Structural Heart
The Journal of the Heart Team

ISSN: 2474-8706 (Print) 2474-8714 (Online) Journal homepage: https://www.tandfonline.com/loi/ushj20

Systematic Transfemoral Transarterial Transcatheter Aortic Valve Replacement in Hostile Vascular Access

Cezar S. Staniloae, Hasan Jilaihawi, Nicholas S. Amoroso, Homam Ibrahim, Kazuhiro Hisamoto, Danielle N. Sin, Hanah Lee, Run Du, Zhen-Gang Zhao, Peter J. Neuburger & Mathew R. Williams

To cite this article: Cezar S. Staniloae, Hasan Jilaihawi, Nicholas S. Amoroso, Homam Ibrahim, Kazuhiro Hisamoto, Danielle N. Sin, Hanah Lee, Run Du, Zhen-Gang Zhao, Peter J. Neuburger & Mathew R. Williams (2019) Systematic Transfemoral Transarterial Transcatheter Aortic Valve Replacement in Hostile Vascular Access, Structural Heart, 3:1, 34-40, DOI: 10.1080/24748706.2018.1556828

To link to this article: https://doi.org/10.1080/24748706.2018.1556828

Accepted author version posted online: 13 Dec 2018.
Published online: 07 Jan 2019.

STRUCTURAL HEART
2019, VOL. 3, NO. 1, 34–40
https://doi.org/10.1080/24748706.2018.1556828

ORIGINAL RESEARCH

Check for updates

Systematic Transfemoral Transarterial Transcatheter Aortic Valve Replacement in Hostile Vascular Access

Cezar S. Staniloae, MD, Hasan Jilaihawi, MD, Nicholas S. Amoroso, MD, Homam Ibrahim, MD, Kazuhiro Hisamoto, MD, Danielle N. Sin, MS, Hanah Lee, MPH, Run Du, MD, PhD, Zhen-Gang Zhao, MD, Peter J. Neuburger, MD, and Mathew R. Williams, MD

Department of Cardiothoracic Surgery and Department of Medicine, NYU Langone Health, New York, New York, USA

ABSTRACT

Background: Traditionally, hostile peripheral access patients undergo TAVR via alternative access. We describe the "transfemoral-first" (TF-1) approach in patients with hostile peripheral access.

Methods: Clinical and procedural data were obtained for all TAVR cases performed from August 2016 to July 2017. Computed tomography was used to assess iliofemoral arteries. Patients were divided into three femoral access groups: routine, hostile, and prohibitive. We attempted TF access in all patients with routine and hostile access. Hostile access was defined as: (1) arterial segments with diameter <5.0 mm; or (2) <5.5 mm with severe calcification (270–360° arc of calcification) or severe tortuosity; or (3) severe tortuosity along with severe calcification. Outcomes of the hostile access group patients who underwent TF-1 are described. The primary endpoint was successful completion of the procedure without major complications by the intended route. The secondary endpoints were procedural complications as defined by the VARC-2 criteria.

Results: Of 377 consecutive patients, 99.5% underwent TF-1 TAVR; two patients (0.4%) had prohibitive access. Twenty-eight (7.4%) patients had hostile access with access side mean minimal lumen diameter of 4.7 mm (range 3.8–5.4 mm). Twenty-six (92.8%) were successfully treated with TF-1 strategy. Twelve (42.8%) of the 26 patients underwent preparatory endovascular treatment prior to TAVR during the same operating room visit. There was 1 (3.5%) major or life-threatening bleeding complication and 2 (7.1%) major vascular complications. There were no deaths or strokes.

Conclusion: Using the safe and effective endovascular approach, TF-1 TAVR is feasible for all-comers—including those with hostile access—with low complication rate. Larger studies are warranted to validate this approach.

ARTICLE HISTORY Received 2 July 2018; Revised 25 November 2018; Accepted 4 December 2018

KEYWORDS Transcatheter aortic valve replacement; transcatheter aortic valve implantation; transfemoral; vascular access

Introduction

Transcatheter aortic valve replacement (TAVR) has proven to be non-inferior to surgical aortic valve replacement (SAVR) for patients at intermediate and high-risk for surgical replacement.[1,2] Patients who undergo TAVR via transfemoral (TF) approach fare better than SAVR patients, or patients that undergo TAVR via transthoracic access approaches.[3,4] Therefore, there is a consensus that the transfemoral approach, when anatomically feasible, should be considered the route of choice for TAVR. Nevertheless, even with contemporary prostheses and delivery systems, difficult or prohibitive access is encountered in up to one fifth of all TAVR cases.[5] Here we describe the results of a "transfemoral-first" (TF-1) approach in subjects with a hostile peripheral access that otherwise would have undergone TAVR via an alternative access.

Materials and methods

We reviewed our database for all TAVR cases performed from August 2016 to July 2017 (Figure 1 depicts the study design). Demographic data and procedural specific data were collected in a prospective fashion. This included the type of valve implanted, the volume of contrast used, the procedural-to-discharge time, and any perioperative complications up to 30 days.

All computed tomography scans were analyzed from the common femoral artery (CFA) to the distal aorta using a dedicated workstation (3Mensio Valves Software, Pie Medical Imaging, Netherlands). The following measurements were obtained: the minimal lumen diameter (MLD), maximum luminal diameter, vessel area at the site of the most severe narrowing, the degree of vessel calcification and tortuosity. The mean lumen diameter was computed as the average vessel diameter (maximal + minimal diameter/2), measured at the MLD. The calcification was defined as severe if covering more than 270° at any given cross section. Tortuosity was considered severe when the greatest angle of tortuosity in the iliofemoral tree was less than 90°. Based on these measurements the patients were divided into three femoral access groups: routine, hostile, and prohibitive. The hostile access

CONTACT Cezar S. Staniloae, MD cezar.staniloae@nyumc.org NYU Langone Health, 550 First Ave., HCC-14, New York, NY 10016, USA.

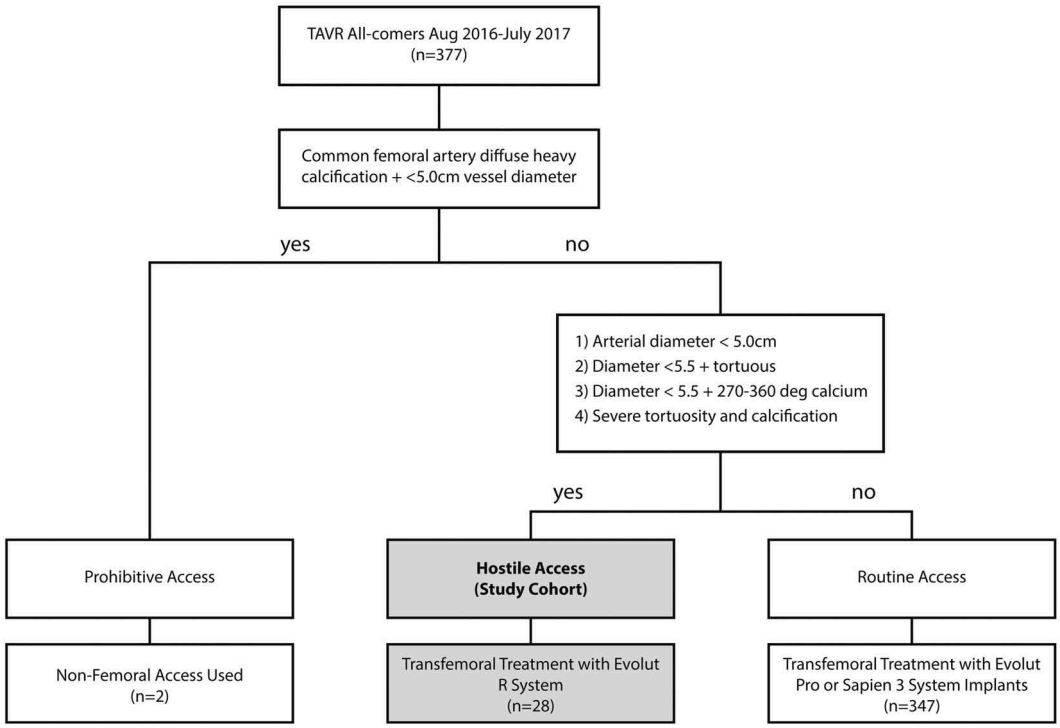

Figure 1. Study design. The "Hostile Access" group, shaded in gray, represents the study cohort of focus.

was described as:[1] segments of the arterial tree with diameter less than 5.0 mm, or[2] less than 5.5 mm with severe calcification (270–360° circumferential calcification) or severe tortuosity, or[3] severe tortuosity along with severe calcification. The prohibitive group included patients deemed by the heart team to have no transfemoral option. The remainder were deemed to be routine access. Figure 2 shows an example of measurements performed in one representative case.

This paper reviews the outcomes of patients included in the hostile group. The primary endpoint was successful

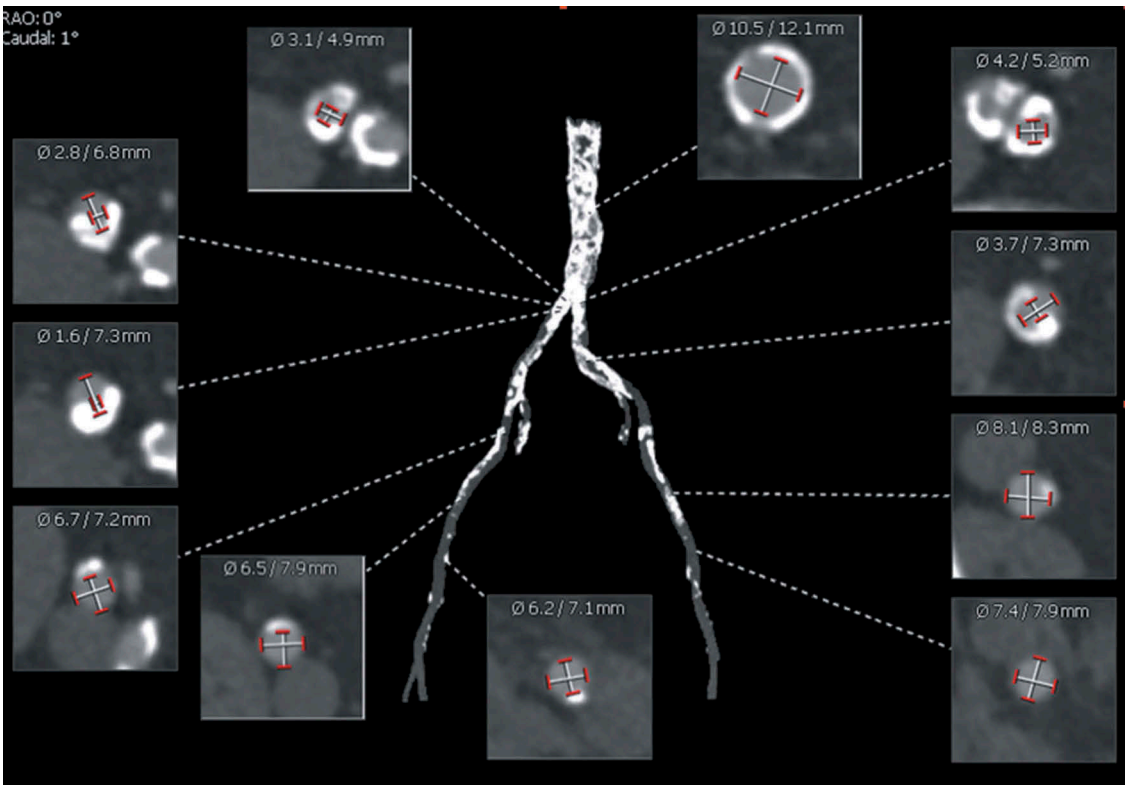

Figure 2. CT angiography measurements—example of diametric iliofemoral measurements.

completion of the procedure without major complications by the intended route. The secondary endpoints were procedural complications as defined by the VARC-2 (Valve Academic Research Consortium-2) criteria.[6] In-hospital outcomes were all-cause mortality, stroke, myocardial infarction (MI), bleeding, and major vascular complications. We also report rates of device success, as determined by VARC-2 criteria, and procedure completion.

Statistical analysis

Background and procedural data were abstracted from consecutive patients per routine for participation in national and institutional registries. Categorical findings are expressed as a percentage amongst study subjects. Quantitative findings were described by the mean with standard deviation. Continuous variables of time and volume were described as medians and ranges. Anatomical vascular measurements were described as a median and interquartile range.

Procedural details for hostile access cases

All the procedures were performed under conscious sedation performed by an anesthesiologist. All cases were performed by an interventional cardiologist and a cardiac surgeon with experience in peripheral endovascular interventions. The Evolut R with InLine sheath valve system (Medtronic, Minneapolis, MN, USA) was used in all cases. The access was first gained on the contralateral (non-interventional) site with a 7 Fr introducer. A cross-over approach was employed in all cases—of note cross-over approach is routinely used in our center for all patients undergoing TAVR. When needed, the contralateral iliofemoral site was treated with balloon angioplasty in order to facilitate crossover technique. A 0.018" crossover wire was positioned into the distal SFA using a standard crossover catheter. This secured a potential bailout procedure in case of iliac or femoral perforation. Next, access to the interventional site was obtained. Preclosure with 2 Perclose (Abbott Laboratories, Abbott Park, IL, USA) devices was performed, and a 14-Fr Cook sheath was attempted to be delivered to the abdominal aorta. If resistance was encountered, peripheral angioplasty was performed with a 6 mm balloon. Balloon inflations were performed until full balloon expansion was achieved (Figure 3). Although linear dissections were noted, none of the 26 successfully treated subjects required additional stenting at the end of the procedure. The sheath was delivered to the distal aorta (Figure 4) and the aortic valve was crossed using a straight Glidewire (Terumo Interventional Systems, Somerset, NJ, USA), which was then exchanged for a Confida wire (Medtronic, Minneapolis, MN, USA). Next, the 14-Fr sheath was removed, and the InLine sheath was introduced. The transcatheter valve was then advanced across the aortic valve. Once the valve was deployed, the delivery system was brought just above the level of the access site. Care was taken to advance a crossover balloon fit to the reference vessel diameter and control angiogram was performed via the balloon lumen. Once the absence of iliac perforation was confirmed, the device was removed and the Perclose device sutures were tightened. Confirmation of a secure closure was performed prior to balloon removal with digital subtraction angiography. When necessary, low-pressure balloon inflation was done at the arteriotomy site to facilitate hemostasis. The post-operative medical treatment consisted of a single antiplatelet agent (acetylsalicylic acid 81 mg daily or clopidogrel 75 mg

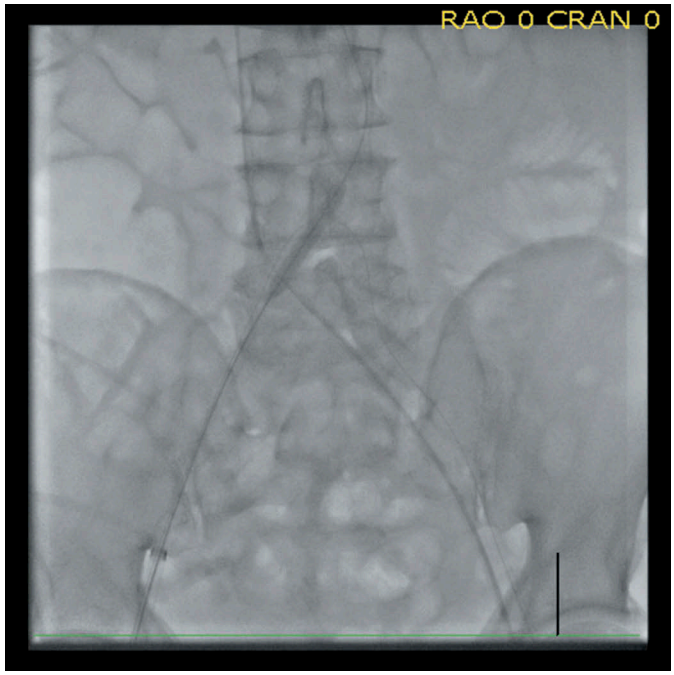

Figure 3. Angioplasty facilitated access. Right common iliac angioplasty was performed in this case of "hostile" access (depicted in Figure 2) with a 6.0 mm wide angioplasty balloon after orbital atherectomy to facilitate passage of the 14Fr inline sheath.

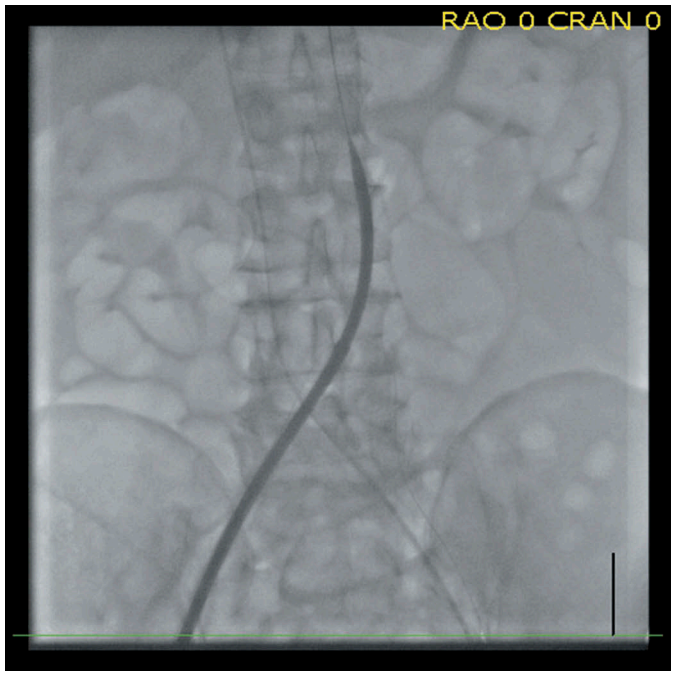

Figure 4. Sheath advanced to abdominal aorta. Attempt to advance a 14-Fr sheath to the abdominal aorta is made before removal and subsequent advancing of the 14-Fr valve delivery system to identify if further endovascular iliofemoral intervention is needed to facilitate safe transfemoral valve delivery.

Table 1. Baseline demographics and anatomical data of hostile access cohort.

Baseline demographics	
Age in years, mean ±SD	82.8 ± 8.6
Female, n (%)	17 (60.7)
BMI, mean (SD)	28.5 (±5.2)
PVD, n (%)	25 (91.1)
Prior stroke, n (%)	2 (7.1)
Left ventricular ejection fraction (%), mean (SD)	48.8 (±9.7)
eGFR ml/min/1.73 m^2, mean (SD)	43.3 (±11.8)
NYHA functional class, median	2
STS risk score mortality %, mean (SD)	7.4 (±4.1)
Anatomical data	
Minimal luminal diameter at access site in mm, mean (range)	4.7 (3.8–5.4)
Minimal cross-sectional area at access site in mm^2, mean (range)	17.8 (11–24.2)
Lesion length (mm), Median (range)	38 (11–61)
Severe calcification, n (%)	28 (100)

Notes. BMI, body mass index (kg/m^2); NYHA, New York Heart Association; STS, Society of Thoracic Surgeons; PVD, symptomatic peripheral vascular disease with claudication Rutherford 2 or higher.

Table 2. Procedural data of hostile access cohort.

Procedural data	
Iliofemoral balloon pre-dilatation with 6 mm balloon, n (%)	13 (46.4)
Atherectomy, n (%)	1 (3.6)
Procedure time in minutes, median (range)	62 (35–124)
Fluoroscopy time in minutes, median (range)	20 (7.7–37.6)
Contrast volume in mL, median (range)	27 (6–60)

Table 3. In-hospital outcomes of hostile access cohort.

Primary outcome	
Successful completion of the procedure without major complications by the intended route, n (%, CI)	26 (92.8; 0.76–0.99)
Secondary outcomes	
Alternative access, n (%)	2 (7.2)
Life-threatening bleeding, n (%)	0 (0)
Absence of major bleeding, n (%, CI)	27 (96.4; 0.82–0.99)
Absence of minor bleeding, n (%, CI)	25 (89.3; 0.72–0.97)
Absence of major vascular events, n (%, CI)	26 (92.8; 0.76–0.99)
Absence of any stroke, n (%, CI)	27 (96.4; 0.82–0.99)
Death, n (%)	0 (0)
Absence of new PPM, n (%, CI)	4 (85.7; 0.67–0.96)
AKI, n (%)	0 (0)
Hospital stay in hours, median (IQR)	31 (21–70)

Notes. n, number of subjects; CI, confidence interval. AKI, acute kidney injury.

daily). For patients already on anticoagulants, the treatment was left unchanged without the addition of an antiplatelet drug.

Results

During the study period we scheduled a total of 377 TAVR procedures. Two patients (0.5%) were deemed to have prohibitive access. We attempted TF TAVR in the remaining 375 (99.5%) patients including 28 (7.4%) subjects which met criteria for hostile access. All patients with hostile access first underwent attempts at TF TAVR.

Patients with challenging access had a mean age of 82.8 ± 8.6 years, 60% were female. Demographics are shown in Table 1. Right femoral artery was utilized for access in 11 patients. The mean MLD on the access side was 4.7 mm (range 3.8–5.4 mm) and the mean smallest cross-sectional area (CSA) was 17.8 mm^2 (range 11–24.2 mm^2). All cases met criteria for severe calcifications. All valves used for hostile cases were Evolut R (26 and 29 mm).

Twelve subjects (42.8%) required preparatory balloon angioplasty prior to advancing the InLine device. One subject underwent orbital atherectomy followed by balloon angioplasty prior to TAVR. Procedural success by intended route was achieved in 26 out of the 28 (92.8%) subjects.

In-hospital survival was 100%. The median length of stay was 31 hours. None of the patients treated successfully required additional vascular intervention after TAVR. Additional procedural and outcomes data regarding the hostile access group are shown in Table 2 and Table 3, respectively.

The two patients who had a failed procedure both had common iliac artery perforation requiring stenting with a covered device followed by balloon aortic valvuloplasty during the same operating room visit. They underwent TAVR at later dates via an alternative approach. Both cases had severe circumferential calcifications (360°); one vessel diameter measured 4.6 mm and the other 4.8 mm at the site of perforation. Both perforations occurred while attempting to pass the valve through the stenotic segment.

Discussion

This study underlines the feasibility and excellent short-term results of using endovascular techniques to "pretreat" aorto-iliac arteries in preparation of TF-TAVR. Moreover, it demonstrates that plain old balloon angioplasty (POBA) can be sufficient to safely treat even the most advanced occlusive disease of the iliofemoral arteries or the distal aorta, to facilitate the transition of a low-profile transcatheter valve system. As a result of applying this TF-1 approach, we were able to perform 99.5% of TAVR via transfemoral access. This approach proved feasible even with circumferential calcium in vessels less than 6.0 mm in diameter. This is in striking contradiction with recent data from the TVT registry, which reported that 13.4% of the total CMS-linked TAVRs performed in 2015 used an alternative access.[5]

Adequate vascular access is critical for successful percutaneous aortic valve replacement. Alternative access pathways were introduced to allow aortic valve replacement in subjects with prohibitive vascular access. In the PARTNER 1 trial, including the continuous access registry, half of TAVR subjects underwent transapical intervention due to "inadequate" vascular access.[7] Subsequently, the direct transaortic approach was developed. It is essential to note that larger delivery sheaths were required in PARTNER 1 trial. Due to the significant invasiveness of these two procedures as well as inferior outcomes when compared with the TF approach, "alternatives" were quickly introduced[7,8] and trans-

subclavian, trans-carotid, and trans-caval procedures have been described.[9–11]

Indeed, the TF-1 approach appears favorable when complications of these alternative access approaches are placed in context (Appendix Table A1), particularly when it is considered that the 7.1% major vascular complication rate we saw in hostile access was similar to the 6.1% seen in PARTNER II with Sapien 3 in more optimal access.[12] Although each alternative access strategy presents significant limitations and safety concerns, the trans-subclavian approach seems to offer the closest outcomes when compared to the TF-TAVR.[13] Nevertheless, in contrast to TF-1, in most centers the use of the subclavian artery still mandates surgical cutdown and general anesthesia, although a percutaneous approach with cross-over balloon technique has been described.[14,15]

Importantly, our experience was that 100% of major vascular complications during TF-TAVR were manageable with endovascular techniques (e.g. angioplasty, covered stent grafts, etc.) using the above approach without change in short-term recovery. Therefore, the morbidity and cost of incurring and treating a major vascular complication during TF-TAVR could easily be superior to the morbidity and cost associated with alternative access. Accordingly, we argue that 100% of patients with hostile, or routine, access deserve TF1-TAVR attempt. Though our single-center experience has been positive, this comparison warrants formal clinical investigation.

Although the introduction of lower-profile delivery systems has allowed an increase in the number of TAVRs performed via the transfemoral route, this approach is still widely underutilized in hostile femoral access. A more aggressive approach for treating preexisting vascular disease, as in our series, would lead to a significant increase in the frequency of TF-TAVR. It has been shown in the percutaneous aortic aneurysm repair literature that various forms of endovascular pretreatment modalities, particularly of the iliofemoral tree, eliminated the need for open repair.[16] The placement of covered stents in the iliac arteries as endoconduits followed by dilation to large diameters causing controlled rupture of the access vessels is known as the "pave and crack" technique. The "pave and crack" technique is at the extreme end of endovascular vessel preparation, not used in our series, but certainly not to be dismissed in cases that cannot be safely addressed with POBA alone.

Our approach to hostile access most consistently utilized "sheath dilation," POBA, and atherectomy. As described above, after preclosure, we attempted to place a 14 Fr sheath in the distal aorta. This "sheath dilation" technique simply allowed advancement of the InLine device in 19 (67.8%) of our cases. If there was significant resistance to sheath advancement, POBA was performed with a 6 mm balloon. The balloon dilation facilitated advancement of the valve system in the remainder of our cases. In one case, due to severe, concentric calcification at the ostium of the iliac artery, we preferred to perform orbital atherectomy prior to POBA (see Figures 2, 3, and 4).

Atherectomy, particularly using calcium-dedicated devices such as the Diamondback 360 (CSI, Minneapolis, MN, USA), can be used as an adjunctive therapy to POBA to facilitate valve passage through the ilio-femoral tree. This approach is well recognized and validated in the world of peripheral interventions, and its use can decrease the number of flow-limiting dissections and facilitate vessel expansion, particularly in heavily calcified vessels.[17] We performed atherectomy followed by POBA in a patient who required valve-in-valve TAVR who had had her first TAVR via transapical access, presumably because of her iliofemoral arterial atherosclerotic disease. After endovascular treatment, the InLine sheath was advanced through the diseased iliac vessels without difficulty, and the procedure was completed without complications. This is a clear example of how using vessel preparation can facilitate TF-TAVR in patients who otherwise would be considered for alternative access.

A different solution to unfavorable peripheral anatomy involves the use of an expandable sheath (Solopath, Terumo Medical, Tokyo, Japan) as an endo-conduit to allow valve delivery. The 19-French expandable/re-collapsible sheath has a 4.45 mm outer diameter on arterial entry, expands to 7.67 mm (inner diameter 6.33 mm), and then re-collapses upon removal by approximately 30%. This approach accommodates the Evolut R system and is most useful in situations where the iliac arteries show long segments of diffuse disease. Following femoral arterial insertion, the sheath is balloon expanded to allow insertion of the delivery system. Once the procedure is completed, the sheath is actively re-collapsed prior to withdrawal by inflating an outer balloon.

This technique is a good alternative to vessel preparation with POBA. Abu Saleh et al.[18] described their favorable experience with the use of the Solopath sheath in 13 patients with small caliber iliofemoral vessels. The main drawback of this approach is the increase of the arteriotomy size. Second, in tortuous and calcified anatomy, complete sheath expansion could be limited.

The last, but not the least contributor to successful TF-TAVR is the introduction of the InLine sheath delivery system for the Evolut R valve. The InLine sheath offers the lowest profile for delivery of a percutaneous valve (14 Fr-equivalent system) and requires only a vessel diameter of 5 mm. It tracks very well in tortuous anatomy, and it is our default device when hostile transfemoral vascular anatomy is encountered. However, our results cannot be generalized to larger-profile devices as Evolut PRO (Medtronic, Minneapolis, MN, USA) or Sapien 3 (Edwards Lifesciences, Irvine, CA, USA). Nevertheless, in large all-comers registries (PRAGMATIC, UK Registry, FRANCE2 Registry) and one meta-analysis there is no signal for greater vascular risk with one valve system over another.[19]

The two cases not treated via the TF approach were patients with severe bilateral CFA disease, which precluded safe preclosure technique. Although there are endovascular options for these scenarios, bailout would involve stenting over the common femoral area, which may potentially lead to unwanted long-term events.

Although this series represents the largest reported data using endovascular preparation to facilitate TF-TAVR, it nonetheless represents a relatively small number of patients and a single-center experience. Larger scale studies, following

standard endovascular techniques will be needed to increase confidence in this particular approach.

Conclusion

In conclusion, the TF-1 concept using endovascular techniques to pretreat iliofemoral arteries is safe and effective even in calcified vessels well under 5 mm in diameter. Using this method, we can successfully perform TF-TAVR in 99.5% of all patients presenting to our center. Truly prohibitive access for TF-TAVR is uncommon and patients with hostile access deserve a TF1-TAVR attempt. Larger studies are warranted to validate this approach in an attempt to expand the population suitable for transfemoral access and thereby contribute to improved TAVR outcomes.

ORCID

Cezar S. Staniloae http://orcid.org/0000-0001-8970-8889
Nicholas S. Amoroso http://orcid.org/0000-0001-6785-6899

Disclosure statements

Dr. Williams reports research funding from Medtronic Inc. and Edwards Lifesciences. Dr. Neuburger is a consultant with Medtronic Inc. Dr Ibrahim reports being proctor for Medtronic Inc. Dr. Jilaihawi is a consultant to Edwards Lifesciences and Venus Medtech and receives an institutional research grant from Medtronic and Abbott Vascular. All other authors have nothing to declare.

References

1. Leon MB, Smith CR. Transcatheter aortic-valve replacement. *N Engl J Med*. 2016;375:700–701.
2. Adams DH, Popma JJ, Reardon MJ, et al. Transcatheter aortic-valve replacement with a self-expanding prosthesis. *N Engl J Med*. 2014;371:967–968. doi:10.1056/NEJMc1408396.
3. Adams DH, Popma JJ, Reardon MJ, et al. Transcatheter aortic-valve replacement with a self-expanding prosthesis. *N Engl J Med*. 2014;370:1790–1798. doi:10.1056/NEJMoa1400590.
4. Blackstone EH, Suri RM, Rajeswaran J, et al. Propensity-matched comparisons of clinical outcomes after transapical or transfemoral transcatheter aortic valve replacement: a placement of aortic transcatheter valves (PARTNER)-I trial substudy. *Circulation*. 2015;131:1989–2000. doi:10.1161/CIRCULATIONAHA.114.012525.
5. Grover FL, Vemulapalli S, Carroll JD, et al. 2016 annual report of the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy registry. *J Am Coll Cardiol*. 2017;69:1215–1230. doi:10.1016/j.jacc.2016.11.033.
6. Kappetein AP, Head SJ, Généreux P, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. *Eur Heart J*. 2012;33:2403–2418. doi:10.1093/eurheartj/ehs255.
7. Elmariah S, Fearon WF, Inglessis I, et al. Transapical transcatheter aortic valve replacement is associated with increased cardiac mortality in patients with left ventricular dysfunction: insights from the PARTNER I trial. *JACC Cardiovasc Interv*. 2017;10:2414–2422. doi:10.1016/j.jcin.2017.09.023.
8. O'Hair DP, Bajwa TK, Popma JJ, et al. Direct aortic access for transcatheter aortic valve replacement using a self-expanding device. *Ann Thorac Surg*. 2018 Feb;105(2):484–490.
9. Greenbaum AB, O'Neill WW, Paone G, et al. Caval-aortic access to allow transcatheter aortic valve replacement in otherwise ineligible patients: initial human experience. *J Am Coll Cardiol*. 2014;63:2795–2804. doi:10.1016/j.jacc.2014.04.015.
10. Modine T, Sudre A, Delhaye C, et al. Transcutaneous aortic valve implantation using the left carotid access: feasibility and early clinical outcomes. *Ann Thorac Surg*. 2012;93:1489–1494. doi:10.1016/j.athoracsur.2012.01.030.
11. Petronio AS, De Carlo M, Bedogni F, et al. Safety and efficacy of the subclavian approach for transcatheter aortic valve implantation with the CoreValve revalving system. *Circ Cardiovasc Interv*. 2010;3:359–366. doi:10.1161/CIRCINTERVENTIONS.109.930453.
12. Thourani VH, Kodali S, Makkar RR, et al. Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis. *Lancet*. 2016;387:2218–2225. doi:10.1016/S0140-6736(16)30073-3.
13. Gleason TG, Schindler JT, Hagberg RC, et al. Subclavian/axillary access for self-expanding transcatheter aortic valve replacement renders equivalent outcomes as transfemoral. *Ann Thorac Surg*. 2018 Feb;105(2):477–483.
14. Schafer U, Deuschl F, Schofer N, et al. Safety and efficacy of the percutaneous transaxillary access for transcatheter aortic valve implantation using various transcatheter heart valves in 100 consecutive patients. *Int J Cardiol*. 2017;232:247–254. doi:10.1016/j.ijcard.2017.01.010.
15. Hyman MC, Vemulapalli S, Szeto WY, et al. Conscious sedation versus general anesthesia for transcatheter aortic valve replacement: insights from the NCDR® STS/ACC TVT registry. *Circulation*. 2017. doi:10.1161/CIRCULATIONAHA.116.026656.
16. Yano OJ, Faries PL, Morrissey N, Teodorescu V, Hollier LH, Marin ML. Ancillary techniques to facilitate endovascular repair of aortic aneurysms. *J Vasc Surg*. 2001;34:69–75. doi:10.1067/mva.2001.116005.
17. Das T, Mustapha J, Indes J, et al. Technique optimization of orbital atherectomy in calcified peripheral lesions of the lower extremities: the CONFIRM series, a prospective multicenter registry. *Catheter Cardiovasc Interv*. 2014;83:115–122. doi:10.1002/ccd.25046.
18. Abu Saleh WK, Tang GH, Ahmad H, et al. Vascular complication can be minimized with a balloon-expandable, re-collapsible sheath in TAVR with a self-expanding bioprosthesis. *Catheter Cardiovasc Interv*. 2016;88:135–143. doi:10.1002/ccd.26336.
19. Athappan G, Patvardhan E, Tuzcu EM, et al. Incidence, predictors, and outcomes of aortic regurgitation after transcatheter aortic valve replacement: meta-analysis and systematic review of literature. *J Am Coll Cardiol*. 2013;61(15):1585–1595. doi:10.1016/j.jacc.2013.01.047.

Appendix

Table A1. Rates of mortality, bleeding and vascular complications with TF-1 TAVR and studies of alternative access TAVR.

Authors	Study Name	Year of Publication	Approach	N	Device	30-day death	Life-threatening bleeding	Major bleeding	Major vascular complication	Minor vascular complication
Current paper	TF-1	2018	TF	28	Evolut R	0	0	3.6	7.1	7.1
Petronio et al.	Italian CoreValve Registry	2012	TS	14 1	CoreValve	5.7	7.8	36.2	5.0	7.1
Gilard et al.	FRANCE 2	2012	TA	56 7	SAPIEN	13.9	1.4	3.4	1.9	1.6
			TS	184	CoreValve	10.1	0.5	3.3	4.3	6.5
Lardizabal	NA	2013	TAo	44	SAPIEN	13.6	13.6	11.4	2.3	NA
			TA	76	SAPIEN	14.5	13.2	27.6	5.3	NA
Arai et al.	NA	2016	TAo	289	BE-Device (72%), SE-Device (28%)	9.3	5.9	NA	NA	NA
			TA	42	BE-Device(100%)	14.3	7.1	NA	NA	NA
Bapat et al.	Route Registry	2016	TAo	301	SAPIEN XT (58%), SAPIEN 3 (42%)	6.1	3.4	NA	3.4	NA
Mylotte et al.	NA	2015	Transcarotid	96	Corevalve (93%), SAPIEN (7%)	6.3	4.2	4.2	4.2	4.2
Greenbaum et al.	NA	2016	Transcaval	100	SAPIEN XT/3 (80%), CoreValve/Evolut R (20%)	8.0	12.1	6.1	19.2	17.2