinine level (Table 1). Anatomic data were not significantly different between the 2 groups (Table 2). As to procedural characteristics, sheath size and effective sheath outer diameter were larger in the US-MANTA group. Table 3 shows the

Table 1
Baseline characteristics

Variables	All (n = 1150)	C-MANTA (n =335)	US-MANTA (n = 815)	p-Value	SD	Matched C-MANTA (n = 299)	Matched US-MANTA (n = 299)	p-Value	SD
Age (years)	79.8 ± 6.9	79.9 ± 6.8	79.8 ± 6.9	0.80	0.01	79.7 ± 6.8	79.2 ± 7.7	0.49	0.069
Female	550 (48%)	178 (53%)	372 (46%)	0.021	0.15	157 (53%)	147 (49%)	0.41	0.067
BMI (kg/m^2)	27.0 ± 5.2	27.0 ± 4.8	26.9 ± 5.3	0.80	0.02	27.0 ± 4.8	27.0 ± 5.8	0.95	0.067
STS PROM	3.8 ± 2.3	4.4 ± 3.3	3.6 ± 1.8	<0.001	0.33	3.8 ± 2.3	3.9 ± 2.0	0.46	0.061
Hypertension	1041 (91%)	306 (91%)	735 (90%)	0.54	0.04	272 (91%)	274 (92%)	0.77	0.024
Dyslipidemia*	854 (74%)	241 (71.9%)	613 (75%)	0.25	0.07	213 (71%)	224 (75%)	0.31	0.083
Diabetes mellitus	331 (29%)	96 (29%)	235 (29%)	0.95	0.004	79 (26%)	73 (24%)	0.57	0.046
Atrial fibrillation	444 (39%)	136 (41%)	308 (38%)	0.37	0.06	117 (39%)	113 (38%)	0.74	0.028
CKD	330 (38%)	145 (43%)	295 (36%)	0.025	0.15	119 (40%)	123 (41%)	0.74	0.027
COPD	239 (21%)	77 (23%)	162 (20%)	0.24	0.076	64 (21%)	66 (22%)	0.84	0.016
Prior PCI	288 (25%)	99 (30%)	189 (23%)	0.024	0.15	83 (28%)	83 (28%)	1.00	0
Prior CABG	115 (10%)	25 (7.5%)	90 (11%)	0.07	0.12	20 (6.7%)	32 (11%)	0.08	0.14
Prior non-CABG	77 (6.7%)	22 (6.6%)	55 (6.8%)	0.91	0.007	17 (5.7%)	26 (8.7%)	0.15	0.047
Prior PAD	120 (10%)	52 (16%)	68 (8.3%)	<0.001	0.22	34 (11%)	41 (14%)	0.39	0.071
Prior stroke	102 (8.9%)	43 (13%)	59 (7.2%)	0.002	0.19	28 (9.4%)	24 (8.0%)	0.56	0.047
Examination data									
Hemoglobin (g/L)	128.0 ± 15.1	128.7 ± 14.5	127.7 ± 15.4	0.28	0.067	129.5 ± 14.2	127.0 ± 15.1	0.041	0.17
Platelet (x10^3/μL)	213.2 ± 70.0	218.5 ± 70.6	211.0 ± 70.0	0.10	0.11	217.3 ± 69.5	213.9 ± 68.4	0.54	0.049
Creatinine (μmol/L)	95.3 ± 55.0	92.4 ± 30.7	96.5 ± 62.3	0.25	0.083	90.4 ± 27.7	94.8 ± 43.5	0.14	0.12
eGFR (ml/min/1.73 m^2)	64.2 ± 19.6	62.6 ± 17.9	64.9 ± 20.3	0.06	0.74	63.6 ± 17.3	63.5 ± 19.4	0.93	0.005
LVEF (%)	57.5 ± 11.2	56.7 ± 12.1	57.8 ± 10.8	0.11	0.096	57.0 ± 12.1	58.0 ± 10.9	0.30	0.087
Peak AV (m/s)	4.18 ± 0.63	4.16 ± 0.68	4.19 ± 0.60	0.54	0.047	4.17 ± 0.68	4.18 ± 0.58	0.88	0.016
mean APG (mmHg)	43.9 ± 14.0	43.4 ± 14.5	44.1 ± 13.9	0.41	0.068	43.5 ± 14.3	43.4 ± 12.8	0.93	0.007
Medication									
SAPT	555 (48%)	149 (45%)	406 (50%)	0.10	0.11	135 (45%)	143 (48%)	0.51	0.054
DAPT	98 (8.5%)	27 (8.1%)	71 (8.7%)	0.72	0.024	25 (8.4%)	33 (11%)	0.27	0.020
Oral anticoagulant	427 (37%)	129 (39%)	298 (37%)	0.54	0.040	110 (37%)	110 (37%)	1.00	0
Vitamin-K antagonist	202 (18%)	91 (27%)	111 (14%)	<0.001	0.34	79 (26%)	44 (15%)	<0.001	0.29
DOAC	227 (20%)	38 (11%)	189 (23%)	<0.001	0.32	31 (10%)	66 (22%)	<0.001	0.32
OAC + APT	54 (4.7%)	21 (6.3%)	33 (4.1%)	0.11	0.10	17 (5.7%)	13 (4.4%)	0.45	0.061
OAC mono	373 (32%)	108 (32%)	265 (32%)	0.93	0.006	93 (31%)	97 (32%)	0.73	0.029

* Defined as presenting LDL cholesterol ≥ 140 mg/dl, triglyceride ≥ 150 mg/dl, HDL cholesterol <40 mg/dl, or taking cholesterol-lowering medicine.

APG = aortic valve pressure gradient; APT = antiplatelet therapy; AV = aortic valve velocity; BMI = body mass index; C-MANTA = conventional MANTA; CABG = coronary artery bypass grafting; CKD = chronic kidney disease; COPD = chronic obstructive pulmonary disease; DAPT = dual antiplatelet therapy; eGFR = estimated glomerular filtration rate; LVEF = left ventricle ejection fraction; DOAC = direct oral anticoagulant; OAC = oral anticoagulant; PAD = peripheral artery disease; PCI = percutaneous coronary intervention; SAPT = single antiplatelet therapy; SD = standardized difference; STS PROM = Society of Thoracic Surgeons predicted risk of mortality; US-MANTA = ultrasound-guided MANTA.

Table 2
Anatomical and procedural characteristics

Variable	All (n = 1150)	C-MANTA (n =335)	US-MANTA (n = 815)	p-Value	Matched C-MANTA (n = 299)	Matched US-MANTA (n = 299)	p-Value
Anatomical data							
Valve in valve	76 (6.6%)	21 (6.3%)	55 (6.8%)	0.77	16 (5.4%)	25 (8.4%)	0.15
CFA depth (mm)	38.5 ± 20.7	39.3 ± 20.2	38.1 ± 20.9	0.36	38.5 ± 19.6	37.7 ± 22.4	0.65
CFA length (mm)	42.5 ± 12.5	42.2 ± 12.0	42.7 ± 12.6	0.54	42.2 ± 12.1	41.7 ± 13.2	0.62
High takeoff	70 (6.1%)	29 (8.7%)	41 (5.0%)	0.019	25 (8.4%)	15 (5.0%)	0.10
MLD (mm)	6.9 ± 1.3	6.9 ± 1.3	7.0 ± 1.3	0.32	6.9 ± 1.3	6.9 ± 1.3	0.94
Max LD (mm)	8.6 ± 1.5	8.5 ± 1.4	8.6 ± 1.5	0.35	8.6 ± 1.4	8.5 ± 1.4	0.92
SFAR	1.11 ± 0.23	1.13 ± 0.20	1.10 ± 0.24	0.055	1.13 ± 0.21	1.12 ± 0.25	0.77
Calc length >1 cm	361 (31%)	113 (34%)	248 (30%)	0.27	96 (32%)	96 (32%)	1.00
MFACS	0.94 ± 1.07	0.97 ± 1.12	0.93 ± 1.04	0.57	0.93 ± 1.13	0.97 ± 1.09	0.63
MFACS ≥3	99 (8.6%)	35 (11%)	64 (7.9%)	0.15	30 (10%)	28 (9.4%)	0.89
Anterior calcification	99 (8.6%)	27 (8.1%)	72 (8.8%)	0.67	25 (8.4%)	32 (11%)	0.33
Posterior calcification	563 (49%)	164 (49%)	399 (49%)	>0.99	140 (47%)	147 (49%)	0.57
Procedural characteristics							
Right approach	1060 (92%)	314 (94%)	746 (92%)	0.21	280 (94%)	269 (90%)	0.10
Sheath size (Fr)	15.7 ± 1.9	16.7 ± 1.7	15.3 ± 2.0	<0.001	16.7 ± 1.7	15.4 ± 2.1	<0.001
Effective sheath OD (mm)	7.4 ± 0.5	7.5 ± 0.4	7.4 ± 0.6	<0.001	7.5 ± 0.5	7.4 ± 0.5	0.011
THV type							
SAPIEN 3	519 (45%)	127 (38%)	392 (48%)	0.002	112 (38%)	151 (51%)	0.001
Evolut R/Pro	196 (17%)	29 (8.7%)	167 (21%)	<0.001	29 (9.7%)	58 (19%)	<0.001
ACURATE neo	385 (34%)	165 (49%)	220 (27%)	<0.001	146 (49%)	73 (24%)	<0.001
LOTUS	18 (1.6%)	0 (0%)	18 (2.2%)	0.003	0 (0%)	10 (3.3%)	0.002
Allegra	23 (2.0%)	14 (4.2%)	9 (1.1%)	0.002	12 (4.0%)	3 (1.0%)	0.020
Portico	9 (0.8%)	0 (0%)	9 (1.1%)	0.07	0 (0%)	4 (1.3%)	0.12

C-MANTA = conventional MANTA; CFA = common femoral artery; LD = lumen diameter; MFACS = MANTA femoral artery calcification score; MLD = minimum lumen diameter; OD = outer diameter; SFAR = sheath to femoral artery ratio; THV = transcatheter heart valve; US-MANTA = ultrasound-guided MANTA.

MANTA-related VC in the PS-matched cohort. MANTA-related all VC was significantly more frequent in matched C-MANTA group (12.0% vs 6.7%, p = 0.025); although, each component did not have significant difference (MANTA-related major: 6.7% vs 3.7%, p = 0.10; minor: 5.4% vs 3.0%, p = 0.15).

Predefined subgroup analysis was performed to confirm the consistent effect of the US-guided technique for MANTA-related VC (Figure 2). The US-guided technique was effective regardless of BMI, CFA MLD, and CFA depth. In contrast, MFACS ≥3 had significant interaction with US-guided technique ($p_{interaction}$ = 0.048), and gender had a trend to have an interaction with US-guided technique ($p_{interaction}$ = 0.08).

Discussion

This study expanded the findings of our previous study that compared C-MANTA and US-MANTA techniques in a larger number of patients. The main results are as follows: (1) MANTA-related all VC were significantly less frequent in the US-MANTA group than the C-MANTA group, and PS matching analysis supported this finding. In addition, the US-guided technique was significantly associated with less frequent MANTA-related VC in the multivariate analysis. (2) However, the US-guided technique was ineffective for patients with MFACS ≥3. (3) Furthermore, MFACS ≥3 was an independent predictor of MANTA-related VC. (4) The most common mechanisms of VCD failure in both

Table 3
Clinical endpoints

	All (n = 1150)	C-MANTA (n =335)	US-MANTA (n = 815)	p-Value	Matched C-MANTA (n =299)	Matched US-MANTA (n = 299)	p-Value
MANTA-related VC	97 (8.4%)	42 (13%)	55 (6.8%)	0.001	36 (12%)	20 (6.7%)	0.025
MANTA-related major VC	50 (3.4%)	22 (6.6%)	28 (3.4%)	0.018	20 (6.7%)	11 (3.7%)	0.09
MANTA-related minor VC	47 (4.1%)	20 (6.0%)	27 (3.3%)	0.039	16 (5.4%)	9 (3.0%)	0.15
MANTA VCD failure	57 (5.0%)	25 (7.5%)	32 (3.9%)	0.012	23 (7.7%)	13 (4.4%)	0.09
Overall VC	125 (11%)	53 (15.8%)	72 (8.8%)	<0.001	45 (15%)	28 (9.4%)	0.034
Overall major VC	62 (5.4%)	26 (7.8%)	36 (4.4%)	0.023	24 (8.0%)	14 (4.7%)	0.09
Overall major VC	63 (5.5%)	27 (8.1%)	36 (4.4%)	0.022	21 (7.0%)	14 (4.7%)	0.22
Bleeding ≥ major	85 (7.4%)	37 (11%)	48 (5.9%)	0.002	34 (11%)	23 (7.7%)	0.13
30-day all-cause mortality	15 (1.3%)	3 (0.9%)	12 (1.5%)	0.57	2 (0.7%)	3 (1.0%)	0.65

C-MANTA = conventional MANTA; US-MANTA = ultrasound-guided MANTA; VC = vascular complications; VCD = vascular closure device.

Table 4
Multivariate analysis for MANTA-related overall vascular complication

Variable	Univariate			Multivariate		
	OR	95% CI	p-Value	OR	95% CI	p-Value
US-guided	1.98	1.30-3.03	0.002	0.56	0.36-0.88	0.011
Female	1.12	0.74-1.70	0.58			
STS-score, per 1 score	1.09	1.01-1.17	0.043	1.04	0.96-1.13	0.34
BMI	1.02	0.98-1.06	0.39			
Prior PAD	1.51	0.83-2.75	0.18			
Hb baseline, per 1 g/L	1.00	0.99-1.01	0.90			
Platelet count, per 1	1.00	0.99-1.00	0.96			
DAPT	0.99	0.51-1.90	0.96			
Anticoagulation	1.00	0.65-1.54	>0.99			
CFA depth, per 1 mm	1.01	1.00-1.02	0.10			
CFA length, per 1 mm	0.99	0.98-1.01	0.49			
High takeoff	2.15	1.09-4.25	0.027	2.00	0.98-6.46	0.07
MLD, per 1 mm	0.75	0.64-1.33	<0.001			
MFACS ≥3	4.59	2.75-7.67	<0.001	3.71	2.13-6.46	<0.001
Right approach	1.10	0.49-2.45	0.82			
Sheath outer diameter, per 1 mm	1.22	0.82-1.81	0.32			
SFAR, per 1	2.27	1.02-5.04	0.048	2.35	0.97-5.70	0.06

BMI = body mass index; CFA = common femoral artery; DAPT = dual antiplatelet therapy; Hb = hemoglobin; MLD = minimum lumen diameter; PAD = peripheral artery disease; SFAR = sheath to femoral artery ratio; STS PROM = Society of Thoracic Surgeons predicted risk of mortality; US = ultrasound.

groups was the anchor protrusion (type 1), followed by the collagen delivery failure (type 5).

Our whole cohort analysis (n = 1,150) showed the consistent incidence of overall VC (11%), major VC (5.4%), and MANTA-related VCs (8.4%) with previous studies.[5,7–11] In addition, both the total cohort comparison and PS-matched comparison showed significantly lower rates of MANTA-related VC in the US-MANTA group. Moreover, multivariate analysis revealed US-guided technique as the independent predictor of MANTA-related VC. Interestingly, the proportions of the breakdowns of MANTA-related VC were similar between the 2 groups, and the mechanisms of MANTA failure were also numerically similar. Type 1 (anchor protrusion) was most commonly observed, followed by type 5 (collagen delivery failure) in both groups. Theoretically, US guidance could avoid the anchor stuck on the posterior calcification (type 2).[15] However, it was not common in both groups. US guidance could also help the physician confirm the anchor in the appropriate position and collagen pad delivered to the vessel wall through the subcutaneous tissue; thus, the US-MANTA technique might reduce overall MANTA failure in our study. In a daily practice with US-guided technique, physicians occasionally needed to tilt the MANTA assembly up more than 45° to get the anchor parallel to the vessel wall or needed to push the collagen pad beyond the green code to deliver it in the proper position. These technical modifications might reduce VCD failure corresponding to the lower incidence of MANTA-related VCs.

In the subgroup analysis, the efficacy of the US-MANTA technique was observed regardless of BMI, CFA diameter, and CFA depth, whereas the MSFACS ≥3 subgroups compared with the less calcification subgroup and men compared with women did not benefit from the US-guided technique. Incomplete apposition because of calcified artery might mainly depend on the calcification of the punctured point. In addition, CFA calcification would disturb the US-guided visualization of the anchor inside of the vessel, especially with proximal CFA calcification. Thus, the US-guided technique might not be as effective as those with less CFA calcification. Therefore, it would be essential to puncture the noncalcified vessel wall and avoid using severely calcified CFA for large-bore arteriotomy. The impact of the gender difference on US-guided technique was not explained theoretically. However, the US-guided technique might have reduced VC in women who had a potentially high risk of developing VC compared with men.[3,21]

The US-MANTA technique may help not only reduce VC but also identify the VCD failure immediately when the MANTA failed in the US image, such as MANTA anchor protrusion and collagen delivery failure. It is crucial to notice the VCD failure immediately once it occurs; otherwise, unrecognized bleeding could cause more significant complications later.

CFA calcification was reported as the access-related VC predictor.[14,20,22] In terms of MANTA failure, posterior CFA calcification could cause the anchor to get stuck (type 2 MANTA failure),[15,23] and anterior calcification could avoid appropriate apposition of the anchor (type 3 MANTA failure).[15] In addition, a calcified arterial wall might not have the appropriate elasticity as a healthy wall; thus, arteriotomy may not shrink after removing a large-bore device and may cause anchor protrusion (type 1 MANTA failure). Moreover, if the physician aims to puncture the proximal CFA and not to puncture the calcification, the risk of collagen delivery failure because of inguinal ligament (type 5 failure) may increase.[23] Therefore, physicians should avoid severely calcified CFA as the large-bore access site and consider puncturing the other side or an alternative approach. First, this study has typical limitations with the registry-based studies. Second, the present study did not consider the maturity of the skill in using MANTA, which

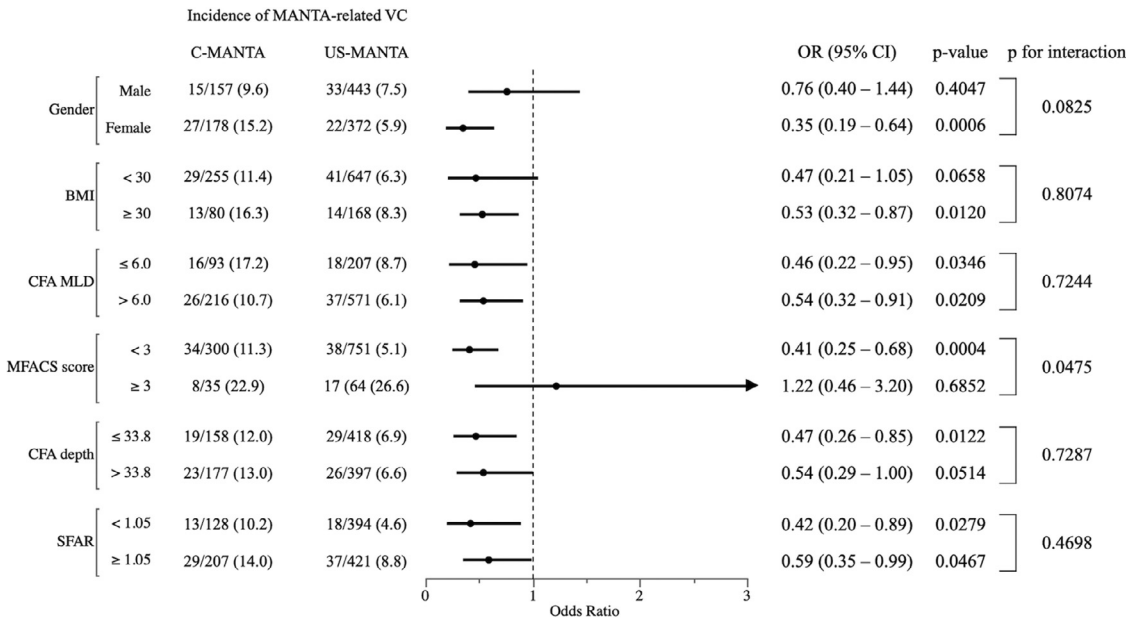

Figure 2. Subgroup analysis of the effect of ultrasound-guided technique for MANTA-related vascular complications Predefined subgroup analysis for MANTA-related overall VCs included gender, BMI (≤30 vs >30), CFA MLD (≤6.0 vs >6.0 mm), MFACS (<3 vs ≥3), CFA depth (≤33.8 vs >33.8 mm), and SFAR (≤1.05 vs >1.05).

might impact the results. Third, our study did not consider the visibility of US-guided images. Therefore, some patients in the US-MANTA group ended up using MANTA without the US-guided technique because of poor visibility. Fourth, 2 recent randomized trials between suture-based and plug-based VCDs demonstrated a higher incidence of access site-related VC with plug-based VCD. Thus, conventional plug-based VCD usage might not be an optimal hemostasis device. The comparison between suture-based VCD and US-guided plug-based VCD could be considered to further investigate the efficacy of the US-MANTA technique. Finally, our study did not perform postprocedural ultrasonography for all the patients; thus, we could have overlooked asymptomatic VC.

Disclosures

Dr. Moriyama reports receiving a consulting fee from Teleflex and is a clinical proctor of Edwards Lifesciences (SAPIEN) and Boston Scientific (ACURATE neo and Lotus Edge). has no conflicts of interest to declare. Dr. Vähäsilta is a clinical proctor of Edwards Lifesciences (SAPIEN). Dr. Laine reports nonregulatory research grants from Teleflex and consulting fees from Edwards Lifesciences, Boston Scientific, and Medtronic. The remaining authors have no conflicts of interest to declare.

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.amjcard.2022.06.046.

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