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Caval-Aortic Access to Allow Transcatheter Aortic Valve Replacement in Otherwise Ineligible Patients

Initial Human Experience

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Objectives This study describes the first use of caval-aortic access and closure to enable transcatheter aortic valve replacement (TAVR) in patients who lacked other access options. Caval-aortic access refers to percutaneous entry into the abdominal aorta from the femoral vein through the adjoining inferior vena cava.

Background TAVR is attractive in high-risk or inoperable patients with severe aortic stenosis. Available transcatheter valves require large introducer sheaths, which are a risk for major vascular complications or preclude TAVR altogether. Caval-aortic access has been successful in animals.

Methods We performed a single-center retrospective review of procedural and 30-day outcomes of prohibitive-risk patients who underwent TAVR via caval-aortic access.

Results Between July 2013 and January 2014, 19 patients underwent TAVR via caval-aortic access; 79% were women. Caval-aortic access and tract closure were successful in all 19 patients; TAVR was successful in 17 patients. Six patients experienced modified VARC-2 major vascular complications, 2 (11%) of whom required intervention. Most (79%) required blood transfusion. There were no deaths attributable to caval-aortic access. Throughout the 111 (range 39 to 229) days of follow up, there were no post-discharge complications related to tract creation or closure. All patients had persistent aorto-caval flow immediately post-procedure. Of the 16 patients who underwent repeat imaging after the first week, 15 (94%) had complete closure of the residual aorto-caval tract.

Conclusions Percutaneous transcaval venous access to the aorta allows TAVR in otherwise ineligible patients, and may offer a new access strategy for other applications requiring large transcatheter implants. (J Am Coll Cardiol 2014;63:2795–804) © 2014 by the American College of Cardiology Foundation

Transcatheter aortic valve replacement (TAVR) is an effective treatment for patients with symptomatic severe aortic stenosis and high or prohibitive surgical risk (1,2). Commercially available transcatheter valves in the United States currently require large 18- to 24-F inner diameter sheaths. This precludes TAVR in as many as one-quarter of patients, particularly women with smaller iliofemoral arteries and those with peripheral artery disease (3,4). Large sheaths can also cause major vascular complications, including rupture, hemorrhage, and death (5,6). Hybrid surgical and other alternative approaches are associated with significant morbidity and mortality, and are contraindicated in many due to unfavorable anatomy or comorbidity (7).

Caval-aortic access entails delivering large vascular sheaths into the abdominal aorta via the femoral vein through the inferior vena cava (IVC). It has been demonstrated in

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Abbreviations and Acronyms

ADO = Amplatzer duct occluder

AVR = aortic valve replacement

CT = computed tomography

IVC = inferior vena cava

MVSDO = Amplatzer muscular ventricular septal defect occluder

TAVR = transcatheter aortic valve replacement

pigs (8). The caval-aortic tract can be closed using nitinol occluder devices, and counterintuitively, is well tolerated even when not repaired. We describe the first use of this technique in humans undergoing TAVR who were believed not to have other access options.

Methods

Case selection. Patients were selected from the high-risk structural heart disease program at Henry Ford Hospital, Detroit, Michigan. All had severe symptomatic aortic valvular heart disease deemed to be high or prohibitive surgical risk. The multidisciplinary team of surgeons, cardiologists, and anesthesiologists concurred these patients would likely benefit from TAVR, but were not suitable for femoral arterial or transapical delivery of the transcatheter valve. For the first 11 patients, transaortic surgical access was not an option at our institution; subsequent patients were also deemed ineligible for transaortic delivery (severe lung disease and morbid obesity, n = 2; porcelain aorta, n = 2; frailty and poor rehabilitation potential, n = 3; previous chest irradiation, n = 1). All underwent TAVR under general anesthesia using Sapien transcatheter heart valves (Edwards Lifesciences, Irvine, California). Patients consented to clinical treatment despite explicitly high risk. The institutional review board of Henry Ford Hospital approved this analysis and report.

Caval-aortic access technique during TAVR. Contrast-enhanced computed tomography (CT) was used to select a caval-aortic crossing trajectory with the least-calcified aortic wall and no interposed structures, to determine suitable angiographic projection angles and fluoroscopic landmarks in relation to lumbar vertebrae. After simultaneous aortography and venography, and heparin administration, a gooseneck snare was positioned to "receive" a crossing guidewire in orthogonal fluoroscopic projections (Fig. 1). A coaxial crossing system (Fig. 2) consisting of a stiff 0.014-inch guidewire (Asahi ConfianzaPro12, Abbott Vascular, Santa Clara, California) inside a 0.035-inch wire convertor (Piggyback, Vascular Solutions, Minneapolis, Minnesota) inside a support catheter (Navicross, Terumo, Somerset, New Jersey) was inserted into a guiding catheter (RDC or RDC1) selected on the basis of caval diameter. The crossing system was directed from the cava towards the aortic snare, which served as a target. The proximal guidewire end was connected to a unipolar electrosurgery pencil (Valleylab, Covidien, Mansfield, Massachusetts) using forceps, and the patient was connected to a ground pad. The distal crossing tip of the guidewire was extended 2 to 5 mm beyond the wire convertor and energized in "cutting mode" at 50 to 70 W to vaporize target tissue during 2- to 3-s bursts. After the first 9 patients, we amputated the distal 1 cm of the guidewire to ease crossing. The snare confirmed intraluminal wire position and provided countertraction to advance the crossing system into the aorta (Online Video 1). The crossing devices were replaced with a rigid guidewire (0.035-inch Lunderquist, Cook, Bloomington, Indiana). The appropriate sized 35-cm-long Edwards TAVR introducer sheath (Retroflex 3 models 9120S23 [22-F] or 9120S26 [24-F]) was delivered from the femoral vein into the IVC, through the caval-aortic tract and into the abdominal aorta in a single step without progressive dilation. Aortography was performed immediately after sheath placement to assure hemostasis. TAVR was then performed in the usual manner.

After TAVR, the tract was closed with a nitinol occluder device marketed to close ductus arteriosus (Amplatzer Duct Occluder [ADO], St. Jude Medical, St. Paul, Minnesota) or intracardiac defects (Amplatzer muscular VSD occluder [MVSDO]) using the accompanying delivery system inside the TAVR sheath. Devices were selected to approach or exceed the outer diameter of the sheath (8.2 and 9.3 mm for Edwards 22-F and 24-F sheaths, respectively) and the distance between the aorta and cava. The occluders were deployed by exposing the distal disk in the aorta, retracting to appose the aortic wall, and then deploying the proximal

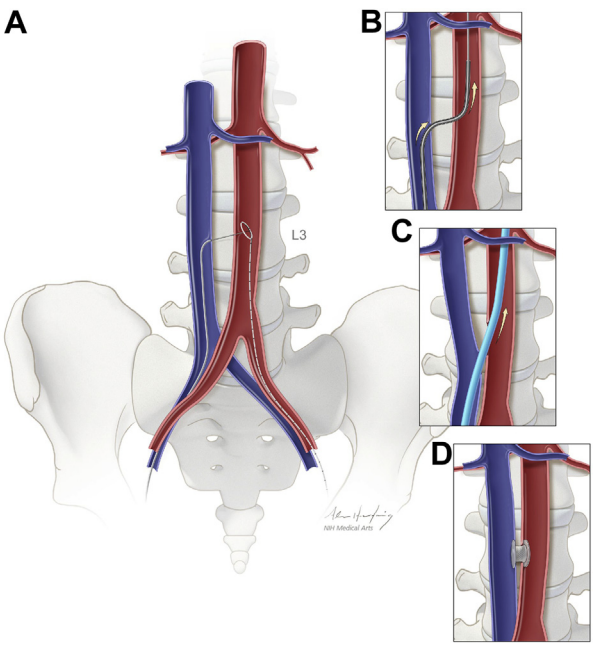

Figure 1 Schematic Depiction of Caval-Aortic Access

(A) A catheter directs a transfemoral vein guidewire from the inferior vena cava towards a snare target positioned in the adjoining abdominal aorta. **(B)** A catheter is advanced over the guidewire into the aorta and used to introduce a more rigid guidewire. **(C)** The valve introducer sheath is advanced from the vena cava into the aorta. **(D)** After completion of transcatheter aortic valve replacement, the aorto-caval access tract is closed with a nitinol occluder.

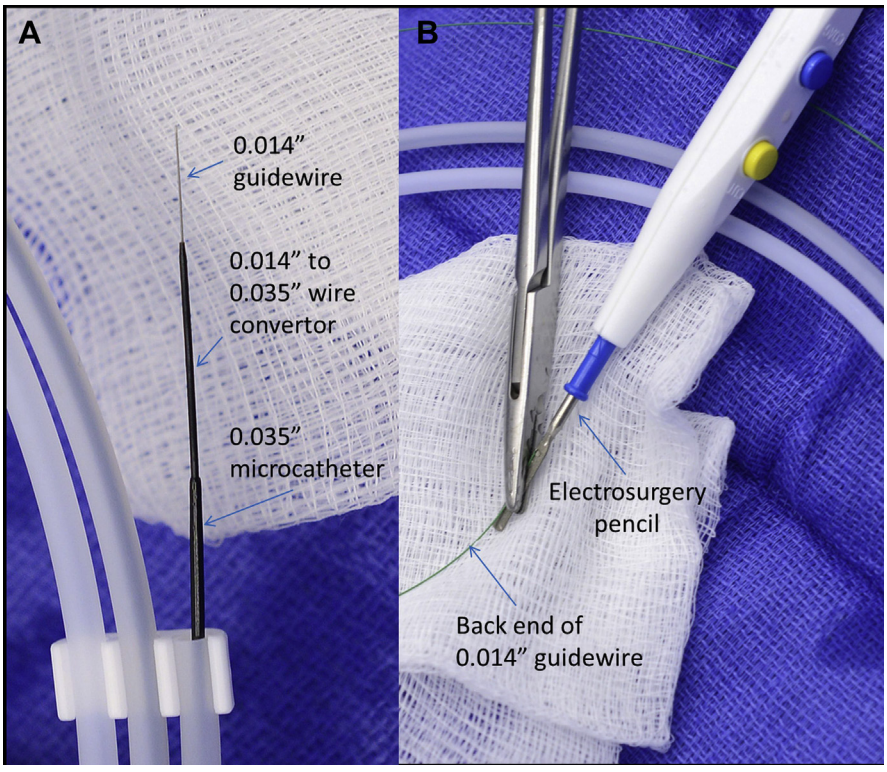

Figure 2 Crossing Apparatus

(A) A 0.014-inch guidewire is mounted coaxially inside a 0.014- to 0.0135-inch wire convertor, inside a 0.035-inch inner-diameter microcatheter. **(B)** The back end of the guidewire is connected to an electrosurgery pencil.

device near or inside the cava. Aortography was performed immediately before and after device release to assure no retroperitoneal accumulation of contrast. The device was recaptured and repositioned if necessary, or replaced after re-advancing the sheath over a previously placed 0.014-inch "buddy" guidewire. All patients received protamine to reverse heparin anticoagulation. The femoral vein access site was closed using 2 prepositioned sutures (Perclose ProGlide, Abbott Vascular).

Patients underwent usual post-TAVR care. The first 8 patients underwent systematic early CT. With further experience, this examination was performed before discharge unless contraindicated, or performed sooner if bleeding was suspected. In-hospital and 30-day outcomes were ascertained during clinical and imaging examinations. Patients with patent caval-aortic tracts at time of discharge were advised to undergo contrast-enhanced CT at 30 days post-procedure.

Analysis. Data are presented as mean ± SD or median (range). Continuous variables were compared using Student's *t*-test. Crossing time was recorded as the interval between the time the caval catheter was first directed at the aorta until the time the introducer sheath was placed in the aorta, usually including aortic root angiography. Closure time was the interval between first advancement of a nitinol occluder device until completion aortography. Major vascular complications and bleeding were classified according to VARC-2 (9), modified to disregard aorto-caval fistulas.

Angiographic appearance of the caval-aortic tract after closure device placement (Fig. 3) was graded as 0: complete hemostasis with occluded aorto-caval fistula; 1: patent aorto-caval fistula without contrast outside the tract; 2: patent aorto-caval fistula with persistent cruciform-pattern contrast outside the aorto-caval fistula; and 3: free extravasation outside the aorto-caval fistula. CT retroperitoneal bleeding after TAVR (Fig. 4) was graded as 0: absent; 1: blood evident without contrast extravasation; 2: blood evident with contrast extravasation; or 3: blood evident with organ displacement or with sentinel clot sign.

Results

Patients. Nineteen patients with symptomatic severe aortic valvular heart disease underwent TAVR using caval-aortic access between July 2013 and January 2014. Baseline demographic characteristics are listed in Table 1. Fifteen patients were women. Table 2 enumerates contraindications to conventional TAVR. Two patients had previous aortic root

procedures, including 1 with a stentless bioprosthetic valve. One had aborted surgical AVR for porcelain aorta, and another patient had aborted transapical TAVR due to friable myocardium. Two had unsuccessful previous attempts to deliver femoral artery introducer sheaths for TAVR. Standard arterial access was not possible because of peripheral artery disease (37%) or inadequate iliofemoral artery caliber for the planned valve. The larger ("best") iliofemoral artery minimal diameter was 5.7 ± 1.0 mm.

Procedural outcomes. A representative procedure is shown in Figure 5 and Online Video 1. Caval-aortic access was successful in all 19 patients. It required 1.4 ± 0.8 puncture attempts and a mean of 20 min (range 10 to 75 min) to perform. Crossings were midway (0.5 ± 0.2) between the right renal artery and the aortic bifurcation, typically over the third lumbar vertebral body (±0.5 vertebrae). At this position, the caval-aortic interluminal distance was 6 ± 3 mm (range 3 to 12 mm), and the caval and aortic diameters were 21 ± 3 mm and 16 ± 4 mm, respectively. There were no hemodynamic changes during puncture or sheath placement, and the sheath was confirmed hemostatic by immediate abdominal aortography in all patients.

TAVR was successful in 17 patients. One (Patient #6) required an emergency procedure to retrieve an embolized transcatheter valve into the left ventricle after low deployment in an annulus that was too large. Another (Patient #12) had valve embolization into the aorta due to failure of rapid pacing during deployment.

All patients underwent successful closure device implantation into the caval-aortic tract, including the 1 who underwent an emergency procedure (Table 2). Closure required 11 min (range 3 to 37 min) and 1.3 ± 0.7 device deployment attempts. In 5 cases, the device was recaptured and replaced because of initial malposition or contrast extravasation before final positioning. Five patients (26%) developed transient hypotension during tract closure, including 3 patients who required device repositioning; 2 other patients who required repositioning did not have hypotension. There were 2 other patients who experienced hypotension during otherwise uncomplicated closure device placement.

At the conclusion of the procedure, there was residual aorto-caval flow through the device tract in all patients (Table 2, Fig. 3). In 12 (63%) patients, there was persistent extra-aortic contrast during completion of aortography (cruciform appearance, n = 11; frank extravasation, n = 1). The device was repositioned in 5 of these patients. Only 4 of these 12 patients had hypotension.

In-hospital and 30-day outcomes. There was 1 TAVR-related death during attempted surgical retrieval of an embolized transcatheter valve (Table 3). All 18 survivors were either extubated immediately after TAVR (n = 15) or on the following morning (n = 3).

Vascular complications requiring intervention. Six patients experienced modified VARC-2 major vascular complications, including 2 who were treated with

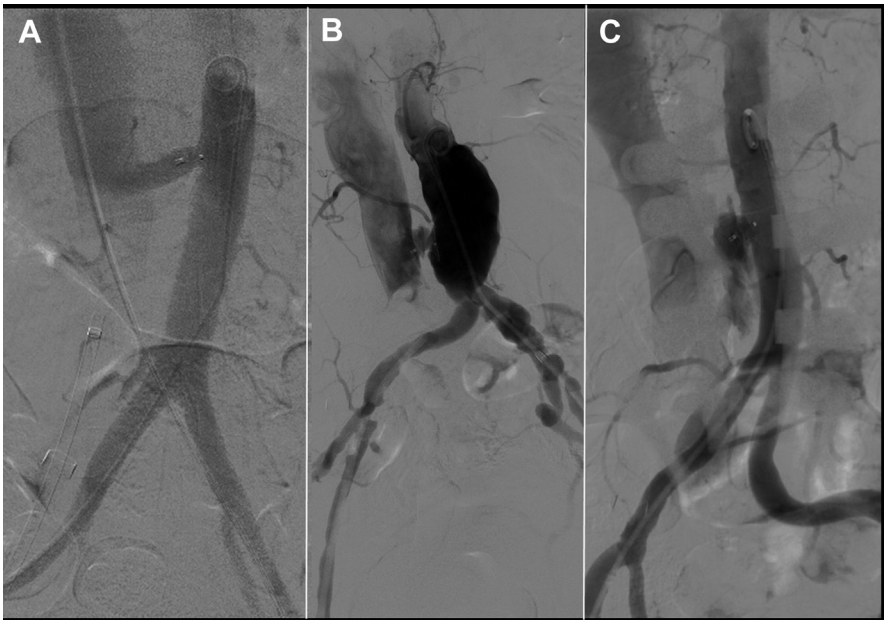

Figure 3 Typical Angiographic Patterns After Caval-Aortic Transcatheter Aortic Valve Replacement

(A) Patent aorto-caval fistula despite closure device (Patient #16). **(B)** Patent aorto-caval fistula with persistent "cruciform" extra-aortic contrast (Patient #13). **(C)** Contrast extravasation (Patient #14).

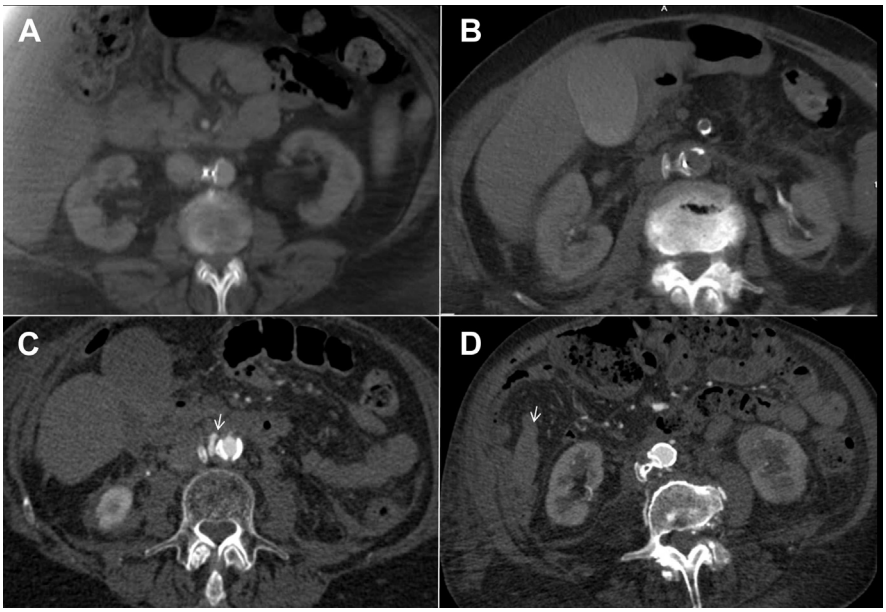

Figure 4 Typical Computed Tomographic Patterns After Caval-Aortic Transcatheter Aortic Valve Replacement

(A) No evident bleeding (Patient #16, day 4). **(B)** Mild retroperitoneal blood accumulation without contrast extravasation (Patient #4, day 1). **(C)** Blood present with contrast extravasation (**arrow**, Patient #3, day 1). **(D)** Large retroperitoneal blood accumulation or organ displacement (Patient #9, day 0). In this patient, pararenal hematoma **(arrow)** is evident.

percutaneous aortic stent-grafts. Patient #3 had mild abdominal pain and some peri-aortic blood evident on CT. Although this patients was hemodynamically stable, she underwent transfemoral aortic tube stent-graft placement 1 day after TAVR. Patient 14 had cruciform-pattern, extra-aortic contrast after device repositioning, and had hypotension that required vasopressors. Six hours afterward, she underwent aortic stent-graft treatment and no longer required vasopressors. Patient 9 had a retroperitoneal hematoma and transient hypotension that was managed conservatively. She had hypotension during closure device repositioning, and required 1 U of blood and transient vasopressors after the procedure.

Vascular complications not requiring intervention. Patient 1 had a small retro-aortic pseudoaneurysm detected on CT that resolved on follow-up CT with conservative management. Patients 17 and 18 had focal self-contained aortic dissections in the vicinity of the caval-aortic closure device. The dissections were partially healed 2 months after TAVR, as imaged by CT.

Computed tomographic evaluation. When obtained during hospitalization (n = 16), CT revealed blood in the retroperitoneal space in 9 patients (56%; mean retroperitoneal bleeding score 0.9 ± 0.9), which was graded as mild in 6 patients (Table 2). One patient (Patient #9 as previously described) had significant retroperitoneal bleeding (Fig. 4).

Bleeding and transfusions. The baseline hemoglobin was 10.9 ± 1.4 g/dl. Fifteen (79%) patients received blood transfusions overall (mean total 3 ± 4 U), 5 only during TAVR, 8 only after TAVR, and 2 both during and after TAVR. These included 2 patients who experienced major gastrointestinal hemorrhage, 1 who required cardiac surgery, 2 who required aortic endografts, and 1 (Patient #9) with retroperitoneal hemorrhage who required overnight vasopressors. The most serious bleeding was observed in the 3 patients with elevated international normalized ratios during TAVR, including the 2 patients who required endografts and the patient who required vasopressors (international normalized ratio 2.3 ± 0.3 vs.

Table 1 Baseline Demographics

Age, yrs	80.7 ± 8.3
Female	15 (79)
BSA, m^2	1.79 ± 0.23
Previous cardiac procedure	7 (37)
Peripheral artery disease	7 (37)
eGFR, mL/min/1.73 m^2	50.8 ± 21.8
Baseline hemoglobin, g/dl	10.9 ± 1.4
NYHA functional class III or IV heart failure	16 (84)
Atrial fibrillation	10 (53)
STS predicted mortality	7.8 ± 3.8
Euroscore II	7.9 ± 6.2
Moderate to severe mitral regurgitation	7 (37)
Aortic valve area, cm^2	0.68 ± 0.16

Values are mean ± SD or n (%).

BSA = body surface area; eGFR = estimated glomerular filtration rate; NYHA = New York Heart Association; STS = Society of Thoracic Surgeons.

Table 2 Caval-Aortic Transcatheter Aortic Valve Replacement Details

Patient #/Sex	Reason for Inoperability	Best Ilio-Femoral MLD (mm)	Sheath Size (F)	Crossing Attempts (n)	Crossing Time (min)	Closure Device	Device Repositioned During Closure
1/F	Previous SAVR and root repair; failed previous TA-TAVR; eGFR<30; STS >10	4.8	22	3	75	12/10-mm ADO	—
2/F	Frailty; immunocompromised	5.1	24	1	23	10/8 -mm ADO	—
3/F	Porcelain aorta; failed SAVR; immunocompromised	6.5	22	3	67	8-mm MVSDO	+
4/F	Severe COPD; frailty	6.6	24	3	17	10-mm MVSDO	—
5/F	Pulmonary artery hypertension; failed TF-TAVR	7.4	22	3	17	8-mm MVSDO	—
6/M	Frailty; previous CABG; low EF	4.9	24	2	16	10/8-mm ADO	—
7/F	Frailty; previous CABG	6.7	22	3	75	6-mm MVSDO	—
8/M	Severe COPD	4.5	24	1	28	8/6-mm ADO	—
9/F	Previous aortic root repair; frailty; failed TF-TAVR; STS >10	5.6	22	2	34	8-mm MVSDO	+
10/F	COPD; porcelain aorta	5.0	22	1	14	6-mm MVSDO	—
11/M	Low EF, previous CABG; eGFR<30; STS >10	6.0	24	1	14	8-mm MVSDO	+
12/M	Frailty, previous CABG	6.1	24	1	10	8-mm MVSDO	—
13/F	Age >90 yrs; frailty; porcelain aorta; STS >10	4.0	22	1	24	6-mm MVSDO	—
14/F	Low EF; previous CABG; STS >10	7.6	24	1	14	8-mm MVSDO	+
15/F	Age >90; frailty; COPD; STS >10	5.6	22	1	20	6-mm MVSDO	—
16/F	COPD, morbid obesity	5.3	24	1	34	10/8-mm ADO	+
17/F	Immunocompromised, porcelain aorta, religious beliefs	5.0	22	1	30	6-mm MVSDO	—
18/F	Frailty, severe COPD	5.0	24	1	15	8-mm MVSDO	—
19/F	Age, frailty, previous radiation/ lymph node dissection	6.5	24	1	10	8-mm MVSDO	—

Continued on the next page

1.4 ± 0.3 without bleeding; p = 0.0002). Overall, these incidents were classified as VARC-2 life-threatening bleeding (16%), major bleeding (32%), minor bleeding (47%), and no bleeding (5%).

No patient had ischemic or embolic complications related to caval-aortic access. One had deep vein thrombosis of the femoral vein used for caval-aortic access, which was treated with anticoagulation. The patient with valve embolization into the aorta experienced an ischemic stroke. Two patients developed contrast-induced nephropathy that required temporary hemodialysis. Nine (50%) patients exhibited mild transient thrombocytopenia (50 to 100,000 cells/μl). One patient experienced profound asymptomatic thrombocytopenia (<50,000 cells/μl), not attributable to heparin, which resolved after 6 weeks.

Mean length of stay after TAVR was 8 ± 8 days (range 2 to 37 days).

Follow-up through 111 ± 57 days (range 36 to 229 days) in the 18 survivors revealed no post-discharge, access-related adverse events. One patient was readmitted for chest pain and another was readmitted for diastolic heart failure. Of the 16 patients who underwent repeat imaging (CT, n = 14; angiography, n = 2) after the first week, 15 (94%) exhibited complete closure of the caval-aortic tract (83% overall closure rate) by 42 ± 50 days (range 7 to 189 days) after TAVR. Follow-up imaging was not performed on 2 patients due to renal insufficiency.

Discussion

We described a novel technique enabling TAVR using 8- to 9-mm outer diameter sheaths in patients who were ineligible to undergo the normal procedure for TAVR. Introducer sheaths were delivered to the aorta via a tract from the IVC created by radiofrequency perforation with subsequent closure using commercial nitinol occluder devices.

Caval-aortic access and tract closure were successful in all 19 patients. One fatality was unrelated to caval-aortic access. All patients tolerated the technique, but most received blood transfusion. Most had a residual aorto-caval shunt upon discharge, which was not hemodynamically significant, and which was occluded in 15 of 18 survivors by 42 days (range 7 to 189 days).

These patients were very ill and were judged to be at extreme risk, often out of proportion to the Society of Thoracic Surgeons predicted mortality score of 7.8 ± 3.8%, as evidenced by the reasons they were ineligible for surgical AVR (Table 2). TAVR in this early series was successful in

Table 2 Continued

Closure Time (min)	Hypotension During Tract Closure	Angiographic Pattern After Closure	Transfusion During TAVR	CT RPH Score	In-Hospital Complication	Length of Stay (days)	Tract Patency	30-Day MACE
17	—	1	—	1	T, V	15	O, day 44	None
11	—	1	+	0	—	9	P, day 36	R
48	+	2	+	2	T, V	11	O, day 7	None
22	—	2	—	1	—	6	O, day 189	None
7	—	1	—	1	T	8	O, day 42	R
13	+	1	+	—	Death	NA	NA	NA
7	—	1	—	0	T	4	O, day 36	None
8	—	1	—	1	—	2	O, day 86	None
37	+	2	+	1	T, V	15	O, day 15	None
8		2	+	0	MI	8	O, day 8	None
21	—	2	—	—	—	8	P, day 1	None
18	+	2	+	2	S, CIN	34	P, day 1	None
3	—	2	—	0	T	8	O, day 120	None
15	+	3	—	1	T, V	13	O, day 7	None
3	—	2	+	—	—	2	O, day 9	None
12	—	1	—	0	T	5	O, day 56	None
7	—	2	—	0	V	8	O, day 54	None
11	—	2	—	1	T, V, GIB	14	O, day 57	None
4	—	2	—	1	T, GIB, CIN	12	O, day 36	None

Values are n.

ADO = Amplatzer duct occluder; CABG = coronary artery bypass grafting; CIN = contrast-induced nephropathy requiring hemodialysis; COPD = chronic obstructive pulmonary disease; EF = ejection fraction; GIB = gastrointestinal bleed; MI = myocardial infarction; MLD = minimal luminal diameter; MVSDO = Amplatzer muscular ventricular septal defect occluder; O = occluded; P = patent; Pt = patient; R = readmission; RPH = retroperitoneal hemorrhage; S = stroke; SAVR = surgical aortic valve replacement; STS = Society of Thoracic Surgeons predicted mortality score; T = transfusion; TA-TAVR = transapical TAVR; TF = transfemoral; V = vascular complication; other abbreviations as in Table 1.

17 of 19 patients (89%), compared with 92% in the post-market Society of Thoracic Surgeons/American College of Cardiology transcatheter valve therapy registry (10). Vascular complications were common in this early experience, with patients having no attractive options. All had heavily calcified and atherosclerotic aortas; 3 had caval-aortic access into abdominal aortic aneurysm. Of the 19 patients, 6 (31%) had vascular complications classified as VARC-2 major: 3 had retroperitoneal bleeding, 1 had a small aortic pseudoaneurysm, and 2 had focal aortic dissections. Two patients with bleeding were managed with stent-grafts, and the others were managed conservatively (Fig. 6). From our perspective, endograft therapy and blood transfusion were the significant complications.

One-quarter of patients in this series had transient hypotension during the procedure, which responded to crystalloid or vasopressors. One of these patients had low baseline filling pressures, and the others presumably had bleeding during (re)positioning of the closure device. Early in the experience, we obtained immediate post-procedure CT systematically; later, we obtained immediate CT only if we suspected active bleeding. Patient 3 underwent aortic stent grafting although she was hemodynamically stable, because she had mild abdominal pain and CT evidence of more-than-mild retroperitoneal blood. In retrospect, we believe we should have managed this patient conservatively. However, 2 patients had significant retroperitoneal bleeding, which manifested as persistent hypotension that required clinical intervention. One of these 2 patients required low-dose vasopressors for <12 h, and the other required endograft therapy to achieve hemodynamic stability.

Retroperitoneal hematoma was expected and common because our technique used permeable closure devices and pressurization of the retroperitoneal space with subsequent venous outflow. Unlike other patients with spontaneous, traumatic, or iatrogenic retroperitoneal arterial hemorrhage, none of our patients developed abdominal compartment syndrome or required surgical evacuation. In our series, baseline hemoglobin was low, and substantial hemoglobin decline and transfusion were common. Blood loss was attributed to major gastrointestinal hemorrhage in 2 patients. We note that in this early experience, patients were volume-expanded and transfused aggressively because of caution. Overall, we consider these complications acceptable in light of

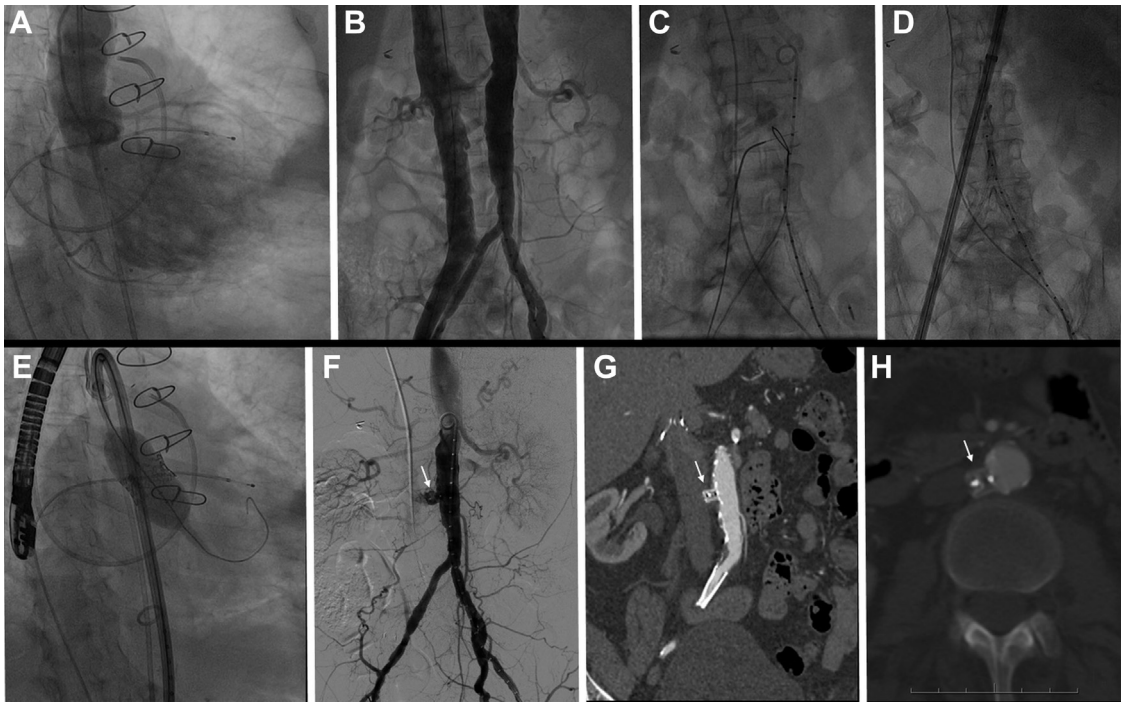

Figure 5 **Planning and Technique of Caval-Aortic Access**

Caval-aortic access for transcatheter aortic valve replacement (TAVR) in Patient 1. **(A)** Aortography shows severe regurgitation of a bioprosthetic aortic valve causing left ventricular dilation and intractable heart failure. **(B)** Simultaneous caval and aortic angiograms. **(C)** A guidewire is directed from the cava and energized to cross into a pre-positioned aortic snare. **(D)** An 8.2-mm diameter sheath is advanced along this guidewire tract from the femoral vein and cava into the aorta. **(E)** TAVR is performed using a 23-mm balloon-expandable valve. **(F)** The caval-aortic tract is closed with a nitinol duct occluder **(arrow)**. Completion aortography shows mild residual aorto-caval shunt across the access tract but no contrast extravasation. **(G, H)** A contrast-enhanced CT performed 42 days later shows complete occlusion of the tract (Online Video 1).

the paucity of therapeutic options available to these patients. We expect bleeding risk to be reduced by purpose-built crossing and closure devices.

The rationale for caval-aortic access is that iliofemoral veins are larger and more compliant than corresponding arteries, the IVC is close to the abdominal aorta usually without interposed structures, and traumatic or aneurysmal aorto-caval fistulas do not necessarily cause immediate hemodynamic compromise (8). We speculate that a patent caval fenestration allows immediate decompression of aortic hemorrhage because of the relatively higher pressure of the retroperitoneal interstitial space. The retroperitoneum behaves as a relatively confined space that retains insufflation gas or saline during laparoscopic procedure, which is pressurized at 5 to 13 mm Hg after 1 liter of fluid infusion in cadavers (11,12). In animals, intentional failure to close the aorto-caval fistula was well tolerated, and free of retroperitoneal bleeding (8). Consistent with these considerations, our first patient became hypotensive when we inadvertently withdrew the sheath tip just outside the aorta, yet still occluded the cava. The pressure returned to normal immediately after we withdrew the sheath farther to allow blood to re-enter the IVC. Five other patients tolerated 5- to 7-min intervals between removal and replacement of the closure device when there was an unconstrained aorto-caval fistula, which is in sharp contrast to the immediate hemodynamic collapse typically seen shortly after iliac artery perforation.

We found the overall procedural time related to caval aortic access and repair to be similar to that typically required for standard femoral artery access for TAVR, including preplacement of vascular sutures, crossover protection, and balloon inflation during vascular hemostasis. In addition, there appeared to be a "learning curve" of fewer puncture attempts and shorter crossing and closing times as we accrued experience (Table 2).

One patient had non-antibody mediated, severe asymptomatic thrombocytopenia (nadir platelet count of 24,000 cells/μl) that resolved at approximately the same time the caval-aortic tract was found to be closed, and 8 others experienced >50% decreases in platelet counts without evidence of other hemolysis. Isolated and profound platelet consumption have been described after device closure of ductus arteriosus; these were attributed to mechanical platelet injury. The thrombocytopenia seen in this series may reflect platelet consumption from bleeding or from residual aorto-caval shunting (13,14).

Table 3 In-Hospital and 30-Day Outcomes

Outcome (n = 19)	In-Hospital	30-Day	Narrative
Death (from any cause)	1	0	During surgery for embolized transcatheter valve
Death (access-related)	0	0	
Vascular complication: arterial	6	0	Three had large retroperitoneal hematomas, 1 had small aortic pseudoaneurysm, and 2 had focal aortic dissection
Requiring intervention	2	0	Two endografts; 1 for retroperitoneal bleeding 24 h post-procedure; 1 for retroperitoneal bleeding with hypotension 6 h post-procedure
Vascular complication: venous	1	0	One deep vein thrombosis at the access site, treated with anticoagulation
Requiring intervention	0	0	
Stroke	1	0	
New-onset claudication	0	0	
New-onset CHF	0	0	
New-onset GI symptoms	1	0	Nausea

Values are n.
CHF = congestive heart failure; GI = gastrointestinal.

Fifteen of the 19 patients who underwent transcaval TAVR in this report were women. This likely reflects the smaller diameter of iliofemoral vessels in women. Twelve (63%) would have had an insufficient iliofemoral artery caliber (≤6.0 mm) to allow TAVR using second-generation 16-F to 20-F devices, and 9 (47%) still would have had an insufficient vessel size (≤5.5 mm) currently required for third-generation 14-F compatible devices, which are both currently under investigation in the United States. Our technique may also enable nonsurgical delivery of other large devices, including thoracic aortic endografts, percutaneous left ventricular assist devices, and future larger valves for aortic insufficiency.

Study limitations. Limitations to the generalizability of our report included the small numbers of patients treated at a single center and the short-term follow-up. However, we expect that purpose-built access and closure devices should outperform the commercial devices we used off-label in this experience.

Conclusions

We have demonstrated feasibility of venous access to the aorta to allow TAVR in otherwise ineligible patients. This technique challenges conventional wisdom about intentionally violating the wall of the aorta. Caval-aortic access

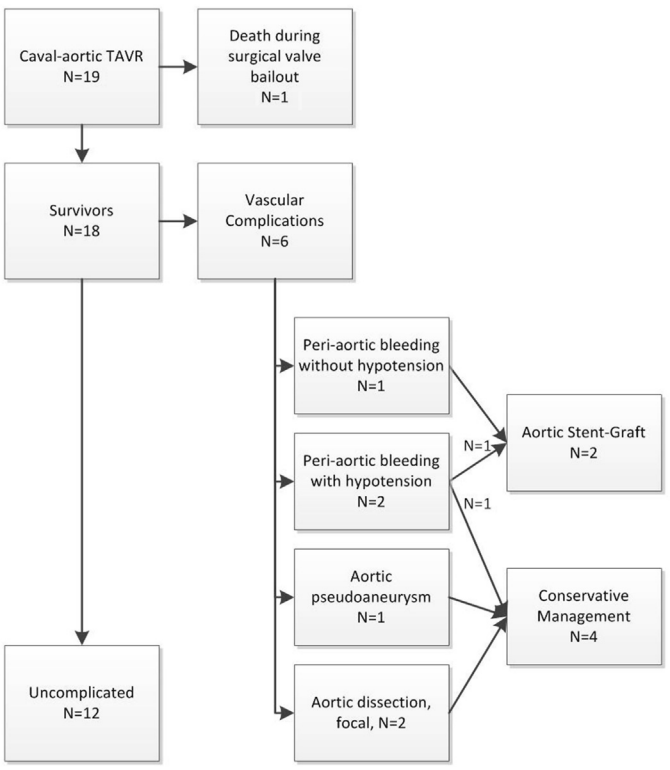

Figure 6 Outcomes of Caval-Aortic Access

Death and major vascular complications are depicted. Abbreviation as Figure 5.

may prove useful for TAVR and other large-caliber device therapy even as future TAVR delivery devices diminish in size. Further clinical testing is warranted.

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Key Words: caval-aortic ■ extra-anatomic procedures ■ transcatheter aortic valve replacement ■ transcaval.

APPENDIX

For an accompanying video, please see the online version of this article.