Transcaval transcatheter aortic valve replacement: a visual case review

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Abstract: Transcatheter aortic valve replacement (TAVR) has emerged as a viable, minimally-invasive and widely adopted approach for the treatment of severe symptomatic aortic stenosis in patients who are intermediate-risk or greater for surgical aortic valve replacement. Numerous studies have demonstrated favorable outcomes with TAVR in this population, particularly with transfemoral access TAVR. Transfemoral TAVR has been shown to be safer and associated less morbidity, shorter lengths of hospital stay and more rapid recovery as compared with traditional thoracic alternative-access TAVR (transapical or transaortic). Despite iterative advancements in transcatheter heart valve technology and delivery system, there remain a portion of patients with iliofemoral arterial vessel sizes that are too small for safe transfemoral TAVR. Paradoxically, these patients are generally higher risk and are thus less favorable candidates for open surgery or traditional alternative-access TAVR. With these considerations in mind, transcaval TAVR was developed as a fully percutaneous, non-surgical approach for aortic valve replacement in patients who are poor candidates for traditional alternative-access TAVR. In this manuscript we describe the principles on which transcaval TAVR was developed, the outcomes from the largest trial completed evaluating this technique as well as describing the technique used to perform this procedure in a case-based format.

Keywords: Transcatheter aortic valve replacement (TAVR); alternative access; transcaval

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Introduction (*Figure 1*)

Transcatheter aortic valve replacement (TAVR) has been developed as a minimally invasive approach to aortic valve replacement in patients who are intermediate or high risk with severe symptomatic aortic stenosis as an alternative to surgical aortic valve replacement. TAVR is an established procedure; over 250,000 procedures have been performed in over 65 countries across the world to date and more than 100,000 procedures have been performed in the US over the past 5 years (2).

The majority of TAVR cases (>80%) can be performed from a percutaneous transfemoral approach (3). However, transfemoral access is not an option in all patients due to diseased or small femoral and pelvic arteries making it unsafe to pass the TAVR delivery sheath without high risk of

Figure 1 Introduction to procedure and heart team (1). Available online: http://www.asvide.com/article/view/24742

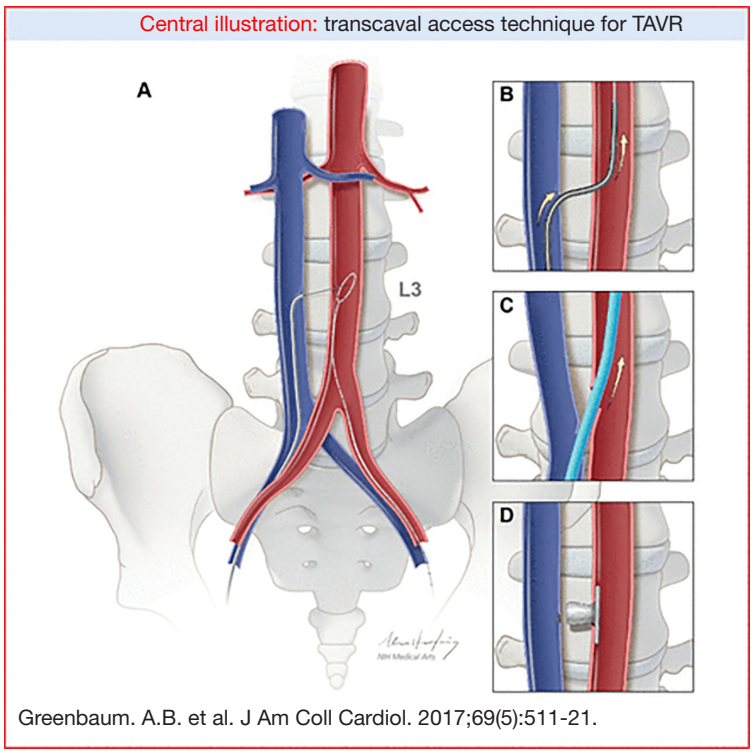

Figure 2 Illustrative transcaval access technique for TAVR. (A) Transcaval access is obtained over an electrified guidewire directed from the inferior vena cava toward a snare in the abdominal aorta; (B) after delivering a microcatheter to exchange for a stiff guidewire; (C) the transcatheter heart valve introducer sheath is advanced from the femoral vein into the abdominal aorta for conventional transfemoral retrograde transcatheter aortic valve replacement (TAVR); (D) the aorto-caval access site is closed with a nitinol cardiac occluder.

injury. This has led to the development of alternative access approaches for delivery of the transcatheter heart valve. Despite the development of a number of alternative access approaches for TAVR, the majority of these approaches are more invasive than transfemoral TAVR and many of them require transthoracic access (transapical/transaortic) which is inferior compared to femoral access (4). This increases the risk for patients compared to transfemoral TAVR which requires no surgery and no instrumentation of the chest cavity. Given the generally high-risk nature of the patients being treated with a non-femoral approach, there has been a great deal of interest in developing an alternative percutaneous non-surgical approach for TAVR. Transcaval TAVR has been developed with these considerations and goals in mind.

Patient selection and workup

Transcaval access TAVR was developed for patients who are not candidates for traditional transfemoral TAVR due to small pelvic arteries and in whom traditional surgical alternative access was felt to be high-risk. Transcaval access TAVR is a fully percutaneous transfemoral technique that accesses the abdominal aorta through the adjacent inferior vena cava (IVC) which allows for delivery of the transcatheter heart valve from a retrograde approach. This takes advantage of the large and distensible veins in the abdomen and pelvis to deliver the valve to the aorta, thus bypassing the small and diseased arteries of the pelvis. Following completion of the TAVR procedure, the arterial component of the venous-arterial shunt is closed with a nitinol cardiac occluder (*Figure 2*).

Each patient who is a candidate for TAVR is evaluated with a specialized contrast-enhanced CT scan. When a patient is not a candidate for transfemoral TAVR the pre-procedural CT is analyzed for alternative access delivery. In the setting of transcaval TAVR, the CT is evaluated for a calcium-free window on the right wall of the abdominal

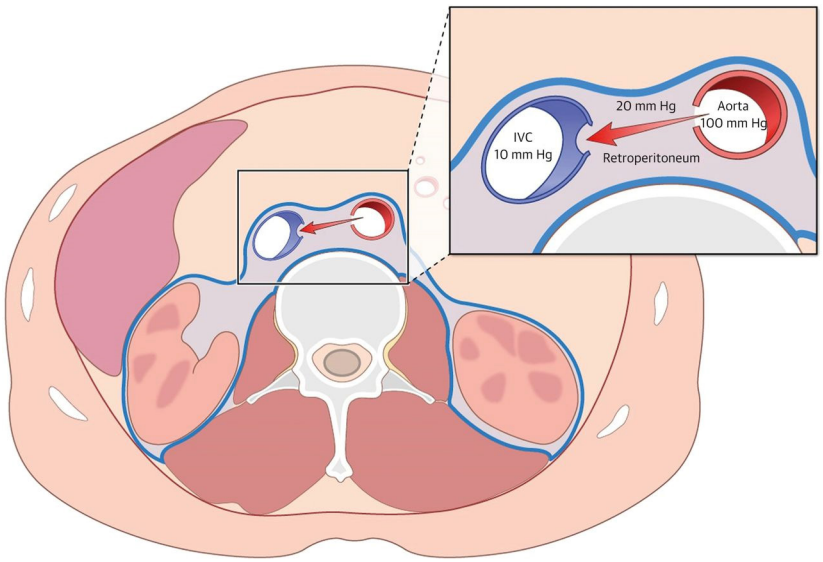

Figure 3 Mechanism of hemodynamic stability after transcaval access. Higher pressure in the relatively confined retroperitoneal space exceeds venous pressure and causes aortic blood to return to the venous circulation through the nearby hole in the inferior vena cava (IVC). The result is an aortocaval fistula rather than hemodynamic collapse.

aorta, close to the vena cava, free of interposed structures where it is feasible to cross from the inferior vena cava to the aorta thus bypassing the iliofemoral vessels (5). In addition, the CT is used to determine bailout with a covered stent in case there is failure of closure with the occluder device.

The physiology of transcaval access provides insight as to why the transcaval access approach is feasible. Studies have demonstrated that the opening created in the vena cava during the procedure serves to decompress aortic bleeding during transcaval access and closure (5). The surrounding retroperitoneal (abdominal) space pressure exceeds the venous pressure and causes blood to return from the aorta into the circulation through the vena cava. The vena cava is the lowest pressure in the abdomen and acts as a natural sink or sump for blood to flow from the aorta to the inferior vena cava (*Figure 3*).

Initial animal studies performed at the U.S. National Institutes of Health demonstrated animals tolerated the aorto-caval shunt even without closure and that transcaval access was feasible (6). The technique was then performed in humans and again the feasibility and safety of the technique was demonstrated in the first 19 patients who underwent aorto-caval shunt closure with a nitinol occluder (7).

The transcaval approach was subsequently systematically assessed in a multi-center prospective study of 100 patients (8). The study demonstrated that transcaval access was successful in 99% of the high-risk patients enrolled in the trial (*Table 1*). Inpatient survival was 96%, and 30-day survival was 92% and there were no deaths as a direct result of transcaval access. Second Valve Academic Research Consortium (VARC-2) life-threatening bleeding was 7% and major vascular complications possibly related to transcaval access were 13% (*Table 2*). By comparison, the rates of life-threatening or disabling bleeding for intermediate risk patients in the PARTNER II trial was 22.6% for transthoracic alternative-access TAVR, and 6.7% for transfemoral TAVR. Therefore, life-threatening bleeding with transcaval TAVR in high-risk patients in this trial compared favorably with the rates of bleeding in lower risk patients in the PARTNER II intermediate risk trial. In summary, this trial confirmed that transcaval access TAVR was a safe and effective option for high-risk patients with limited options.

Equipment list (*Table 3*)

Transcaval case report (Figure 4)

This is a 75-year-old frail female with multiple co-morbidities including chronic obstructive pulmonary disease, atrial fibrillation, history of cerebrovascular

Table 1 Baseline characteristics (N=100)

Characteristics	Values
Age, yrs	79.5 (73.0, 85.0)
Female	58
Race	
White	84
Black	9
Other	7
Left ventricular ejection fraction, %	52.8±15.6
CHF (NYHA functional class)	3.2±0.6
Right ventricular enlargement or dysfunction	24
Coronary artery disease	89
Previous cardiac surgery	44
End stage renal disease or dialysis	10
eGFR, mL/min/1.73 m²	52.6±23.6
NT-pro-BNP/BNP, pg/mL	421 (183, 1,070)
Long-term anticoagulation	42
STS predicted risk of mortality, %	9.6±6.3
Euroscore II predicted risk of mortality, %	10.9±9.8
TVT risk score, %	9.2±7.2
Site-reported reasons unsuitable for conventional access	
Clinical 86/100	
Frailty	54
Advanced pulmonary disease	39
Immunosuppression	8
Morbid obesity	7
Technical 91/100	
Factors impending transaortic access: porcelain aorta, threatened grafts, previous chest radiation, previous sternal wound infection, inadequate working length	53
Factors impending transapical access: failed previous transapical, chest radiation, chest wound infection, fatty myocardium	11
Inadequate ilio-femoral artery diameter irrespective of calcification or tortuosity	82

Values are n (25^{th}, 75^{th} percentile), n, or mean ± SD. CHF, congestive heart failure; Egfr, estimated glomerular filtration rate; NYHA, New York Heart Association; NT-proBNP, N-terminal pro-brain natriuretic peptide; STS, Society of Thoracic Surgeons; TVT, Transcatheter Valve Therapy Registry.

accident, coronary artery disease, peripheral arterial disease, severe symptomatic aortic with disabling heart failure symptoms. The patient was evaluated by the cardiac surgery team and felt to be a high risk for surgical aortic valve replacement (30-day STS predicted mortality 8.2%).

The patient's procedure was performed in the hybrid cardiac catheterization laboratory at Oklahoma Heart Institute. The transcaval technique has been previously

Table 2 Outcomes through 30 days (N=100)

Outcome	Results
Death within 30 days	7 Cardiovascular
	1 Noncardiovascular
Stroke	5 Ischemic
Myocardial infarction	2 Peri-procedural
Contrast induced nephropathy requiring dialysis	2
Acute kidney injury classification	Grade 0 (n=87)
	Grade 1 (n=9)
	Grade 2 (n=0)
	Grade 3 (n=3)
Thrombocytopenia $<50\times10^3/\mu L$	5 (4 with patent fistula)
Non-access related bleeding (e.g., gastrointestinal)	15
Transfusion during TAVR/after TAVR/during or after TAVR	14/30/35
Transfusion units among those transfused (median) (n=35/100)	2.0 (2.0, 4.0)
Follow-up CT scan before discharge	87
Post-TAVR LOS (days), median (quartiles)	4 [2–6]
Post-TAVR ICU LOS (days), median (quartiles)	1 [1–3]
VARC-2 composite early safety*	75

*, Second Valve Academic Research Consortium (VARC-2) composite early safety is 30-days freedom from mortality, stroke, life-threatening bleeding, acute kidney injury stage 2 or 3 coronary obstruction requiring intervention, major vascular complication, or valve-related dysfunction requiring repeat procedure. CT, computed tomography; TAVR, transcatheter aortic valve replacement; LOS, length of stay.

described in detail (10). The methodology for interpreting a CT scan for planning transcaval TAVR has also been previously described in detail (5). The standard pre-procedural TAVR planning CT scan is analyzed to determine an appropriate preselected target site for crossing from the inferior vena cava into the abdominal aorta (*Figure 5A*).

Moderate/conscious sedation was administered by anesthesiology. Bilateral percutaneous femoral venous and arterial access was obtained using modified Seldinger technique. Initial simultaneous aortogram and vena cava-gram were performed to evaluate the anatomy and correlate with the findings on pre-procedural CT scanning (*Figure 5B*). A crossing catheter was placed in the inferior vena cava and a goose neck snare at the predetermined crossing site was placed in the aorta. Next an energized 0.014" diameter guidewire was passed from the vena cava across to the aorta and captured by the snare, thereby creating the caval-aortic tract (*Figure 5C*). Next, through this caval-aortic tract, the transcatheter heart valve sheath (Edwards Lifesciences eSheath 14F) used to deliver the heart valve was then advanced from the IVC into the aorta (*Figure 5D*). Once in the aorta the patient's iliofemoral arteries that were not adequate for transfemoral access have been bypassed and deployment of a 26-mm Edwards SAPIEN 3 transcatheter heart valve with standard technique was performed from a standard retrograde aortic approach.

After successful placement of the transcatheter aortic valve, the caval-aortic tract was then closed using a nitinol occluder device (10/8 mm Amplatzer Duct Occluder, Abbott). The occluder device is used to close the opening in the side wall of the aorta this is done as the large delivery sheath is removed from the aorta. Closure of the aorta was then evaluated with angiography. Initially angiography demonstrated an aorto-caval shunt and mild retroperitoneal bleeding. Given these findings, we proceeded with adjunctive balloon angioplasty of the infra-renal abdominal

Table 3 Equipment List

Stage	Equipment
Crossing	Crossing guide
	6F or 7F 55 cm Guides of various shapes (LIMA, RDC-1, Hockey Stick, FR/JR4)
	Snare Guide
	6 Fr JR4 Coronary Guide 90–100 cm
	Crossing guidewire
	Astato XS 20 0.014”, 300 cm, Asahi
	Confianza Pro 12 0.014”, 300 cm, Asahi
	Transition device
	Piggyback 145 cm, Vascular solutions
	Finecross MG 130 or 150 cm, Terumo
	CXI 0.035” straight tip micro-catheter, Cook
	1.25–2.00 mm NC coronary balloons may be required to dilate aortic side of the tract if the microcatheters do not cross
	Micro-catheter 0.035”
	Navicross 90 cm
	Cook CXI 90 cm
	Minnie 90 cm
	Quick Cross Extreme 90 cm braided
	Seeker 90 cm
	Corsair
	Turnpike
	Sheath guidewire
	Lunderquist Extra Stiff 260 cm 0.035” Straight or single-curve
	Sheath
	Edwards eSheath 14-16 F (depending on valve size)
	Cook RCFW 18Fr×40 cm
	Cook XVFCW 20Fr×40 cm
	Snare (aorta diameter + 5 mm, round up)
	Amplatz Goose-Neck 15–35 mm
	Electrosurgery pencil
	Needle driver, large
	Accessories
	Tuohy-Borst + 3-way stopcock
	Co-Pilot + 3-way stopcock
Closure	Deflectable guiding catheter
	Agilis NxT SML Curl 71 cm 8.5 Fr
	DiRex Boston Scientific 8.5 Fr/17 mm/71 cm
	Loading system
	Amplatzer Torqueview 7 Fr 45°

Table 3 (*continued*)

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Stage	Equipment
	Closure devices
	ADO-1 Amplatzer Duct Occluder 12/10, Abbott
	ADO-1 Amplatzer Duct Occluder 10/8, Abbott
	ADO-1 Amplatzer Duct Occluder 8/6, Abbott
	Buddy guidewire
	0.014" BMW 300 cm or other light-or-medium weight guidewire
	Aortic occlusion balloon (sized 1:1 to aorta or oversized)
	Cook Coda 32 mm (12 Fr)
	Cook Coda 40 mm (14 Fr)
	Medtronic Reliant 46 mm (12Fr)
	Armada PTA 14 mm or Z-Med (7 Fr)
	Cordis MaxiLD 16–18 mm (10 Fr)
	Bard Atlas/Atlas Gold 12-26 mm (7–12 Fr)-diameter sized to aorta 1:1
	Sheath for occlusion balloon
	7-14 Fr×10-14 cm, Any Sheath (minimum Fr size, based on balloon chosen)
	Covered stent/endograft (extension + Endologix delivery system)—size chosen based on analysis of aorta
	Trivascular Ovation iX iliac limb extension 16 mm × 45 mm (OD 4.3 mm)
	Trivascular Ovation iX iliac limb extension 18 mm × 45 mm (OD 4.3 mm)
	Trivascular Ovation iX iliac limb extension 22 mm × 45 mm (OD 4.7 mm)
	Trivascular Ovation iX iliac limb extension 28 mm × 45 mm (OD 5.0 mm)

Figure 4 Transcaval case presentation (9).
Available online: http://www.asvide.com/article/view/24743

aorta (10 mm × 40 mm Atlas Gold balloon, Bard) simultaneous with re-constraining and slight repositioning of the ADO device, so that it was more perpendicular to the caval-aortic tract with the disc of the device parallel to the aortic wall. It is not uncommon to have a persistent aortocaval shunt immediately post procedure. This is felt to be acceptable unless there is bleeding into the retroperitoneal space or the aorto-caval shunt is felt to be causing heart failure (7,8).

CT of the abdomen and pelvis was performed on post-procedure day 1 and demonstrated no residual aortocaval shunt and no retroperitoneal bleeding (*Figure 5E*). Study findings demonstrate that 36% of the aorto-caval fistulas to be closed immediately following transcaval TAVR, 53% closed by the time of hospital discharge and 64% of fistulas

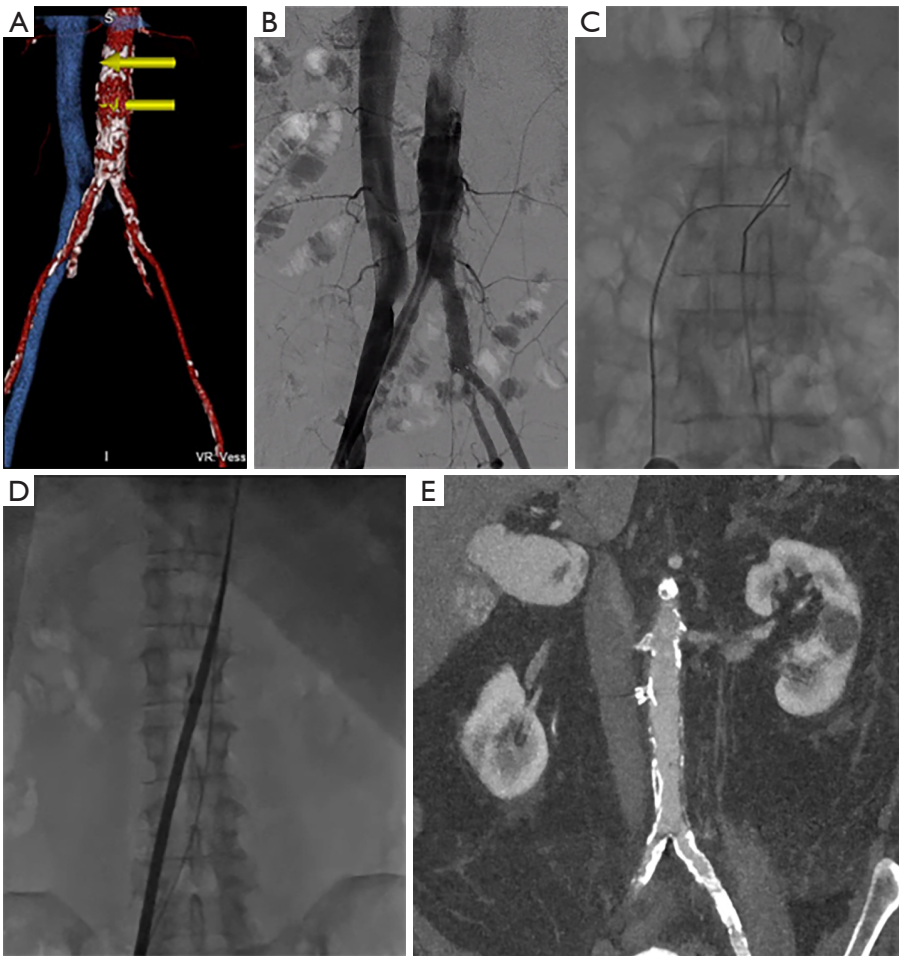

Figure 5 Standard steps for transcaval TAVR procedure. (A) CT plan with yellow arrows showing suitable crossing target; (B) Aortogram/cavagram; (C) electrified wire crossing into aortic snare; (D) TAVR delivery sheath from femoral vein into aorta; (E) final closure of aorto-caval tract with ADO-1 plug.

were closed at 30 days (8).

Post-operative management

The patient was monitored in the cardiovascular step down unit following the procedure and was out of bed later the same day. The patient did well throughout her hospitalization and was discharged home on day two following his procedure. Follow-up post-procedure CT angiogram of the abdomen and pelvis was performed at 1 month and 1 year following the procedure. Both of these studies demonstrated the closure device to be in good position with no aorto-caval shunting, aortic pseudoaneurysm or other abnormality at the site of the caval-aortic tract. The patient is now greater than one year out following transcaval TAVR and is doing extremely well with no congestive heart failure symptoms with normal function of her aortic valve prosthesis.

Conclusions

To date, approximately 450 transcaval TAVR procedures have been performed worldwide and this approach is a safe and effective option for patients who are poor candidates for transfemoral TAVR and standard thoracic alternative-access TAVR. As described above, transcaval access and closure for TAVR is standardized and reproducible and overall the approach is safe and effective for high-risk patients with limited options for TAVR. Ongoing follow-up of patients treated with this approach and future studies will help

us determine the long-term outcomes of this technique, particularly related to transcaval access.

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None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Informed Consent: Written informed consent was obtained from the patient for publication of this manuscript and any accompanying images.

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