

Transcaval Access and Closure

A promising new route for TAVR and other procedures.

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When transfemoral access is not available for transcatheter aortic valve replacement (TAVR), the risk of immediate and late complications is increased.¹ Patients may have worse underlying comorbidities, but surgical transapical and transaortic access may also contribute to morbidity. A fully percutaneous strategy would be attractive in patients whose iliofemoral arteries are too small or too diseased for conventional transarterial access.

Transcaval access is a new approach to introduce large devices into the abdominal aorta.^{2,3} From the femoral vein, an electrified guidewire is directed from the inferior vena cava into a snare prepositioned into the adjoining abdominal aorta. After guidewire exchange, the standard introducer sheath is then advanced from the femoral vein into the abdominal aorta, allowing retrograde TAVR to be performed as usual. Afterward, a permeable nitinol cardiac occluder device is implanted (“off-label”) in the caval-aortic tract. Transcaval TAVR has been performed in more than 134 patients so far.

Surgically exposed aortic and caval rents are thought to be catastrophic. However, when the retroperitoneal space surrounding the aorta and cava is not surgically exposed, it appears to pressurize from aortocaval fistula. As soon as the retroperitoneal pressure exceeds venous pressure, aortic bleeding decompresses into the venous space. Recognizing this physiology led to our clinical development of the transcaval technique.

HOW TO PERFORM TRANSCAVAL ACCESS

Transcaval access is straightforward and teachable.⁴ However, readers are cautioned not to undertake this procedure without training and proctorship from experienced operators, careful planning from baseline CT, and a complete inventory of essential equipment on hand. Transcaval TAVR is the topic of an National Heart, Lung, and Blood Institute (NHLBI)–sponsored, multicenter investigational device exemption (IDE) trial (NCT02280824) of patients believed to have no good alternative access options, as determined by local multidisciplinary heart teams.

Recommendation (Transcaval eligibility)	Favorable-Feasible based on caval-aortic distance 11mm, proximity to bifurcation
Target entry site lumbar vertebra	Lower edge L3 body (L 3,4)
Orthogonal projection	RAO 10°
Caval-aortic lumen distance X-Y	11 mm
Interposed / nearby structures	None / Bowel anterior
Caval lumen diameter	25 mm
Aortic lumen diameter (+3/0/-1cm)	12 mm / 11 mm / 10 mm
Target distance above aorto-iliac bifurcation	10 mm
Target distance below R renal artery	73 mm
Endograft bailout limb access	RCIA 4.4 mm / LEIA 4.2 mm
CFV to target centerline distance	23 cm
Caveat & Comments	Low target. Interposed bowel and diverging aorta at higher locations.

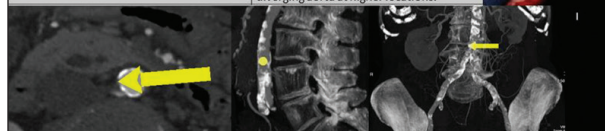


Figure 1. A representative transcaval treatment plan based on a contrast-enhanced CT.

Plan on CT

Contrast-enhanced CT is used to plan key aspects of the procedure.⁵ First, a target is selected. The target must have a calcium-free window on the right wall of the abdominal aorta, close to the vena cava, free of interposed structures such as bowel or lymph nodes, and away from branches that could be obstructed by a closure device, such as right renal arteries and left renal veins or the aortic bifurcation. The lumbar spine level of the intended target is recorded so that the operator can correspond (“register”) the CT findings with live fluoroscopy during the procedure. Other geometric parameters are posted, including the distance between the cava and the aorta (to select the closure device), the angle between the centers of the cava and aorta on the axial slice (to select the working and orthogonal projection angles during caval-aortic crossing), the diameter of the cava and aorta (to select the guiding catheters and snare), and the intravascular distance between the groin and aorta (to ensure that the intended vascular introducer sheath has sufficient working length for safe purchase inside the aorta). Finally, the images are used to plan a bailout covered stent and delivery route in case of closure device failure. A table of the findings and repre-

Courtesy of Marcus Y. Chen, NHLBI.

sentative images are posted inside the procedure suite during TAVR (Figure 1).

Vascular Access and Arteriography

Standard vascular access for transcaval TAVR begins with a small sheath in the right femoral vein, which we prefer to “preclose.” Separate venous access is obtained for temporary transvenous pacemaker placement, which we prefer to place after transcaval access. The “better” femoral artery is accessed for pig-tail angiography, for snare placement, and in case bailout covered stent placement is required. Simultaneous, low-volume, abdominal aortography and cavagraphy are performed at the CT-selected projection angle, and the intended crossing target, including calcium “signature,” is visually registered with the baseline CT. Unfractionated heparin is administered before crossing.

Crossing

The next step is to assemble a coaxial crossing system. A 0.014-inch X 300-cm coronary chronic total occlusion (CTO) guidewire (Confianza Pro 12, Asahi Intecc Co LTD) is loaded inside a lockable polymer jacket (Piggyback Wire Convertor [145 cm], Vascular Solutions), which is loaded into a braided 0.035-inch X 90-cm microcatheter (such as Navicross, Terumo Interventional Systems) to ensure a smooth transition. The distal 10 mm of the guidewire is amputated, and the back end of the guidewire is clamped to an electrosurgery pencil set to pure “cut” mode at 50 W, taking care to ensure no short circuits are created by wet towels or wire loops.

A single-loop snare (Amplatz GooseNeck, Medtronic plc), 5 mm larger than the aortic lumen diameter, is directed through a 6-F JR4 guiding catheter and hemostatic valve to appose the right wall of the aorta at the intended crossing target.

The coaxial crossing system is directed at the target through a 7-F X 55-cm renal guiding catheter in the cava. The preplanned orthogonal projection ensures that the crossing system is precisely aimed at the snare “bull’s-eye” (Figure 2). Once proper aim is confirmed, the guidewire is electrified and advanced into the aorta. Snaring confirms the intra-aortic position, and the guidewire and snare

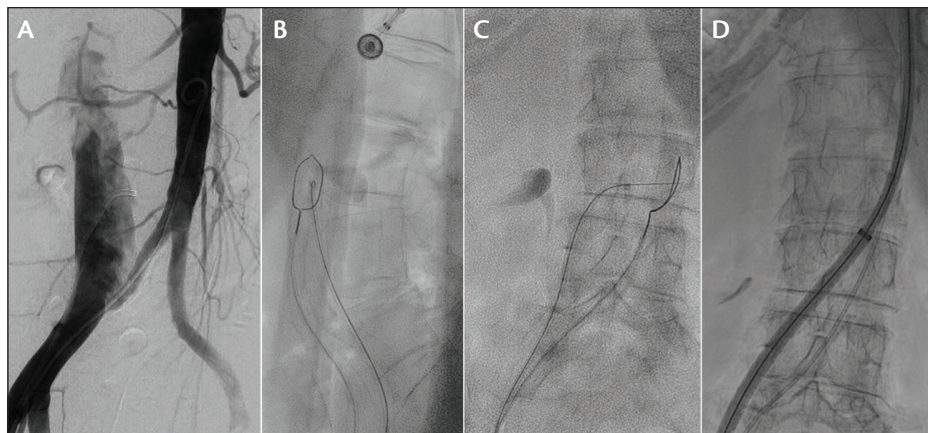


Figure 2. Transcaval crossing. Baseline caval and aortography (A). Orthogonal alignment of crossing system with “bull’s-eye” of snare in aorta (B). Electrified guidewire crosses into aortic snare (C). After exchanging for a rigid 0.035-inch guidewire, the TAVR introducer sheath is advanced from the femoral vein into the aorta (D).

are then advanced to the aortic arch, and gentle traction is applied. The 0.035-inch wire convertor and then the braided microcatheter are sequentially advanced into the thoracic aorta across the caval-aortic tract. A rigid 0.035-inch guidewire (Lunderquist, Cook Medical) is exchanged through the microcatheter into the aortic arch. Finally, the TAVR introducer sheath is advanced from the femoral vein across the caval tract into the aorta in a single step without predilatation. So far, the sheath has always been hemostatic across the aortic wall, even the expandable eSheath (Edwards Lifesciences), which may recoil slightly. TAVR is then performed as usual.

Closure

After TAVR, protamine is administered fully to reverse heparin anticoagulation. The caval-aortic access tract is closed using (off-label) one of two marketed permeable nitinol cardiac occluder devices selected according to Table 1. When the cava and aorta are close to each other, a double-disc device is employed; otherwise, a single-disc device is used. Surprisingly, it does not seem to matter when the device does not reach all the way from the aorta to the venous side.

A 0.014-inch soft buddy wire is placed through the TAVR sheath in case of inadvertent pull-through, and a 5-F MP catheter, a 0.035-inch Lunderquist guidewire, and appropriate sheath and dilator are kept nearby to rapidly recross if necessary.

The selected nitinol occluder is positioned above the crossing site inside a deflectable 8.5-F sheath (Agilis NXT SML Curl, St. Jude Medical), and a pigtail catheter is positioned in the nearby aorta through the separate access site for angiography. First, the aortic disc is exposed. The TAVR

TABLE 1. HOW TO SELECT A CLOSURE DEVICE

Distance Between Aorta and Caval Lumens	THV Sheath Outer Diameter > 7 mm Fully Expanded (> 18 F inner diameter)	THV Sheath Outer Diameter ≤ 7 mm Fully Expanded (18 F inner diameter)
≤ 7 mm	8-mm Amplatzer Muscular VSD Occluder*	6-mm Amplatzer Muscular VSD Occluder*
> 7 mm	10/8 Amplatzer Duct Occluder* Generation 1	8/6 Amplatzer Duct Occluder* Generation 1

Abbreviations: THV, transcatheter heart valve; VSD, ventricular septal defect.
*St. Jude Medical.

sheath is then withdrawn briskly into the cava. At this point, there is aortocaval flow and often a decline in blood pressure that usually stabilizes quickly. The Agilis sheath is then deflected while the aortic disc, in a push-pull maneuver, is oriented horizontally within the aortic lumen. The assembly is then withdrawn to appose the aortic disc against the right wall of the aorta, and the Agilis sheath is withdrawn as it is straightened to implant the neck of the device across the aortic wall and, if a ventricular septal defect occluder is used, to position the other disc inside the cava. The nitinol device delivery cable is then pushed forward to form the caval side of the device.

At this point, a small-volume, hand injection through the pigtail, usually with digital subtraction and suspended respiration, demonstrates the aortocaval fistula and any persistent extravasation. Assuming the aortic disc is in the intended position, the closure device is rarely removed, replaced, or repositioned, and at this point, we generally advise detaching the delivery cable, withdrawing the 0.014-inch buddy guidewire and closing the venous access site to allow time to elapse (Figure 3).

Managing Hypotension

Persistent hypotension immediately after transcaval closure, seen in approximately 10% to 15% of cases, likely has one of three causes: (1) if the cause is extravasation, it is clearly evident on aortography; (2) rarely, the patient does not tolerate the acute left-to-right shunt because of severe underlying cardiomyopathy or pulmonary hypertension, which is evident on echocardiography as acute right ventricular failure; and (3) conventional TAVR complications, such as pacemaker perforation, may be responsible, which also are evident on echocardiography.

Hypotension caused by extravasation or acute shunt is remedied by immediate aortic balloon tamponade using a compliant balloon (Reliant, Medtronic plc; Coda, Cook Medical; Tyshak, B. Braun Interventional Systems; etc), accompanied by volume infusion. One or two 5-minute inflations achieve tract occlusion and hemostasis in approximately half of the cases. Should this fail, a self-expanding

covered stent (such as the AFX iliac limb extender or aortic limb extender, Endologix Inc.), selected during the planning stage, also achieves immediate hemodynamic stability, and has been used in approximately 5% to 10% of cases.

At conclusion of the procedure, only a few aortocaval tracts are completely occluded. Occlusion appears more common with smaller introducer sheaths. Approximately 80% have patent aortocaval fistulas, usually with a “cruiform” pattern of blood swirling around the neck of the device before returning the vena cava. Most fistulas are clini-

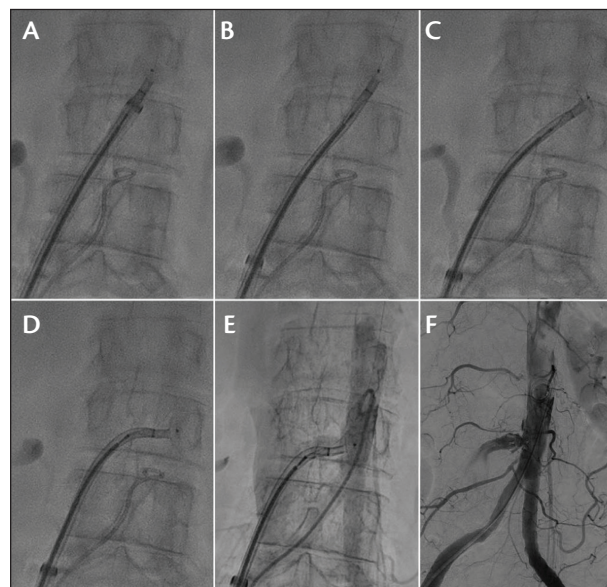


Figure 3. Closing the transcaval access port with a duct occluder in the same patient as Figures 1 and 2. The aortic disc is exposed through a deflectable sheath (A). The TAVR sheath is briskly withdrawn from the aorta to the cava (B). Note the buddy guidewire alongside the closure device. Using push-pull maneuvers, the deflectable sheath is used to turn the closure device sideways (C, D) until it is apposed to the right wall of the aorta (E). After release of the cable, the final closure result is shown, with residual aortocaval fistula and minor aortic dissection but no retroperitoneal contrast accumulation (F).

cally insignificant, and most spontaneously occlude over the following days or weeks in our experience.

Postprocedure and Postdischarge Care

After the procedure, low-grade retroperitoneal bleeding can be managed conservatively overnight, usually without blood transfusion, by using intravenous fluids and even low-dose vasopressor infusion. Vigorous hydration may prevent contrast nephropathy.

Because this is a new procedure, we recommend careful surveillance after transcaval TAVR, analogous to surveillance after endovascular aortic aneurysm repair, including predischarge, 30-day, and 12-month contrast-enhanced, arterial-phase CT scans. Antiplatelet and anticoagulation therapy are used as otherwise indicated.

INITIAL RESULTS

Initial results with this new procedure have been encouraging. We are not aware of any patients who died or required surgical aortic rescue as a direct consequence of transcaval access. In the first human experience, which included 19 patients at Henry Ford Hospital, transcaval access and closure success was 100%, 79% received blood transfusions, 11% underwent covered stent placement, the length of stay was 8 ± 8 days, and the fistula was closed in 94% of the 15 patients who underwent follow-up imaging after the first week.

Results have improved as we refined the technique, including complete protamine reversal before undertaking tract closure. In recent transcaval experience, blood transfusions have decreased to less than 20%, endograft rates to 5%, and length of stay to 5 ± 6 days.⁶

In a preliminary, single-center comparison of outcomes after transcaval versus transapical TAVR at Henry Ford Hospital, transcaval access was associated with a lower rate of 30-day mortality and a higher rate of blood transfusion and contrast nephropathy.⁷ These patients were considered poor candidates for transapical access, but survival after 1 year was comparable.

The transcaval technique has been applied successfully in a wide range of settings, including a target within a Dacron aortic graft,⁸ heparin-induced thrombocytopenia, aortic aneurysm with and without lamellated thrombus, valve-in-valve TAVR, uremia, cirrhosis, severe tricuspid regurgitation with elevated right atrial pressures, and religious objection to blood transfusion.

THE FUTURE OF TRANCAVAL ACCESS

We have been performing this procedure since July 2013, so the long-term outcomes after transcaval TAVR are not known. To date, we have no evidence of late adverse events, failure, or erosion related to transcaval closure devices, but

we hope to know more when the IDE trial is completed.

With the commercial introduction of TAVR devices suitable for delivery through femoral arteries as small as 5 mm, we expect the need for transcaval TAVR to decline by as much as 50%. Nevertheless, this important alternate access niche is likely to remain. To that end, we are working to develop an impermeable, purpose-built, transcaval closure device to achieve immediate and universal hemostasis.

Transcaval access may be helpful for other interventional applications. For example, large and complex thoracic aortic endografts may better be delivered via a transcaval route than other options in specific cases. Transcaval access has been employed for temporary percutaneous left ventricular assist device (Impella, Abiomed) support after TAVR⁹ and might have value to allow more protracted support using larger devices without surgical access.

Transcaval access and closure may prove a viable alternative access option for patients who otherwise have “no good access options,” pending results of the IDE trial. With further technical and device refinement, transcaval access and closure may become a suitable alternative to transapical and transaortic access. ■

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