Acta Cardiol Sin 2018;34:37–48
Original Article
doi: 10.6515/ACS.201801_34(1).20170911A

Valvular Heart Disease

Use of Internal Endoconduit for Unfavorable Iliac Artery Anatomy in Patients Undergoing Transcatheter Aortic Valve Replacement – A Single Center Experience

Yung-Tsai Lee,[1] Wei-Hsian Yin,[1,2] Ho-Ping Yu[1] and Jeng Wei[1]

Background: Transfemoral (TF) access is associated with lower rates of surgical conversion and mortality compared with non-TF access for transcatheter aortic valve replacement (TAVR). Therefore, efforts should be made to make this procedure even less invasive, allowing more TAVR procedures to be performed through femoral access. We herein describe our single-center experience of using one-stage percutaneous internal endoconduits for TAVR in patients with unfavorable iliac artery anatomy.

Methods: Between March 2013 andMarch 2016, 113 consecutive patients with severe aortic stenosis at high risk for conventional cardiac surgery underwent TAVR at the Cheng Hsin General Hospital. The patients can be divided into Cohort A (March 2013-December 2014) and Cohort B (January 2015-March 2016).

Results: In the Cohort A, 6 out of the 53 (11.4%) with unfavorable iliac artery anatomy were treated by trans-subclavian approach (n = 3, 5.7%) or direct aortic approach (n = 3, 5.7%); while in the Cohort B, none (0%) of the 5 patients with unfavorable iliac artery anatomy among 60 consecutive TAVR cases needed non-TF approach (Cohort A vs. Cohort B = 11.4% vs. 0%, p = 0.024) and they were all successfully treated with the use of an internal endoconduit.

Conclusions: The use of internal endoconduits can further increase the number of patients who can be treated through femoral artery access for TAVR and substantially reduce the need of non-TF approaches.

Key Words: Alternative access • Internal endoconduit • Transcatheter aortic valve replacement • Transfemoral approach

INTRODUCTION

Transcatheter aortic valve replacement (TAVR) has become the treatment of choice for inoperable patients with severe aortic stenosis (AS), and it is an accepted alternative to surgical aortic valve replacement in high-risk patients.[1] Moreover, it is now gradually being applied in intermediate and even low-risk patients.[2,3] Despite technological improvements in TAVR devices and the rapidly growing level of physician familiarity with the use of these devices, vascular access complications are a clinically relevant issue in TAVR procedures and can significantly affect overall clinical outcomes.[4-8]

Typically, the standard transfemoral (TF) approach is the most widely adopted technique for retrograde TAVR. However, this approach is often not possible in patients with unsuitable iliofemoral anatomy such as small-caliber vessels, excessive peripheral or aortic atherosclerosis, severe tortuosity or previous peripheral arterial stenting or surgery.[4-8] Many alternative such as trans-

Received: February 16, 2016 Accepted: September 11, 2017
[1]Heart Center, Cheng-Hsin General Hospital; [2]Faculty of Medicine, School of Medicine, National Yang Ming University, Taipei, Taiwan.
Corresponding author: Dr. Wei-Hsian Yin, Heart Center, Cheng Hsin General Hospital, No. 45, Cheng-Hsin Street, Pei-Tou, Taipei 112, Taiwan. Tel: 886-2-2826-1242; Fax: 886-2-2826-1242; E-mail: yinwh@pchome.com.tw

apical, direct aortic, subclavian, axillary, brachiocephalic, and carotid access approaches have been described in the literature and are currently successfully performed worldwide.[4-8]

Considering that TF access is associated with lower rates of surgical conversion and 30-day and 1-year mortality compared with non-TF access for TAVR,[4-8] and that TF access has been associated with a greater incidence of vascular complications,[4-8] efforts should be made to make this procedure even less invasive, thereby allowing for more TAVR procedures to be performed through femoral access to substantially reduce the frequency of access-related complications with non-TF approaches.

Although a variety of novel types of sheaths with superior deliverability and transcatheter valve delivery systems with smaller profiles have been developed to facilitate valve passage and reduce the rate of vascular complications related to TAVR, they are not generally available worldwide.[9-12] We have found that the use of an "internal endoconduit"[13] is an attractive approach for those who are undergoing TAVR with unfavorable iliofemoral anatomy as a one-stage procedure. Therefore, in this study, we report our single-center experience of using internal endoconduits to overcome access limitations in the setting of TAVR.

METHODS

TAVR at Cheng Hsin

The TAVR procedure was first performed in Taiwan in 2010, after which eight TAVR centers became active by December 2015. The main valve technology available is the Medtronic CoreValve prosthesis (Medtronic Inc., Minneapolis, MN, USA), and it was the only approved device until July 2015. The default strategy for all patients was the TF approach; however, approaches involving a subclavian or a direct aortic approach were also used.

Between March 2013 and March 2016, 113 consecutive patients underwent TAVR, (the TAVR program was first introduced at Cheng Hsin General Hospital in March 2013). All patients with severe AS at high risk for conventional cardiac surgery with sternotomy and cardiopulmonary bypass were referred to our TAVR multidisciplinary team composed of interventional cardiologists, imaging cardiologists, cardiothoracic surgeons, and anesthetists. Of the 113 cases, CoreValve devices were used in 101 (89.4%), Sapien XT (Edwards Lifesciences, Irvine, CA, USA) prosthesis in two (1.8%), and Lotus valves (Boston Scientific, Natick, MA, USA) in 10 (8.8%) cases.

Choice of vascular access and TAVR procedures

The choice of access site was based on a "TF first" approach. If a TF access was not feasible because of diseased peripheral vessels, a subclavian artery or transaortic implantation was considered. Decisions were based on pre-procedural imaging diagnostics (computed tomography, angiography, and trans-esophageal and transthoracic echocardiography) performed for all patients.

All implantations were performed in a hybrid theater, and the study patients were treated under general anesthesia. TF TAVR was conducted with the use of percutaneous closure devices or after surgical cut-down of the femoral artery in case of vessel calcification or severe obesity. The subclavian artery was dissected free for access through a 4- to 5-cm left infraclavicular incision for those who underwent the trans-subclavian approach. For transaortic access, an upper median ministernotomy was performed. In most cases, after balloon valvuloplasty during rapid ventricular pacing, valve deployment was performed under fluoroscopy.

After TAVR, all patients were admitted to an intensive care unit and monitored for at least 1 day, where their heart rate was continuously monitored until discharge. Platelet inhibition was achieved with aspirin 100 mg per day in all patients. After TAVR, an additional dose of 75 mg of clopidogrel was administered postprocedurally for 3 months. The patients with an indication for warfarin therapy received clopidogrel and warfarin without aspirin.

Description of the "internal endoconduit" technique

An internal endoconduit is a novel technique first described by Peterson et al. in 2008 to address the issue of iliac rupture owing to large sheath requirements during thoracic endovascular repair (TEVAR).[13] An iliac covered stent graft was deployed percutaneously across the prohibitively stenotic area using a TF approach followed by balloon-angioplasty inside the endoconduit, thereby creating a proximal and distal seal to control rupture of

the diseased segment. The endoconduit then allowed for the safe passage of the large-diameter delivery sheath. Internal endoconduits allow for aggressive iliac angioplasty, however this is performed in a more controlled fashion, with a theoretically lower risk of life-threatening hemorrhages from vessel rupture (Figure 1A).[13-16] Among the commercially available covered stents, Viabahn Endoprosthesis (W. L. Gore & Associates, Newark, DE, USA) has been recommended over other iliac limb endoprostheses to overcome device oversizing and iliac tortuosity.[13,14,17]

One of the major concerns with the use of internal endoconduits is that the origin of the internal iliac artery is often not spared (Figure 1B).[13-16] Embolization of a patent internal iliac artery adjacent to the diseased segment may then be needed before deployment of the endoconduit to prevent retrograde hemorrhage. Complications of decreased pelvic perfusion may be a concerns for patients with acute coverage or coil embolization of patent internal iliac arteries. It has also been recommended that patency of the internal iliac and superficial circumflex iliac arteries should be maintained whenever possible in an effort to optimize pelvic perfusion through collateral circulation.[13-16] If high-grade stenosis of the origin of the internal iliac artery is present, coiling is not routinely performed. Based on these considerations, when both iliac arteries have critical stenoses, the more diseased side should be used as the access site for endoconduit placement.[13-16]

If the common femoral artery is also severely diseased thereby precluding the passage of the large-diameter delivery sheath, a polyester graft can be anastomosed to the endoconduit in the iliac artery in an end-to-side fashion for placement of the sheath (Figure 1C, before). The end of the graft conduit is controlled with a clamp for hemostasis during the TAVR procedure. After the procedure, the graft conduit can be used as an iliofemoral bypass graft in the setting of symptomatic occlusive disease (Figure 1C, after).[15]

Definitions of device success, procedural success, and vascular access site complications

According to the Valve Academic Research Consortium-2 consensus document,[18] device success was defined as 1) the absence of procedural mortality, 2) correct positioning of a single prosthetic heart valve into the proper anatomical location, and 3) intended performance of the prosthetic heart valve (no prosthesis-patient mismatch and mean aortic valve gradient < 20 mmHg or peak velocity < 3 m/s, and no moderate or severe prosthetic valve regurgitation). Procedural success was defined as achievement of a successful deployment of the TAVR device and retrieval of the delivery system in the absence of mortality, conversion to surgical aortic valve replacement, or myocardial infarction.

Major vascular access site or access-related vascular injuries were defined as any dissection, stenosis, perforation, rupture, arterio-venous fistula, pseudoaneurysm, hematoma, irreversible nerve injury, compartment syndrome, percutaneous closure device failure leading to

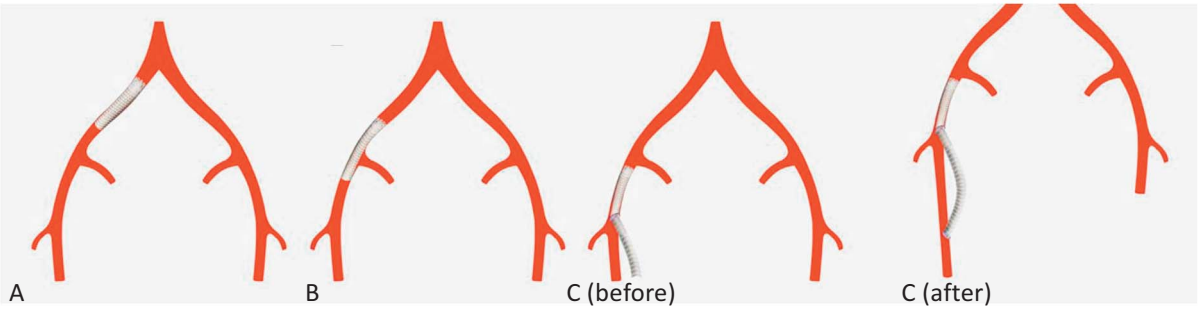

Figure 1. *An iliac covered stent graft was deployed percutaneously across the prohibitively stenotic area using a transfemoral approach, followed by employing balloon-angioplasty inside the endoconduit, thereby creating a proximal and distal seal, and controlling rupture of the diseased segment (A). One of the major concerns with the use of internal endoconduits is that the origin of the internal iliac artery is often not spared (B). Embolization of a patent internal iliac artery adjacent to the diseased segment before deployment of the endoconduit may be needed to prevent retrograde hemorrhage. If the common femoral artery is also severely diseased, a polyester graft can be anastomosed to the endoconduit in the iliac artery in an end-to-side fashion to allow for placement of the sheath (C, before). The end of the graft conduit is controlled with a clamp for hemostasis during the TAVR procedure. After the procedure, the graft conduit can be used as an iliofemoral bypass graft in the setting of symptomatic iliac occlusive disease (C, after).*

death, life-threatening or major bleeding, visceral ischemia, or neurological impairment; distal embolization (non-cerebral) from a vascular source requiring surgery or resulting in amputation or irreversible end-organ damage; the use of an unplanned endovascular or surgical intervention associated with death, major bleeding, visceral ischemia or neurological impairment; any new ipsilateral lower extremity ischemia documented according to patient symptoms, physical examinations, and/or decreased or absent blood flow in the lower extremities in angiography; or surgery for access site-related or permanent access site-related nerve injuries. Minor access site or access-related vascular injuries were defined as any vascular injury not leading to death, life-threatening or major bleeding, visceral ischemia, or neurological impairment; distal embolization treated with embolectomy and/or thrombectomy and not resulting in amputation or irreversible end-organ damage; any unplanned endovascular stenting or unplanned surgical intervention not meeting the criteria for a major vascular complication; or vascular repair or the need for vascular repair (via surgery, ultrasound-guided compression, transcatheter embolization, or stent-graft).

Statistical analysis

Data were analyzed using SPSS software version 18.0 for Windows (SPSS Inc., Chicago, IL, USA). Univariate comparisons of demographics, procedural, and outcome parameters between two groups were performed. Continuous variables are expressed as mean ± standard deviation and were compared using the Student's t-test or the Wilcoxon rank sum test. Categorical variables are presented as percent frequency and were compared using Pearson's chi-square test or Fisher's exact test. All variables are two-tailed, and a p value < 0.05 was considered to be statistically significant.

RESULTS

Baseline characteristics of the study patients

The 113 included patients with severe aortic stenosis at high risk for conventional cardiac surgery who underwent TAVR at Cheng Hsin General Hospital between March 2013 and March 2016 were divided into two cohorts. The demographic data of the two cohorts are shown in Table 1. The incidence rates of chronic ob-

Table 1. Baseline characteristics of the study patients

	Cohort A (N = 53)	Cohort B (N = 60)	p value
Age, yrs	81 ± 6	80 ± 8	0.614
Male, n (%)	26 (49%)	29 (48%)	1
Body mass index, kg/m^2	24 ± 4	25 ± 4	0.155
Systemic hypertension, n (%)	29 (55%)	44 (73%)	0.062
Diabetes mellitus, n (%)	18 (34%)	18 (30%)	0.803
Peripheral vascular disease, n (%)	11 (21%)	19 (32%)	0.272
Previous stroke, n (%)	8 (15%)	5 (8%)	0.407
Previous atrial fibrillation, n (%)	19 (36%)	21 (35%)	1
Previous permanent pacemaker implantation, n (%)	2 (4%)	3 (5%)	1
Chronic obstructive pulmonary disease, n (%)	14 (26%)	5 (8%)	0.021
Serum creatinine, mg/dl	1.45 ± 1.16	1.74 ± 1.97	0.341
Anemia, n (%) (male < 14; female < 12)	43 (81%)	43 (72%)	0.339
Coronary artery disease, n (%)	38 (72%)	35 (58%)	0.199
Previous myocardial infarction, n (%)	2 (4%)	3 (5%)	1
Previous percutaneous coronary intervention, n (%)	21 (40%)	10 (17%)	0.012
Previous coronary artery bypass grafting, n (%)	4 (8%)	8 (13%)	0.490
Previous valve surgery, n (%)	5 (9%)	6 (10%)	1
Heart failure, n (%) (NYHA functional class ≥ III)	21 (40%)	45 (75%)	< 0.001
Aortic regurgitation grade ≥ moderate, n (%)	16 (32%)	17 (28%)	0.993
Pulmonary artery systolic pressure > 55 mmHg, n (%)	14 (26%)	11 (18%)	0.420
Mitral regurgitation ≥ moderate, n (%)	22 (42%)	21 (35%)	0.605
Left ventricular ejection fraction, %	49 ± 11	51 ± 9	0.136
EuroSCORE II, %	38.82 ± 18.27	43.06 ± 23.03	0.285

NYHA, New York Heart Association.

structive pulmonary disease and previous percutaneous coronary interventions were significantly higher, and the incidence of heart failure was significantly lower in Cohort A compared to Cohort B. However, there were no significant differences in age, gender, other baseline characteristics, and EuroSCORE II between the two groups.

Echocardiographic/computed tomographic measurements and procedural characteristics of the study patients

Echocardiographic/computed tomographic measurements and procedural characteristics are shown in Table 2. The Medtronic CoreValve was used in most of the TAVR patients. The mean measured aortic annulus diameter was significantly larger in Cohort A and therefore, more 29 mm and 31 mm CoreValve devices were implanted and a larger aortic valve area was obtained after TAVR in Cohort A. The TF approach was used significantly more frequently in Cohort B (Cohort A vs. Cohort B = 89% vs. 100%, p = 0.024), however, the other procedural characteristics including the use of the TF approach and immediate procedural outcomes were similar in both groups.

Baseline characteristics, echocardiographic/computed tomographic measurements, procedural characteristics, and immediate outcomes of the 11 patients with unfavorable iliofemoral anatomy

In Cohort A (March 2013-December 2014), 6 out of the 53 (11.4%) with unfavorable iliofemoral artery anatomy were treated with the trans-subclavian approach (n = 3, 5.7%) or direct aortic approach (n = 3, 5.7%); while in Cohort B (January 2015-March 2016), all of the five patients with unfavorable iliac artery anatomy were successfully treated with the use of an internal endoconduit, and none of them (0 of 60, 0%) needed a non-TF approach (Cohort A vs. Cohort B = 11.4% vs. 0%, p = 0.024) (Tables 3 and 4). Although some of the patients in Cohort A were proctored, the vessel sizes of the iliofemoral arteries of the patients who underwent TAVR through an alternative access in Cohort A and those who underwent TAVR using an internal endoconduit were similar (Table 4). The process and criteria regarding the decision making regarding the choice of vascular access was consistent throughout the whole study period.

A comparison of the patients with an unfavorable iliofemoral anatomy who underwent alternative access TAVR in Cohort A and TF TAVR with an internal endoconduit in Cohort B revealed no significant differences in baseline demographic characteristics, co-existing illnesses, procedural characteristics and immediate procedural outcomes (Tables 3 and 4).

Cases using an internal endoconduit for unfavorable iliac artery anatomy

The first case was an 87-year-old female. On arrival at our emergency department, she exhibited marked acute pulmonary edema, hypotension and impending cardiogenic shock. The need for an urgent intervention for this symptomatic severe AS was discussed with the patient and her family members. She refused to undergo open heart surgery, hence the heart team ultimately agreed to attempt TAVR.

We used real-time 3D transesophageal echocardiography (TEE) to define the diameter and size of the aortic annulus, which is the standard procedure for urgent or emergent TAVR in our current practice. The TEE showed severe AS (aortic valve area of 0.28 cm2, and mean and peak aortic valve gradients of 104 and 172 mmHg, respectively); an aortic annulus diameter (min × max) of 19.0 mm × 23.4 mm with an aortic annulus perimeter of 68.4 mm (derived average diameter 21.7mm); and coronary ostia heights of 12.6 and 13.8 mm for the left and right coronary arteries, respectively. Aortoiliac angiography was performed, which revealed severe stenosis of the right external iliac artery, measuring 4.65 mm at its narrowest point. The right internal iliac artery was occluded, and the right common iliac artery was also heavily calcified (Figure 2A). In addition, the left common iliac artery and the left external iliac artery contained extensive calcified vascular disease, with the narrowest point of the left external iliac artery measuring 4.25 mm.

To facilitate the passage of the 18 Fr introducer sheath, we selected a 10 mm × 10 cm Viabahn Endoprosthesis for use as an internal endoconduit to line the right external iliac artery with our proximal landing zone just 1 cm distal to the ostium of the right common iliac artery (Figure 2B). With the Viabahn Endoprosthesis deployed, a 10 mm × 4 cm noncompliant balloon angioplasty catheter (Mustang, Boston Scientific, Way Marl-

Table 2. Echocardiographic/computed tomographic measurements, procedural characteristics, and 30-day VARC complications of the study patients

	Cohort A (N = 53)	Cohort B (N = 60)	p value
Aortic annulus diameter, mm	23 ± 3	22 ± 2	0.024
Baseline echocardiography			
PPG, mmHg	76.32 ± 28.26	71.10 ± 32.67	0.369
MPG, mmHg	47.26 ± 17.73	42.55 ± 20.15	0.192
AVA, cm^2	0.67 ± 0.22	0.73 ± 0.28	0.200
THV valve device			
CoreValve, n (%)	52 (98%)	49 (81%)	0.012
Sapien XT, n (%)	1 (2%)	1 (2%)	1
Lotus, n (%)	0 (0%)	10 (17%)	0.005
THV valve size, mm			
23, n (%)	1 (2%)	8 (13%)	0.058
25, n (%)	0 (0%)	2 (3%)	0.531
26, n (%)	25 (47%)	33 (55%)	0.521
27, n (%)	0 (0%)	1 (2%)	1
29, n (%)	20 (38%)	15 (25%)	0.209
31, n (%)	7 (13%)	1 (2%)	0.043
TF approach, n (%)	47 (89%)	60 (100%)	0.024
Pre-dilatation, n (%)	49 (93%)	59 (98%)	0.290
Post-dilation, n (%)	42 (79%)	52 (87%)	0.423
Immediate TEE after procedure			
PPG, mmHg	16.94 ± 7.67	16.27 ± 7.68	0.641
MPG, mmHg	9.32 ± 4.34	8.85 ± 4.66	0.581
AVA, cm^2	1.81 ± 0.26	1.65 ± 0.27	0.001
Paravalvular aortic regurgitation ≥ moderate, n (%)	2 (4%)	6 (10%)	0.357
2^{nd} device needed, n (%)	6 (11%)	3 (5%)	0.373
Device success, n (%)	45 (85%)	57 (95%)	0.137
Procedural success, n (%)	52 (98%)	59 (98%)	1
Conversion to SAVR, n (%)	0 (0%)	0 (0%)	-
Coronary obstruction, n (%)	1 (2%)	0 (0%)	0.950
Annulus rupture, n (%)	0 (0%)	0 (0%)	-
30-day VARC-2 complications			
All-cause mortality, n (%)	2 (4%)	1 (2%)	0.913
Cardiac mortality, n (%)	2 (4%)	0 (0%)	0.422
Non-cardiac mortality, n (%)	0 (0%)	1 (2%)	1
Non-fatal myocardial infarction, n (%)	1 (2%)	0 (0%)	0.950
Non-fatal stroke, n (%)	1 (2%)	4 (7%)	0.439
Bleeding, major or life-threatening, n (%)	4 (8%)	5 (8%)	1
Vascular access site complication			
Minor, n (%)	4 (8%)	5 (8%)	1
Major, n (%)	3 (6%)	1 (2%)	0.524
Acute kidney injury			
Stage 1 or 2, n (%)	3 (6%)	4 (7%)	1
Stage 3, n (%)	2 (4%)	4 (7%)	0.792
Permanent pacemaker implantation, n (%)	8 (15%)	10 (17%)	1
Intensive care unit stay, days	4 ± 8	4 ± 9	0.983

AVA, aortic valve area; MPG, mean pressure gradient; PPG, peak pressure gradient; SAVR, surgical aortic valve replacement; TEE, transesophageal echocardiography; THV, transcatheter heart valve; VARC-2, Valve Academic Research Consortium-2.

Table 3. Baseline characteristics of the 11 patients with unfavorable ilio-femoral anatomies

	Cohort A (N = 6)	Cohort B (N = 5)	p value
Age, yrs	80 ± 5	85 ± 6	0.189
Male, n (%)	3 (50%)	1 (20%)	0.689
Body mass index, kg/m^2	21 ± 3	22 ± 3	0.431
Systemic hypertension, n (%)	4 (67%)	4 (80%)	1
Diabetes mellitus, n (%)	3 (50%)	3 (60%)	1
Peripheral vascular disease, n (%)	3 (50%)	5 (100%)	0.240
Previous stroke, n (%)	1 (17%)	0 (0%)	1
Previous atrial fibrillation, n (%)	2 (33%)	1 (20%)	1
Previous permanent pacemaker implantation, n (%)	0 (0%)	0 (0%)	-
Chronic obstructive pulmonary disease, n (%)	3 (50%)	0 (0%)	0.240
Serum creatinine, mg/dl	2.88 ± 2.69	1.06 ± 0.26	0.171
Anemia, n (%) (male < 14; female < 12)	6 (100%)	4 (80%)	0.924
Coronary artery disease, n (%)	4 (67%)	4 (80%)	1
Previous myocardial infarction, n (%)	0 (0%)	0 (0%)	-
Previous percutaneous coronary intervention, n (%)	3 (50%)	2 (40%)	1
Previous coronary artery bypass grafting, n (%)	0 (0%)	1 (20%)	0.924
Previous valve surgery, n (%)	0 (0%)	0 (0%)	-
Heart failure, n (%) (NYHA functional class ≥ III)	4 (67%)	5 (100%)	0.521
Aortic regurgitation grade ≥ moderate, n (%)	1 (17%)	0 (0%)	1
Pulmonary artery systolic pressure > 55 mmHg, n (%)	2 (33%)	2 (40%)	1
Mitral regurgitation ≥ moderate, n (%)	3 (50%)	2 (40%)	1
Left ventricular ejection fraction, %	46 ± 13	55 ± 0	0.175
EuroSCORE II, %	43.00 ± 17.84	56.07 ± 30.37	0.396

NYHA, New York Heart Association.

borough, MA, USA) was positioned within it. Under controlled, metered insufflation to its full profile (Figure 2C), the Viabahn stent was dilated to its maximum diameter along its entire length. An angiogram was then performed to ensure proper dilation of the right external iliac artery and that free rupture of the vessel had not occurred. With the right external iliac artery now dilated to 8 mm, we were able to insert an 18 Fr introducer sheath for TAVI (Figure 2D). A 26-mm CoreValve was then deployed at the aortic annulus under angiographic guidance. An immediate post-procedural aortogram showed that the CoreValve device was in a good position, with mild aortic regurgitation (Figure 2E). Intra-operative post-procedural TEE also demonstrated that the CoreValve was functioning well with a mean systolic pressure gradient of 8 mmHg, a peak systolic pressure gradient of 16 mmHg, and mild paravalvular aortic regurgitation. The 18 Fr sheath was withdrawn, and an angiogram obtained through the sheath demonstrated complete seal of the iliofemoral stent graft without evidence of kinking, narrowing, or extravasation (Figure 2F). The surgical cut-down was then closed and hemostasis obtained. A normal femoral pulse was present upon completion of the procedure, and the patient was neurologically intact. Her symptoms subsequently improved from NYHA class IV to class II, and she was discharged from the hospital on post-procedure day 12 without any significant complications.

Four subsequent instances in which an unfavorable iliac artery anatomy was encountered in the setting of TAVR in Cohort B were similarly dealt with using internal endoconduits to successfully allow passage of the delivery sheath, providing a seal for the controlled iliac artery rupture. No complications of decreased pelvic circulation were noted, and no late complications related to a decrease in pelvic perfusion or iliac artery hemorrhage were noted in any of the patients.

DISCUSSION

The TF approach is typically used as the default vas-

Table 4. Echocardiographic/computed tomographic measurements, procedural characteristics, and immediate procedural outcomes of the 11 patients with unfavorable ilio-femoral anatomies

	Cohort A (N = 6)	Cohort B (N = 5)	p value
Aortic annulus diameter, mm	24.43 ± 2.38	20.66 ± 0.82	0.008
Baseline echocardiography			
PPG, mmHg	81.33 ± 22.35	92.00 ± 59.69	0.721
MPG, mmHg	50.67 ± 15.46	56.00 ± 35.71	0.768
AVA, cm^2	0.58 ± 0.19	0.56 ± 0.24	0.892
Vessel sizes of the ilio-femoral arteries			
Left common iliac a. diameter, mm	4.62 ± 2.48	6.09 ± 0.51	0.358
Left external iliac a. diameter, mm	4.47 ± 2.66	5.08 ± 0.45	0.671
Left common femoral a. diameter, mm	4.91 ± 1.34	5.21 ± 0.55	0.694
Right common iliac a. diameter, mm	5.63 ± 1.10	6.23 ± 1.25	0.465
Right external iliac a. diameter, mm	5.81 ± 0.88	5.30 ± 0.59	0.357
Right common femoral a. diameter, mm	4.28 ± 1.97	5.35 ± 0.92	0.355
Vascular access			
Trans-subclavian, n (%)	3 (50%)	0 (0%)	0.240
Trans-aortic, n (%)	3 (50%)	0 (0%)	0.240
Transfemoral (with internal endoconduit), n (%)	0 (0%)	5 (100%)	0.007
THV valve device			
CoreValve, n (%)	6 (100%)	3 (60%)	0.354
Lotus, n (%)	0 (0%)	2 (40%)	0.354
THV valve size, mm			
23, n (%)	0 (0%)	2 (40%)	0.354
26, n (%)	2 (33%)	3 (60%)	0.782
29, n (%)	4 (67%)	0 (0%)	0.097
Pre-dilatation, n (%)	5 (83%)	5 (100%)	1
Post-dilation, n (%)	5 (83%)	3 (60%)	0.853
Immediate TEE after procedure			
PPG, mmHg	14.67 ± 2.66	24.20 ± 16.57	0.194
MPG, mmHg	7.83 ± 1.72	13.60 ± 11.06	0.235
AVA, cm^2	1.71 ± 0.16	1.80 ± 0.18	0.421
Paravalvular aortic regurgitation ≥ moderate, n (%)	0 (0%)	0 (0%)	-
2^{nd} device needed, n (%)	1 (17%)	0 (0%)	1
Device success, n (%)	5 (83%)	5 (100%)	1
Procedural success, n (%)	6 (100%)	5 (100%)	-
Conversion to SAVR, n (%)	0 (0%)	0 (0%)	-
Coronary obstruction, n (%)	0 (0%)	0 (0%)	-
Annulus rupture, n (%)	0 (0%)	0 (0%)	-

AVA, aortic valve area; MPG, mean pressure gradient; PPG, peak pressure gradient; SAVR, surgical aortic valve replacement; TEE, transesophageal echocardiography; THV, transcatheter heart valve.

cular access for TAVR. However, despite advances in delivery system design, unfavorable iliac artery anatomy remains one of the most common difficulties in using TAVR to treat patients with severe valvular AS.[4-8] Various vascular accesses can be used to overcome these obstacles, each possessing advantages and disadvantages with which the operators must be familiar.[4-8] Although all of these 'alternative' TAVR access routes have applications, they also have limitations; therefore, a patient-tailored strategy with a pre-procedural access decision remains essential.[4-8] Herein, we reported five patients with severe valvular AS and unfavorable iliac artery anatomy in the setting of a TF approach for TAVR. We also described a novel approach with the use of percutaneous internal endoconduits for TAVR, and demonstrated that its use may increase the number of TAVR

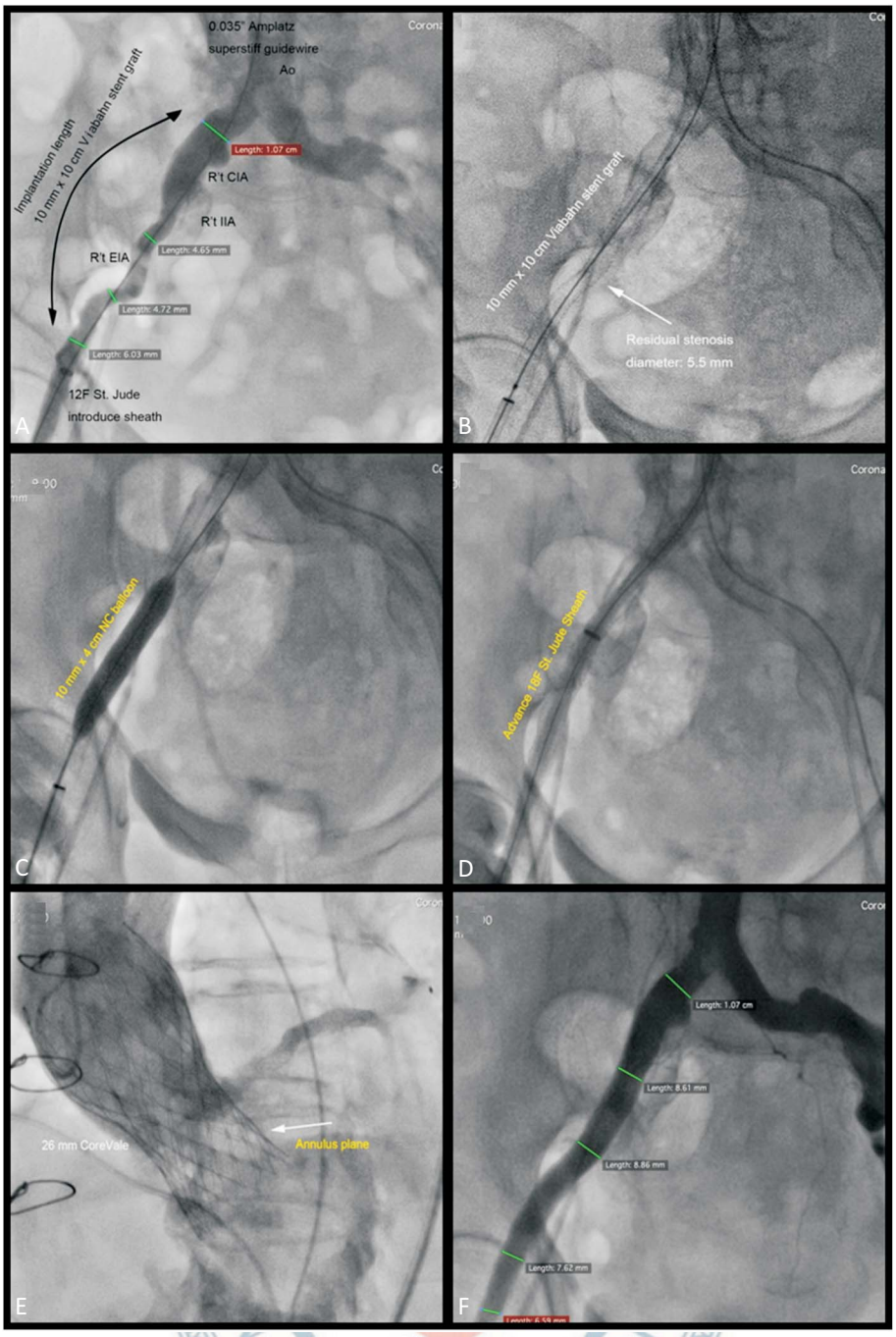

Figure 2. *(A) Aorto-iliac angiogram showing a severely diseased right common iliac artery and external iliac artery. The right internal iliac artery was occluded. (B) A 10 mm × 10 cm Viabahn endoprosthesis for use as an internal endoconduit was lined in the right external iliac artery and common iliac artery. (C) Aggressive angioplasty with a 10-mm noncompliant balloon within the internal endoconduit. (D) A delivery sheath (18 Fr) is shown passing through the internal endoconduit after balloon angioplasty. (E) An immediate post-procedural aortogram after TAVI showed good positioning of the CoreValve and mild aortic regurgitation. (F) A peripheral angiogram was performed to ensure proper dilation of the right external iliac artery and that free rupture of the vessel had not occurred.*

procedures that can be performed through femoral access to substantially reduce the need for non-TF approaches.

To date, few studies have directly compared clinical outcomes between TF and non-TF TAVR. The clinical outcomes of transapical and direct aortic TAVR have

been associated with a similar survival duration, and both significantly worse than the TF route, especially in institutions performing a low volume of transapical TAVR.[4-8] This difference in mortality rate may be due to the more advanced risk profile in non-TF patients, however it is possible that the procedures themselves confer an increased risk. For example, the transapical approach is technically demanding as it requires direct left-ventricle-apex surgical exposure, which can be structurally friable in elderly patients and in patients with severe hypertrophy.[8,19-21] Although the direct aortic approach is an encouraging technique that appears to have a shorter learning curve and does not interfere with left ventricular function, this approach is mainly preferred by experienced operators and is only used in less than 10% of patients.[8,19,20,22] Subclavian access may represent the safest non-TF access route for TAVR because its clinical outcomes are not significantly different from TF.[8,19,20,23] However, the presence of an internal mammary coronary artery bypass graft is a relative contraindication for the subclavian approach.[8,19,20,23] Moreover, specific vascular complications have been associated with alternative access routes.[8,19-23] Therefore, efforts to make the TF procedure even less invasive and to avoid the complications inherent in this approach are warranted. In doing so, we can expand the number of patients eligible for TF TAVR and avoid possible devastating access-related complications of non-femoral approaches.

One solution could be to optimize the management of vascular access in TF TAVR.[4-8] In a recently published study from the UK TAVI registry, surgical femoral approaches were used in approximately 11% of procedures in 2007 to 2009, but this increased in later years to about 20%, despite a reduction in the size of many TAVR delivery systems.[19] The authors explained that this may be due to the early attempts to make TAVR as "non-invasive" as possible with the use of percutaneous TF access even in settings where the anatomy was unfavorable, which may have resulted in vascular complications that may be avoided with the use of a surgical femoral approach.[19] Their data support this explanation, showing a higher vascular complication rate during the early years when surgical femoral access rates were low.[19] Hence, it cannot be over-emphasized that in addition to being able to recognize and manage potential vascular complications, TAVR operators should also be able to identify unfavorable anatomy that carries a high risk of devastating complications in advance, and to adopt a surgical femoral approach to avoid them.[24,25] Another solution could be to optimize the device function with superior deliverability. Accordingly, several new low-profile delivery systems to facilitate valve passage and to reduce the rate of vascular complications related to TAVI have been developed.[9-12] The initial clinical experience has been promising, however a larger series with longer follow-up are warranted to confirm these initial positive results.[9-12] As the sizes of access sheaths reduce further, it is possible that more patients will be eligible for the TF approach resulting in a reduction in non-TF procedures.

Another attractive alternative is to use internal endoconduits for unfavorable iliac artery anatomy in patients undergoing TF TAVR as a one-stage procedure, as demonstrated in the present study. The endoconduit was first described by Yano et al. in 2001 as an alternative approach for difficult iliofemoral anatomy in stent-graft repairs of aortic aneurysms.[26] In 2008, Peterson et al. first used the percutaneous covered stent technique to overcome access limitations in the setting of TEVAR.[13] The use of an internal endoconduit can avoid the high mortality and morbidity rates of direct prosthetic iliac conduits to bypass difficult iliofemoral access for stent-graft delivery.[13-16] Moreover, iliac artery endoconduits have emerged as important alternatives to retroperitoneal open iliac conduits to aid in TF delivery for TEVAR.[15] The procedural techniques and potential complications relevant to internal endoconduits have been discussed in detail.[13-16] According to the recommendations of these studies, the commercially available Viabahn-covered stent is recommended over other iliac limb endoprostheses due to the advantages of a lower profile, less oversizing, and greater flexibility.[17] This is why we chose the Viabahn stent in our cases, which showed excellent results. In our series, passage of an introducer sheath with an outer diameter of 18 to 20 Fr and the TAVR device through a 9-mm to 10-mm Viabahn, after angioplasty with a noncompliant balloon, was easily achieved, and the whole TAVR procedure could be accomplished immediately after the set-up of an internal endoconduit without difficulty, resulting in good immediate results.

One of the major concerns with endoconduits is the possible coverage of the origin of the internal iliac ar-

tery, with associated complications such as spinal cord ischemia, gluteal necrosis, and buttock claudication.[13-16] Although embolization of a patent internal iliac artery adjacent to the diseased segment before deployment of the endoconduit may prevent retrograde hemorrhage, this was not necessary in our patients because their internal iliac arteries were also severely diseased and occluded. Other adverse events associated with this procedure such as hemorrhage or hypotension caused by iliac artery rupture or retroperitoneal dissection[13-16] were also theoretically possible, but fortunately were not encountered in our cases. Although some operators have attempted peripheral vessel pre-dilatation with a semi-compliant balloon or stenting before the passage of large bore sheaths and TAVR devices in patients with small diseased peripheral vessels,[27,28] this carries the risk of stent shifting during advancement of the sheath, aortic balloon, and valve, and a high rate of acute peri-procedural complications.

The most impressive and convincing result of our experience was that, since we adopted internal endoconduits as a routine approach for the patients undergoing TAVR with an unfavorable iliac artery anatomy, all five of the patients among the 60 consecutive TAVR cases in the second cohort (January 2015-March 2016) were successfully treated by the TF approach. Moreover, the six cases in Cohort A would have been solved using endoconduits if we had applied them it earlier. However, although the use of iliac endoconduits can potentially broaden the applicability of the TF approach for TAVR without substantially increasing the mortality and morbidity rates if iliofemoral artery problems are anticipated before TAVR and the endoconduit is planned as an elective procedure, not all access problems can be solved with this endoconduit method. In the extreme cases with peripheral vascular diseases involving the aorto-iliac junction and circumferential un-dilatable calcification in addition to stenosis, if transapical, direct aortic, or subclavian implantation is not suitable, sheathless implantation of a self-expanding aortic valve or transcaval approach may be other options.[29,30,31]

CONCLUSIONS

The use of internal endoconduits can further increase the number of patients with AS who can be treated with TAVI through a femoral artery access. Therefore, until the valve bioprostheses used in TAVR become universally available with a lower profile design, we suggest that the off-label use of iliac stent-grafts as internal endoconduits may allow for significantly more selected TAVR cases to be performed with a femoral access, and that this may significantly reduce the rate of vascular complications. Nonetheless, larger series need to be examined before any conclusions can be reached about the safety of this technique.

ACKNOWLEDGEMENTS

We thank Ms. Chin-Feng Cheng for her assistance in preparing this manuscript.

CONFLICTS OF INTEREST

All the authors declare no conflict of interest.

REFERENCES

1. Nishimura RA, Otto CM, Bonow RO, et al. 2014 AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease: executive summary: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation* 2014;129:2440-92.
2. Thyregod HG, Steinbrüchel DA, Ihlemann N, et al. Transcatheter versus surgical aortic valve replacement in patients with severe aortic valve stenosis: 1-year results from the all-comers NOTION randomized clinical trial. *J Am Coll Cardiol* 2015;65:2184-94.
3. Leon MB, Smith CR, Mack MJ, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. *N Engl J Med* 2016;374:1609-20.
4. Toggweiler S, Leipsic J, Binder RK, et al. Management of vascular access in transcatheter aortic valve replacement: part 1: basic anatomy, imaging, sheaths, wires, and access routes. *JACC Cardiovasc Interv* 2013;6:643-53.
5. Toggweiler S, Leipsic J, Binder RK, et al. Management of vascular access in transcatheter aortic valve replacement: part 2: vascular complications. *JACC Cardiovasc Interv* 2013;6:767-76.
6. Bax JJ, Delgado V, Bapat V, et al. Open issues in transcatheter aortic valve implantation. Part 1: patient selection and treatment strategy for transcatheter aortic valve implantation. *Eur Heart J* 2014;35:2627-38.

7. Bax JJ, Delgado V, Bapat V, et al. Open issues in transcatheter aortic valve implantation. Part 2: procedural issues and outcomes after transcatheter aortic valve implantation. *Eur Heart J* 2014; 35:2639-54.
8. Blackman DJ, Baxter PD, Gale CP, et al. Do outcomes from transcatheter aortic valve implantation vary according to access route and valve type? The UK TAVI Registry. *J Interv Cardiol* 2014;27: 86-95.
9. Eggebrecht H, Kahlert P, Thielmann M, et al. Usefulness of a novel balloon-expandable vascular sheath for facilitated large-bore arterial access for transcatheter aortic valve implantation. *EuroIntervention* 2011;6:893-4.
10. Dimitriadis Z, Scholtz W, Faber L, et al. Balloon expandable sheath for transfemoral aortic valve implantation: a viable option for patients with challenging access. *J Interv Cardiol* 2013; 26:84-9.
11. Sinning JM, Werner N, Nickenig G, Grube E. Medtronic CoreValve Evolut R with EnVeo R. *EuroIntervention* 2013;9(Suppl):S95-6.
12. Borz B, Durand E, Tron C, et al. Expandable sheath for transfemoral transcatheter aortic valve replacement: procedural outcomes and complications. *Catheter Cardiovasc Interv* 2014;83: E227-32.
13. Peterson BG, Matsumura JS. Internal endoconduit: an innovative technique to address unfavorable iliac artery anatomy encountered during thoracic endovascular aortic repair. *J Vasc Surg* 2008;47:441-5.
14. Peterson BG. Conduits and endoconduits, percutaneous access. *J Vasc Surg* 2010;52(4 suppl):60S-4S.
15. van Bogerijen GH, Williams DM, Eliason JL, et al. Alternative access techniques with thoracic endovascular aortic repair, open iliac conduit versus endoconduit technique. *J Vasc Surg* 2014;60: 1168-76.
16. Wu T, Carson JG, Skelly CL. Use of internal endoconduits as an adjunct to endovascular aneurysm repair in the setting of challenging aortoiliac anatomy. *Ann Vasc Surg* 2010;24:114.e7-11.
17. De Backer O, Arnous S, Sandholt B, et al. Safety and efficacy of using the Viabahn endoprosthesis for percutaneous treatment of vascular access complications after transfemoral aortic valve implantation. *Am J Cardiol* 2015;115:1123-9.
18. 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;33:2403-18.
19. Ludman PF, Moat N, de Belder MA, et al. Transcatheter aortic valve implantation in the United Kingdom: temporal trends, predictors of outcome, and 6-year follow-up: a report from the UK transcatheter aortic valve implantation (TAVI) registry, 2007 to 2012. *Circulation* 2015;131:1181-90.
20. Fröhlich GM, Baxter PD, Malkin CJ, et al. Comparative survival after transapical, direct aortic, and subclavian transcatheter aortic valve implantation (data from the UK TAVI Registry). *Am J Cardiol* 2015;116:1555-9.
21. van der Boon RM, Marcheix B, Tchetche D, et al. Transapical versus transfemoral aortic valve implantation: a multicenter collaborative study. *Ann Thorac Surg* 2014;97:22-8.
22. Bapat VN, Bruschi G. Transaortic access is the key to success. *EuroIntervention* 2013;9(Suppl):S25-32.
23. Petronio AS, De Carlo M, Giannini C, et al. Subclavian TAVI: more than an alternative access route. *EuroIntervention* 2013;9(Suppl): S33-7.
24. Zamorano JL, Goncalves A, Lang R. Imaging to select and guide transcatheter aortic valve implantation. *Eur Heart J* 2014;35: 1578-87.
25. Reinthaler M, Aggarwal SK, De Palma R, et al. Predictors of clinical outcome in transfemoral TAVI: circumferential iliofemoral calcifications and manufacturer-derived recommendations. *Anatol J Cardiol* 2015;15:297-305.
26. Yano OJ, Faries PL, Morrissey N, et al. Ancillary techniques to facilitate endovascular repair of aortic aneurysms. *J Vasc Surg* 2001;34:69-75.
27. Ruparelia N, Buzzatti N, Romano V, et al. Transfemoral transcatheter aortic valve implantation in patients with small diseased peripheral vessels. *Cardiovasc Revasc Med* 2015;16:326-30.
28. Aslan AN, Kasapkara HA, Sivri S, et al. Successful simultaneous ipsilateral stenting of common iliac artery stenosis and transfemoral aortic valve replacement. *Turk Kardiyol Dern Ars* 2017; 45:89-93.
29. Geis NA, Chorianopoulos E, Kallenbach K, et al. Feasibility of sheathless transfemoral aortic valve implantation in patients with small access vessel diameters. *Clin Res Cardiol* 2014;103: 775-80.
30. Greenbaum AB, Babaliaros VC, Chen MY, et al. Transcaval access and closure for transcatheter aortic valve replacement: a prospective investigation. *J Am Coll Cardiol* 2017;69:511-21.
31. Chen YH, Chang HH, Chen PL, et al. Procedural characteristics and outcomes of transcatheter aortic valve implantation: a single-center experience of the first 100 inoperable or high surgical risk patients with severe aortic stenosis. *Acta Cardiol Sin* 2017; 33:339-49.