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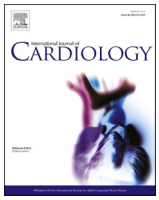

# Unilateral-access vs. bilateral-access in transfemoral transcatheter aortic valve replacement: A slim fit approach

Ana Rita Pereira [a,b,1], Ahmed A.M. al Jaff [a,1], Jose Montero-Cabezas [a], Arend de Weger [c], Dario Candura [c], Johan Wouter Jukema [a,d], Fatih Arslan [a], Madelien V. Regeer [a], Nina Ajmone Marsan [a], Frank van-der-Kley [a,*]

[a] Department of Cardiology, Leiden University Medical Center, Leiden, the Netherlands
[b] Department of Cardiology, Hospital Garcia de Orta, Almada, Portugal
[c] Department of Cardio-Thoracic Surgery, Leiden University Medical Center, Leiden, the Netherlands
[d] The Netherlands Heart Institute, Utrecht, the Netherlands

A B S T R A C T

*Background:* Vascular complications remain prevalent on transfemoral transcatheter aortic valve replacement (TF-TAVR) with a significant proportion related to the secondary arterial access. We hypothesized that placing the second sheath ipsilateral and distal to the delivery sheath could reduce vascular complications with similar safety and efficacy.

*Objectives:* Comparing vascular complications and clinical outcomes when placing the secondary arterial sheath in the ipsilateral (unilateral-access) versus in the contralateral (bilateral-access) femoral artery during TF-TAVR.

*Methods:* Patients who underwent TF-TAVR using unilateral-access as first-choice approach were retrospectively compared with a contemporaneous bilateral-access group. The primary endpoint was the incidence of vascular complications related to femoral access according to the VARC-3 criteria. A propensity-score analysis was performed accounting for the differences in clinical, vascular, and procedural characteristics.

*Results:* A total of 217 patients were included, of whom 150 (69.1 %) underwent TF-TAVR through bilateral- and 67 (30.9 %) through unilateral-access. Vascular complications occurred in 16.0 % of the bilateral-access group and 10.4 % of the unilateral-access group ($p = 0.280$). The unilateral-access group achieved high procedural success with normalization of peak aortic velocity and low rates of paravalvular leaks, valve migration and pacemaker requirement. After propensity-score matching, the overall complications rate was superior in the bilateral-access group (54.4 % vs 35.1 %, $p = 0.038$) due to a trend of higher vascular complications (26.3 % vs 12.3 %, $p = 0.058$) and a significant higher occurrence of bleeding complications (17.5 % vs 1.8 %, $p = 0.008$).

*Conclusions:* Unilateral-access TF-TAVR is feasible, safe, and potentially enhances procedural efficiency and patient satisfaction while maintaining the capacity for bailout interventions in managing vascular complications.

## 1. Introduction

Transcatheter aortic valve replacement (TAVR) is currently the recommended treatment for severe aortic stenosis in older patients or those considered at high-risk or unsuitable for surgery [1,2]. Among patients undergoing TAVR, the transfemoral approach (TF-TAVR) is the most common and preferred route [1–3]. In addition to the femoral valve-delivery sheath, a second arterial access is required for aortic root angiography in order to visualize the aortic cusps for valve positioning and implantation. It is also used for peripheral intervention in case of vascular complications at the main vascular access. Since the first TAVR was performed [4], better procedural planning, ultrasound-guided puncture of vascular access sites, advancements in valve-delivery systems, and improvements of closure device techniques have collectively contributed to reducing the rate of vascular complications [3,5–7]. Despite these advancements, vascular complications remain a prevalent procedural risk and are associated with increased morbidity and mortality. Of note, a significant proportion of these complications can be attributed to the secondary arterial access, often established through the contralateral femoral artery or radial artery [3,8]. In this regard, it is

*Abbreviations and acronyms:* CFA, Common femoral artery; CIA, Common iliac artery; CT, Computed tomography; EIA, External iliac artery; MDCT, Multidetector computed tomography; NYHA, New York Heart Association; PVL, Paravalvular leak; SFA, Superficial femoral artery; TAVR, Transcatheter aortic valve replacement; TF-TAVR, Transfemoral transcatheter aortic valve replacement; VARC, Valve Academic Research Consortium.

* Corresponding author at: Department of Cardiology, Leiden University Medical Center, Albinusdreef 2, 2333 ZA. Postbus 9600, 2300 RC Leiden, the Netherlands.
*E-mail address:* f.van_der_kley@lumc.nl (F. van-der-Kley).

[1] These authors contributed equally to this work and share first authorship.

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hypothesized that an unilateral-access approach could potentially reduce vascular access-related complications for TF-TAVR. In the unilateral approach, the main arterial access is located at the common femoral artery (CFA), with the secondary arterial access either at the CFA distal to the main vascular access or at the superficial femoral artery (SFA). This study aims to determine the impact of unilateral vs. bilateral access TF-TAVR, focusing on vascular complications and clinical outcomes.

## 2. Methods

### 2.1. Study population

All consecutive patients who underwent TF-TAVR using unilateral-access as the first approach from February 2020 to February 2021 were included in this proof-of-concept, single-center, retrospective, observational cohort study. The unilateral-access (main arterial access at the CFA and secondary arterial access at the ipsilateral SFA) was adopted as an approach for TF-TAVR in February 2020. Patients underwent unilateral access at operator's discretion if they presented a mean luminal diameter of the iliofemoral axis $\geq$ 6 mm. This criterion took into account the commonly used sheath delivery size (14-18Fr) in addition to the pigtail catheter size (5-6Fr).

For comparison purpose, a reference group was defined including all consecutive patients who underwent TF-TAVR using bilateral access (main arterial access at the CFA and secondary arterial access at the contralateral CFA) in 2019. In 2019, the bilateral-access was the default approach for TF-TAVR. At that time, the technique was well-established, materials and valve generation were analogous, and the operator's learning curve had already been achieved.

Exclusion criteria for both groups included nonfemoral access for valve replacement, bilateral-or unilateral-access as bail-out approach instead first-choice approach, valve-in-valve TAVR, and absence of contrast-enhanced multidetector computed tomography (MDCT) before TAVR.

Clinical, biochemical, echocardiographic, preprocedural MDCT, procedural, and outcome data were collected from the departmental electronic clinical files (EPD vision, version 12.9.9.3; Leiden, the Netherlands) and retrospectively analyzed.

The institutional review board approved the study and waived the need of patient's written informed consent for this retrospective analysis of clinically acquired data.

### 2.2. Clinical evaluation

All patients were examined at the outpatient clinic and evaluated by a multidisciplinary heart-team, which included clinical cardiologists, cardiac imaging specialists, interventional cardiologists, and cardiac surgeons. The preprocedural assessment was performed following standard protocols as previously described [1,2,9,10].

### 2.3. Multidetector computed tomography data acquisition

All patients underwent preprocedural MDCT for assessment of the aortic root and peripheral vascular anatomy. MDCT data were acquired using either a 64-detector (Aquilion64, Toshiba Medical Systems, Otawara, Japan) or 320-detector row CT scanner (AquilionOne, Toshiba Medical Systems, Tochigi-ken, Japan) according to a dedicated cardiac protocol, as earlier described [9]. Details can be found in the supplementary material (supplement 1).

### 2.4. Vascular access evaluation

Vascular accesses were evaluated using the 3mensio Valve™ software, release 10.0 (Pie Medical Imaging, Maastricht, the Netherlands). All analyses were conducted by an experienced user, who was blinded to patient details and clinical outcomes. Vascular diameters and areas were determined using center-line reconstruction to ensure perpendicularity and accurate measurement of the vascular lumen. A three-dimensional reconstruction model was used to determine the absolute angle of the iliofemoral system. For each patient, the following measurements were obtained on the side of the delivery sheath:

1. The minimal luminal area at the level of the common iliac artery (CIA), external iliac artery (EIA) and CFA – $mm^2$;
2. Mean luminal diameter at the point of minimal luminal area – mm;
3. Calcification: defined as a total circumferential arc $<90^\circ$ (mild), $90–180^\circ$ (moderate), $> 180^\circ$ (severe) according to previous publications [11,12];
4. Tortuosity: defined as the absolute angle of the iliofemoral system and classified as mild ($<45^\circ$), moderate ($45–90^\circ$), and severe ($>90^\circ$) according to previous publication [11,12];
5. Sheath to femoral artery ratio (SFAR) – calculated by dividing external sheath diameter in mm by the minimal diameter of the CFA [11];
6. Sheath to femoral artery area ratio (SFAAR) – calculated by dividing the external sheath area in $mm^2$ by the minimal area of the CFA [13].

Fig. 1 illustrates the computed tomography analysis of the iliofemoral system.

### 2.5. Transcatheter aortic valve replacement

All TF-TAVR procedures were performed following standard protocols according to the best contemporary clinical practices, including valve type, device sizing and periprocedural anti-thrombotic therapy management [9,10]. In both groups, femoral punctures were performed under ultrasound-guidance. In the bilateral-access group, arterial accesses were obtained in both CFAs. In the unilateral-access group, the primary femoral arterial access was obtained in the CFA, and the secondary sheath was placed at the ipsilateral SFA. Generally, the sequence involved an echo-guided puncture of the CFA, insertion of 0.035-in. wire, preclosing with two Perclose Proglide™ devices (Abbott Vascular, Santa Clara, California) and placement of an 8Fr sheath. This was followed by an echo-guided puncture of the SFA (unilateral-access) or contralateral CFA (bilateral-access) for placement of a 6Fr sheath as secondary arterial access. Cardiac pacing during aortic balloon valvuloplasty (when necessary) and valve deployment was performed using either the delivery wire or with a transvenous temporary pacemaker through a 5Fr sheath placed in the femoral vein. In the unilateral-access group, the ipsilateral femoral vein was used. For the bilateral group, the choice of location of the venous sheath (ipsilateral or contralateral) was left at operator's discretion. At the end of the procedure, hemostasis at the primary vascular access was achieved using the preclosing systems. An angiogram of the iliofemoral system was performed via the secondary sheath. If a vascular complication requiring intervention was detected, the secondary sheath was used for this purpose. Final hemostasis of the secondary arterial access was performed using a collagen plug-based device (AngioSeal™; Terumo Corporation, Tokyo, Japan). Femoral vein hemostasis was achieved by manual compression. Fig. 2 illustrates the unilateral-access technique. Postprocedural transthoracic echocardiogram were performed in all patients.

### 2.6. Clinical follow-up and outcomes definition

The primary endpoint of this study was the incidence of vascular complications (sub-classified as minor and major complications) related to femoral access. Secondary endpoints included: (1) 30-day all-cause mortality, (2) 30-day all-cause- hospital readmission, (3) 30-day stroke or transient ischemic attack, (4) 30-day bleeding, (5) 30-day new permanent pacemaker implantation, (6) peri-procedural myocardial infarction ($\leq$ 72 h after the index procedure), (8) 72-h acute kidney

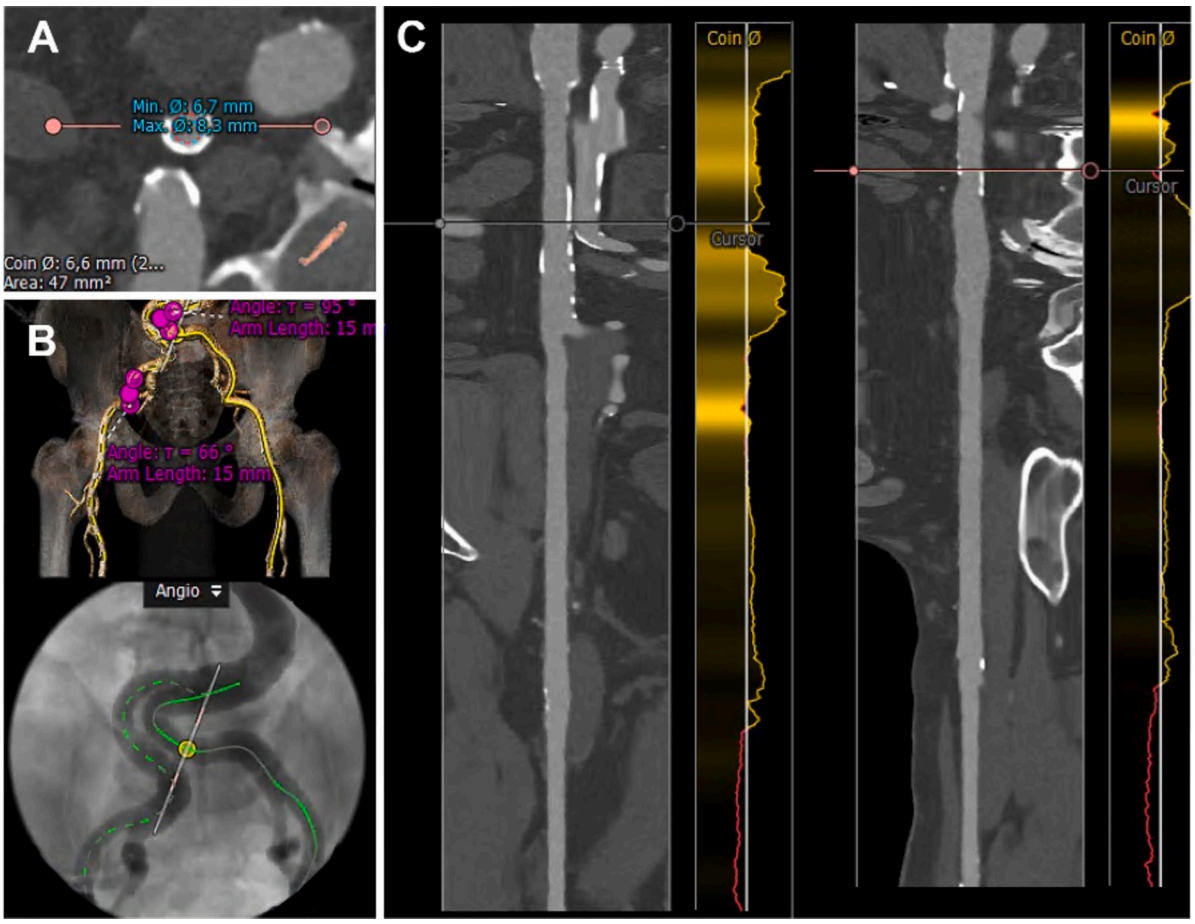


**Fig. 1.** Computed tomography-analysis of the iliofemoral system using the 3mensio Valve™ software. A) Vessel diameter and area; B) Three-dimensional reconstruction model used for the absolute angle of the iliofemoral system; C) Centre-line reconstruction of the iliofemoral system to ensure measurements of vessel diameter and area perpendicular to the axis of the vessel.

injury and (9) valve migration. Overall complication rate was defined as the occurrence of any primary or secondary endpoint. All the endpoints were retrospectively collected from the electronic clinical files and reported according to the Valve Academic Research Consortium 3 (VARC-3) criteria [14]. This process were performed by one investigator and independently validated by another one, both blinded for the type of vascular access performed (unilateral versus bilateral access).

### 2.7. Statistical analysis

Normally distributed continuous variables are presented as mean ± standard deviation and compared using the Student's *t*-test. Non-normally distributed continuous variables are presented as medians with interquartile ranges (IQR) and compared using the Mann-Whitney *U* test Categorical variables are expressed as frequencies (percentage) and compared using the chi-squared test or Fisher exact test as appropriate. To minimize treatment-selection bias and account for clinical, vascular, and procedural differences, a propensity score analysis using the nearest neighbor method (1,1 matching with a tolerance of 0.05) was performed to compare the unilateral and bilateral access groups. This yielded 57 patients in each matched cohort. The following variables were selected for matching, since they have been previously identified as independent factors for vascular complications in previous studies: age, gender, peripheral arterial disease, valve type, main access sheath size, main access closure device, vessel mean luminal diameter, iliofemoral tortuosity and iliofemoral calcification [5,11–13,15]. A post-hoc power analysis was also conducted to assess the adequacy of the sample size for detecting statistically significant differences in the endpoints. All statistical tests were 2-sided and $p$ values $<0.05$ were considered statistically significant. However, $p$-values were not adjusted for multiple comparisons, so results should be interpreted with caution regarding the potential for type I errors. All statistical analyses, excluding the power analysis, were performed using SPSS, version 29.00 (IBM SPSS, Chicago). The power analysis was conducted with G*Power software, version 3.1.9.6 (Heinrich-Heine-Universität, Düsseldorf, Germany) using a chi-squared test with an alpha error probability of 0.05.

## 3. Results

### 3.1. Baseline characteristics

A total of 217 patients were included in the final analysis: 150 (69.1 %) underwent the procedure via bilateral femoral access, and 67 (30.9 %) via unilateral femoral access.

Mean age was 78.6 ± 7.6 years in the bilateral-access group and 77.6 ± 8.2 years in the unilateral-access group ($p = 0.379$); 53.9 % of patients were male (52.0 % in bilateral vs. 58.2 % in unilateral group, $p = 0.397$). Other baseline characteristics were also comparable between groups with exception of dyslipidaemia (69.3 % in bilateral vs. 41.8 % in unilateral group, $p < 0.01$) and NYHA functional class, which was worse in the unilateral-access patients ($p = 0.039$). Baseline characteristics are summarized in Table 1.

### 3.2. Main vascular access site

Characteristics of the main vascular access site measured by MDCT

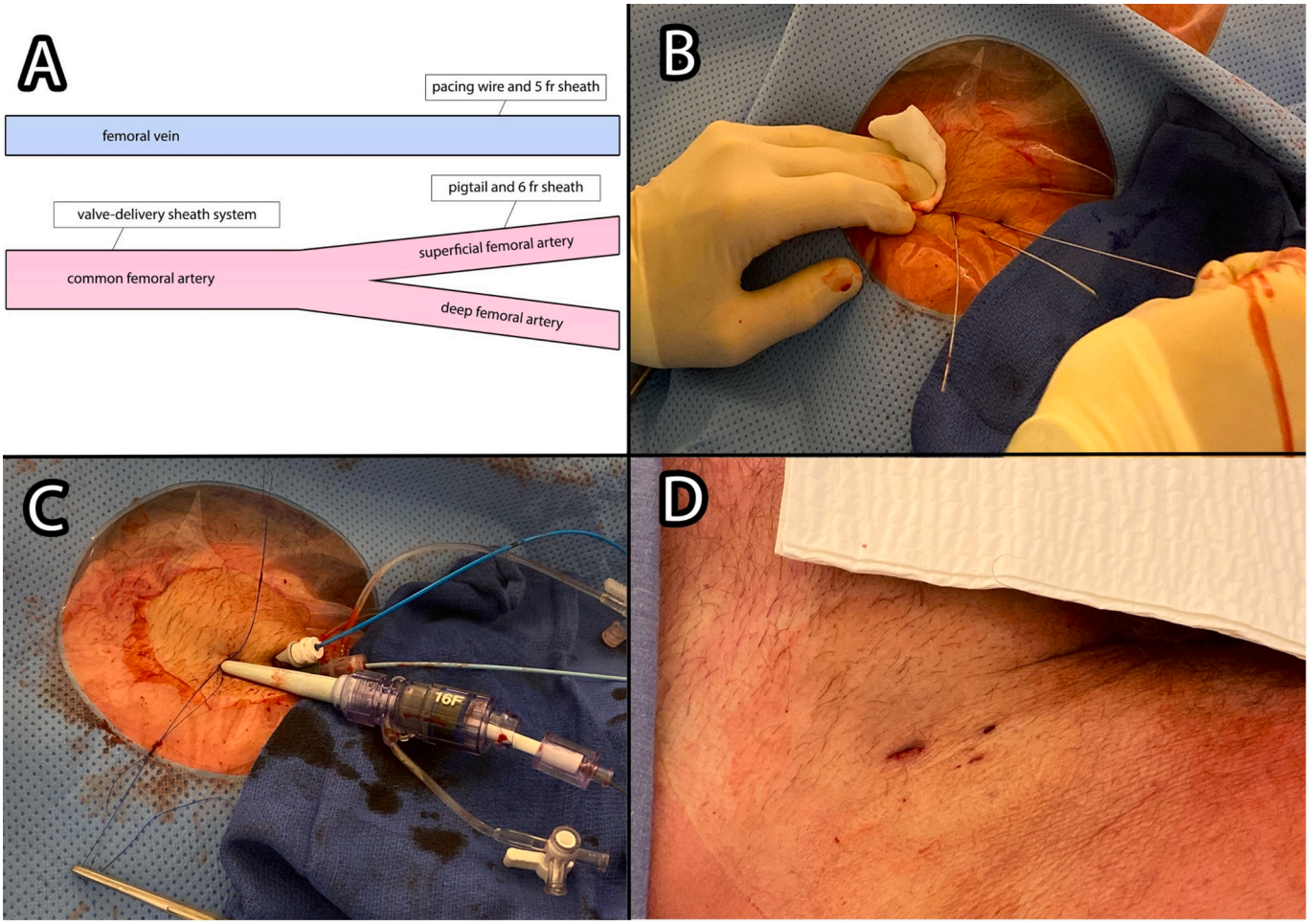


**Fig. 2.** Unilateral-access transfemoral technique. A) In unilateral-access group, main femoral arterial access is obtained in the common femoral artery (CFA); secondary arterial access is placed at the ipsilateral superficial femoral artery (SFA) and venous access for transvenous temporary pacemaker is placed at the ipsilateral femoral vein (except when pacing is performed with the delivery wire). B) Guidewires in place after ultrasound-guided femoral punctures; C) 16Fr valve delivery system is placed at the main femoral arterial access (CFA), 6Fr sheath and pigtail catheter for aortic root angiography are placed at the secondary arterial access (SFA); optional: 5Fr sheath and transvenous temporary pacemaker are placed at the ipsilateral femoral vein. Note that two preclosing suture-based devices are being used at the delivery system site. D) Final result after arterial and venous sheaths removal and hemostasis.
CFA – common femoral artery; Fr – French; SFA – superficial femoral artery.

are listed in Table 2. The mean dimensions of the CFAs and the CIAs were similar between unilateral- and bilateral-access groups, except for the EIAs which were significantly larger dimensions in the unilateral-access group. The majority of patients had moderate or severe tortuosity (51.2 %) and calcification (55.3 %) with no differences among groups. There was also no significant difference in the calculated sheath-to-artery ratios.

### 3.3. Procedural characteristics

The procedure was performed under local anaesthesia in 202 patients (93.1 %). Sheath size was significantly higher in the unilateral-access group with 70.1 % of patients receiving a 16Fr sheath compared to 34.0 % in the bilateral-access group ($p < 0.001$). The most frequently implanted valve was the balloon-expandable valve SAPIEN3™ (Edwards Lifesciences, Irvine, California), and was significantly more used in the bilateral-access group (81.3 % vs. 64.2 %, $p = 0.006$). Post-dilation was required in 29 patients (13.4 %). Main vascular access closure was performed using a suture-mediated closure system in most cases (93.1 %). Secondary vascular access was closed using a collagen plug-based device in all procedures. Mean duration of the procedure, fluoroscopic time and total contrast volume were similar in both groups. Overall, TAVR reduced the mean transvalvular gradient from 41.3 ± 14.6 mmHg at baseline to 9 ± 4.4 mmHg after procedure. Echocardiographic paravalvular leak (PVL) was graded as none in 142 (65.4 %) and mild (grade 1) in 60 (27.6 %) patients with non-significant differences between the groups. Table 3 lists procedural characteristics.

### 3.4. Outcomes

Vascular complications (major and minor) were reported in 12.9 % of the overall population; 14.0 % for the bilateral-access group and 10.4 % for the unilateral-access group ($p = 0.471$). This corresponds to a 35 % relative risk reduction in vascular complications with the unilateral approach. When major and minor vascular complications were separately assessed, no differences between groups were found. The majority of complications were managed conservatively through manual compression. ($n = 16$; 57.1 %). Percutaneous treatment was necessary in 8 patients (28.6 %), of which 6 underwent balloon angioplasty and 2 stent implantations. Four patients (14.3 %) required surgical treatment. No significant differences were observed between the groups regarding secondary outcomes (Table 4). A post-hoc power analysis was performed. The analysis indicated that the study had moderate power (statistical power of 0.4) for the described findings.

**Table 1**
Baseline and preprocedural echocardiographic characteristics.

| Variable | Bilateral Access ($n = 150$) | Unilateral Access ($n = 67$) | p Value |
|---|---|---|---|
| Age, years, mean ± SD | 78.6 ± 7.6 | 77.6 ± 8.2 | 0.379 |
| Male, n (%) | 78 (52.0 %) | 39 (58.2 %) | 0.397 |
| BMI, Kg/m$^2$, mean ± SD | 27.1 ± 4.7 | 26.8 ± 5.2 | 0.691 |
| Hypertension, n (%) | 125 (83.3 %) | 49 (73.1 %) | 0.082 |
| Dyslipidemia, n (%) | 104 (69.3 %) | 28 (41.8 %) | <0.001 |
| Diabetes, n (%) | 28 (18.7 %) | 14 (20.9 %) | 0.701 |
| Smoking, n (%) | 62 (41.3 %) | 21 (31.3 %) | 0.370 |
| Previous thoracotomy, n (%) | 25 (16.7 %) | 9 (13.4 %) | 0.545 |
| Coronary artery disease, n (%) | 74 (49.3 %) | 31 (46.3 %) | 0.676 |
| Cerebrovascular disease, n (%) | 24 (16.0 %) | 11 (16.4 %) | 0.938 |
| Peripheral artery disease, n (%) | 15 (10.0 %) | 5 (7.5 %) | 0.551 |
| Previous CABG, n (%) | 20 (13.5 %) | 8 (11.9 %) | 0.751 |
| Previous PCI, n (%) | 53 (35.8 %) | 26 (38.8 %) | 0.673 |
| Atrial fibrillation, n (%) | 54 (36.0 %) | 25 (37.3 %) | 0.853 |
| Previous pacemaker implantation, n (%) | 20 (13.3 %) | 6 (8.9 %) | 0.359 |
| COPD, n (%) | 22 (14.7 %) | 8 (11.9 %) | 0.591 |
| NYHA functional class, n (%) | | | |
| Class I-II | 39 (26.0 %) | 9 (13.4 %) | 0.039 |
| Class III-IV | 111 (74.0 %) | 58 (86.6 %) | |
| EuroSCORE II, mean ± SD | 5.5 ± 4.9 | 4.8 ± 4.6 | 0.299 |
| Creatinine, mg/dL, mean ± SD | 1.1 ± 0.6 | 1.1 ± 0.4 | 0.624 |
| eGFR, mL/min/m$^2$, mean ± SD* | 63.2 ± 19.1 | 61.3 ± 18.8 | 0.495 |
| eGFR <60 mL/min/1.73 m2 mean ± SD | 66 (44.0 %) | 32 (47.8 %) | 0.607 |
| Hemoglobin, g/dL, mean ± SD | 12.5 ± 1.8 | 12.7 ± 1.8 | 0.352 |
| Peak velocity, m/s, mean ± SD | 4.0 ± 0.7 | 4.3 ± 2.7 | 0.215 |
| Mean gradient, mmHg, mean ± SD | 41.2 ± 15.0 | 41.1 ± 13.3 | 0.970 |
| Aortic valve area, cm$^2$, mean ± SD | 0.8 ± 0.2 | 0.8 ± 0.2 | 0.180 |
| LVEF systolic dysfunction, n (%) | 38 (25.3 %) | 15 (22.4 %) | 0.641 |
| Mild (LVEF 40–49 %), n (%) | 17 (11.3 %) | 5 (22.4 %) | 0.849 |
| Moderate (LVEF 30–39 %), n (%) | 14 (9.3 %) | 7 (10.4 %) | |
| Severe (LVEF <30 %), n (%) | 7 (4.7 %) | 3 (4.5 %) | |
| Aortic stenosis | | | 0.573 |
| High gradient, n (%) | 119 (79.3 %) | 48 (71.6 %) | |
| Classical low-flow, low-gradient, n (%) | 19 (12.7 %) | 10 (14.9 %) | |
| Paradoxical low-flow, low-gradient, n (%) | 11 (7.3 %) | 8 (11.9 %) | |
| Aortic regurgitation, n (%) | 1 (0.7 %) | 1 (1.5 %) | |

BMI – body mass index; CABG – coronary artery bypass grafting; COPD – chronic obstructive pulmonary disease; eGFR – estimated glomerular filtration rate; LVEF – left ventricular ejection fraction; PCI – percutaneous coronary intervention; SD – standard deviation.
* eGFR estimated by the CKD-EPI Creatinine Equation.

### 3.5. Propensity score-matched population

Baseline clinical, main vascular access and procedural characteristics of the propensity score-matched population are presented in Supplementary Table 1. Regarding outcomes, there was a higher rate of overall complications in the bilateral-access group (54.4 % vs 35.1 %, $p = 0.038$) mostly due to a trend of higher rate of vascular complications (26.3 % vs 12.3 %, $p = 0.058$) and a significant higher occurrence of bleeding complications (17.5 % vs 1.8 %, $p = 0.008$). The remaining secondary outcomes were similar between groups. Central illustration and Table 5 provide the propensity-matched outcomes.

**Table 2**
Main vascular access characteristics.

| Variable | Bilateral Access ($n = 150$) | Unilateral Access ($n = 67$) | $p$ Value |
|---|---|---|---|
| Common femoral artery | | | |
| MeanLD, mm, mean ± SD * | 8.2 ± 1.7 | 8.4 ± 1.2 | 0.318 |
| MinLA, mm$^2$, mean ± SD | 54.0 ± 23.9 | 56.5 ± 15.9 | 0.375 |
| External iliac artery | | | |
| MeanLD, mm, mean ± SD * | 7.3 ± 1.6 | 7.8 ± 1.4 | 0.015 |
| MinLA, mm$^2$, mean ± SD | 43.2 ± 19.7 | 49.1 ± 18.4 | 0.039 |
| Common iliac artery | | | |
| MeanLD, mm, mean ± SD * | 9.1 ± 4.4 | 9.6 ± 4.4 | 0.424 |
| MinLA, mm$^2$, mean ± SD | 65.1 ± 34.2 | 68.6 ± 27.0 | 0.452 |
| Sheath:artery ratio | | | |
| SFAR MeanLD, mean ± SD | 1.7 ± 0.3 | 1.6 ± 0.3 | 0.536 |
| SEIAR MeanLD, mean ± SD | 1.5 ± 0.3 | 1.5 ± 0.3 | 0.248 |
| SCIAR MeanLD, mean ± SD | 1.9 ± 0.9 | 1.9 ± 0.8 | 0.894 |
| SFAR MinLD, mean ± SD | 1.5 ± 0.3 | 1.5 ± 0.2 | 0.604 |
| SEIAR MinLD, mean ± SD | 1.4 ± 0.3 | 1.4 ± 0.3 | 0.179 |
| SCIAR MinLD, mean ± SD | 1.6 ± 0.4 | 1.8 ± 1.5 | 0.201 |
| SFAAR, mean ± SD | 2.8 ± 1.2 | 2.8 ± 0.8 | 0.582 |
| SEIAAR, mean ± SD | 2.3 ± 0.9 | 2.4 ± 0.9 | 0.348 |
| SCIAAR, mean ± SD | 3.4 ± 1.8 | 3.3 ± 1.4 | 0.733 |
| Iliofemoral tortuosity | | | |
| Absolute angle value, mean ± SD | 46.8 ± 15.5 | 45.0 ± 18.2 | 0.460 |
| Mild (< 45°), n (%) | 68 (45.3 %) | 35 (52.2 %) | 0.368 |
| Moderate (45–90°), n (%) | 77 (51.3 %) | 28 (41.8 %) | |
| Severe (>90°), n (%) | 4 (2.7 %) | 2 (3.0 %) | |
| Iliofemoral calcification | | | 0.976 |
| No, n (%) | 10 (6.7 %) | 4(6.0 %) | |
| Mild (arc <90°), n (%) | 56 (37.3 %) | 27 (40.3 %) | |
| Moderate (arc 90–180°), n (%) | 43 (28.7 %) | 19 (28.4 %) | |
| Severe (> 180°), n (%) | 41 (27.3 %) | 17 (25.4 %) | |

MeanLD – mean lumen diameter at the level of minimal luminal area; MinLA – minimal lumen area; SCIAR – sheath:common iliac artery diameter ratio; SCIAAR – sheath:common iliac artery area ratio; SEIAR – sheath:external iliac artery diameter ratio; SEIAAR – sheath:external iliac artery area ratio; SFAR – sheath:femoral artery diameter ratio; SFAAR – sheath:femoral artery area ratio; SD – standard deviation.
* MeanLD = (maximal lumen diameter at the level of minimal luminal area + minimal lumen diameter at the level of minimal luminal area) /2.

## 4. Discussion

The main findings for the present analysis are: 1) the unilateral-access TF-TAVR presented low rates of VARC-3 vascular and bleeding complications; 2) after propensity score matching, the unilateral-access group demonstrated numerically fewer vascular complications and significantly fewer bleeding complications compared to the bilateral-access group; 3) no major differences were observed in the remaining secondary endpoints. This collectively underscores the feasibility and safety of the unilateral-access approach.

To our knowledge, the first study to compare unilateral versus bilateral in TF-TAVR was conducted by Khubber et al. [3] This study found that using two arterial sheaths placed in a single femoral artery for both valve delivery and aortic root angiography was effective and safe. The rate of peripheral vascular complications was low (10.3 %) and comparable between the bilateral- and unilateral-access groups (10.8 %

**Table 3**
Procedural characteristics.

| Variable | Bilateral Access ($n = 150$) | Unilateral Access ($n = 67$) | $p$ Value |
|---|---|---|---|
| Local anaesthesia, n (%) | 136 (90.7 %) | 66 (98.5 %) | 0.108 |
| Sheath size, n (%) | | | < 0.001 |
| 14 Fr | 97 (64.7 %) | 20 (29.9 %) | |
| 16 Fr | 51 (34.0 %) | 47 (70.1 %) | |
| 18 Fr | 2 (1.3 %) | 0 (0 %) | |
| Valve type, n (%) | | | 0.006 |
| Edwards SAPIEN3™ | 122 (81.3 %) | 43 (64.2 %) | |
| Medtronic Evolut Pro™ | 28 (18.7 %) | 24 (35.8 %) | |
| Valve size, mm, mean ± SD | 26.5 ± 2.5 | 27.0 ± 2.1 | |
| 23 | 40 (26.7 %) | 8 (11.9 %) | 0.042 |
| 26 | 46 (30.7 %) | 28 (41.8 %) | |
| 29 | 64 (42.7 %) | 31 (46.3 %) | |
| Main vascular access closure device, n (%) | | | 0.007 |
| Perclose proglide™ | 135 (90.0 %) | 67 (100 %) | |
| Manta™ | 15 (10.0 %) | 0 | |
| Secondary vascular access closure device, n (%) | | | 1.000 |
| AngioSeal™ | 150 (100 %) | 67 (100 %) | |
| Post-implantation balloon dilation, n (%) | 16 (10.7 %) | 13 (19.4 %) | 0.081 |
| Procedure time, min, mean ± SD | 32.7 ± 16.1 | 31.8 ± 18.9 | 0.449 |
| Fluoro time, min, median (IQR) | 7.5 ± 5.1 | 6.5 ± 4.3 | 0.136 |
| Contrast, mL mean ± SD | 64.0 ± 22.7 | 61.6 ± 20.3 | 0.510 |
| Peak velocity, m/s, mean ± SD | 1.9 ± 0.5 | 1.9 ± 0.4 | 0.590 |
| Mean gradient, mmHg, mean ± SD | 9.2 ± 4.2 | 9.3 ± 4.6 | 0.960 |
| Paravalvular leaks, n (%) | | | 0.342 |
| Grade 1 | 44 (20.4 %) | 16 (23.9 %) | |
| Grade 2 | 7 (4.7 %) | 7 (10.4 %) | |
| Grade 3 | 1 (0.7 %) | 0 (0 %) | |

IQR – interquartile range; SD – standard deviation.

**Table 4**
Outcomes.

| Variable | Bilateral Access (n = 150) | Unilateral Access (n = 67) | p Value |
|---|---|---|---|
| Overall complications | 55 (36.7 %) | 24 (35.8 %) | 0.905 |
| Vascular complications VARC, n (%) | 21 (14.0 %) | 7 (10.4 %) | 0.471 |
| Major | 13 (8.7 %) | 6 (9.0 %) | 0.423 |
| Minor | 8 (5.3 %) | 1 (1.5 %) | |
| 30-day all-cause mortality, n (%) | 1 (0.7 %) | 1 (1.5 %) | 0.523 |
| 30-day all-cause hospital readmission, n (%) | 5 (3.3 %) | 0 | 0.327 |
| 30-day stroke or transient ischemic attack, n (%) | 2 (1.3 %) | 0 (0 %) | 0.999 |
| 30-day bleeding VARC, n (%) | 12 (8.0 %) | 1 (1.5 %) | 0.051 |
| VARC 1 | 2 (1.3 %) | 0 (0 %) | 0.272 |
| VARC 2 | 5 (3.3 %) | 1 (1.5 %) | |
| VARC 3 | 5 (3.3 %) | 0 (0 %) | |
| VARC 4 | 0 (0 %) | 0 (0 %) | |
| 30-day new permanent pacemaker implantation, n (%) | 10 (6.7 %) | 4 (6.0 %) | 0.847 |
| Periprocedural myocardial infarction, n (%) | 0 (0 %) | 1 (1.5 %) | 0.309 |
| 72 h acute kidney injury, n (%) | 9 (6.0 %) | 2 (3.0 %) | 0.509 |
| Valve migration, n (%) | 2 (1.3 %) | 0 % | 0.999 |
| Surgical conversion | 0 | 0 | |

vs. 8.6 %, $p = 0.543$) [3]. Our study aligns with these results regarding feasibility and rate of vascular complications but, after propensity score matching, we observed significantly fewer bleeding events in the unilateral-access group. We attribute this difference to a potentially

**Table 5**
Propensity-matched outcomes.

| Variable | Bilateral Access (n = 57) | Unilateral Access ($n = 57$) | p Value |
|---|---|---|---|
| Overall complications | 31 (54.4 %) | 20 (35.1 %) | 0.038 |
| Vascular complications | 15 (26.3 %) | 7 (12.3 %) | 0.058 |
| Major | 5 (8.8 %) | 1 (1.8 %) | 0.113 |
| Minor | 10 (17.5 %) | 6 (10.5 %) | |
| 30-day all-cause mortality, n (%) | 1 (0.9 %) | 1 (0.9 %) | 1.000 |
| 30-day all-cause hospital readmission, n (%) | 1 (1.8 %) | 0 | 0.999 |
| 30-day stroke or transient ischemic attack, n (%) | 1 (1.8 %) | 0 | 0.999 |
| 30-day bleeding VARC, n (%) | 10 (17.5 %) | 1 (1.8 %) | 0.008 |
| VARC 1 | 2 (3.5 %) | 0 | 0.035 |
| VARC 2 | 4 (7.0 %) | 1 (1.8 %) | |
| VARC 3 | 4 (7.0 %) | 0 | |
| VARC 4 | 0 | 0 | |
| 30-day new permanent pacemaker implantation, n (%) | 4 (7.0 %) | 3 (5.3 %) | 0.999 |
| Periprocedural myocardial infarction, n (%) | 0 | 1 (1.8 %) | 0.999 |
| 72 h acute kidney injury, n (%) | 3 (5.3 %) | 2 (3.5 %) | 0.999 |
| Valve migration, n (%) | 1 (1.8 %) | 0 | 0.999 |
| Surgical conversion | 0 | 0 | 1.000 |

faster management of the peripheral vascular complications, highlighting one of the potential advantages of the unilateral-access technique.

Additionally, our study presents some methodological differences: 1) we used ultrasound guidance in all cases (compared occasional usage of ultrasound guidance at the operator's discretion at Khubber et al. study); 2) secondary access was obtained at the ipsilateral SFA and not at the CFA; 3) hemostasis of the secondary access was achieved with a collagen plug-based device (versus manual compression) and 4) we collected data on all types of bleeding complications, not just major bleeding complications.

Several other studies have explored alternative approaches involving the secondary arterial access. The transradial access has been proved to be safe and feasible, associated with a significant decrease in vascular and bleeding complications [8,16]. However, it limits the ability to deliver dedicated material for peripheral interventions in case of complications. In addition, the transradial access is increasingly used for the delivery of cerebral protection devices, impeding its used for other purposes during the procedure [17]. The unilateral-access TF-TAVR, as proposed in our study, overcomes these constraints, allowing rapid delivery of dedicated material to treat vascular complications if required, while maintaining the transradial available for further uses. Another approach is the all-in-one technique used for the ACURATE neo/neo2™ self-expandable valve (Boston Scientific, MA, USA) [18–20]. In this technique, the expandable delivery iSleeve sheath (Boston Scientific, MA, USA) is used for the valve catheter and the pigtail at the same time, avoiding an extra arterial puncture. [18–20] But, this is not applicable for the Medtronic™ or Edwards Lifesciences™ valves due to the sheath characteristics and the device-sheath ratio, impending the advancement of a pigtail in parallel [19]. Performing a TF-TAVR without a secondary access has also been described by Aroney et al. [17] In this study, calcification and anatomical marks of the aortic root were used for safe transcatheter aortic valve alignment and deployment. This single access technique shows high procedural success with low rates of vascular complications [17]. Nevertheless, one of the main limitations of the latest two described techniques is the absence of a back-up vascular access site, precluding the possibility of performing a final iliofemoral angiogram and the prompt recognition and management of an access-site related complication. The unilateral-access TF-TAVR addresses this important limitation and is applicable to all valve types and delivery systems. Placing the secondary sheath ipsilateral and distal to the primary access facilitates peripheral intervention when needed. This

approach simplifies procedures and eliminates the need for a conventional femoral crossover, which can be challenging due to tortuosity or acute angulation of the aortoiliac system. These aspects potentially reduce the use of resources including time and equipment, thereby enhancing the cost-effectiveness of the technique. In addition, this method preserves alternative arterial access sites for future percutaneous interventions and empirically facilitates patient's mobilization and positioning, contributing for better patient comfort and easier management on the ward. Lastly, the mean transvalvular gradient and PVL after procedure, along with the secondary endpoints (including 30-day all-cause death, all-cause hospital readmission, cerebrovascular events, myocardial infarction, pacemaker implantation and acute kidney injury) were similar to previous reports and comparable between unilateral- and bilateral-approaches, emphasizing the feasibility and safety of the proposed unilateral-access TF-TAVR [3,16,19,21–26].

### 4.1. Study strengths and clinical contribution

The main strength and clinical contribution of this study is the comparison of unilateral-access versus bilateral-access TF-TAVR. We used propensity score analysis to match patients based on the most common predictors of vascular complications, particularly key vascular access characteristics assessed by MDCT [12,13,15]. This approach helped address for imbalances, reduce confounding factors and improve comparability. Additionally, ultrasound-guidance was consistently employed for transfemoral access puncture, aligning with current best practices and clinical evidence [7,27].

### 4.2. Study limitations

This study is a retrospective, observational, single-center analysis with a relatively small sample size. Selection bias remains a concern, as the choice of unilateral-access was left to the operator's discretion. This may have resulted in a selection of patients with more favorable anatomy or lower anticipated risk for complications for the unilateral group. Although we adjusted for potential biases using propensity score analysis, this method can only account for measured variables, and unmeasured confounders may still have influenced the outcomes. Additionally, the study endpoints were reported by investigators rather than adjudicated by an independent committee. The small sample size limits the statistical power of the study, increasing risk of type II errors. As a result, the study may have been underpowered to detect smaller but clinically significant effects. This highlights the need for caution in interpreting the results. Furthermore, as all cases were performed at a single high-volume center, the techniques may not be easily transferable to other patient populations. Larger, multicenter, randomized studies are needed to confirm the benefits of this approach.

## 5. Conclusions

Unilateral-access TF-TAVR is feasible, safe, and potentially enhances procedural efficiency and patient satisfaction while maintaining the capacity for bailout interventions in managing vascular complications.

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## Ethics approval statement

The institutional review board approved the study and waived the need of patient's written informed consent for this retrospective analysis of clinically acquired data.

None of the article contents are under consideration for publication in any other journal or have been published in any other journal. No portion of the text has been copied from other material in the literature.

## CRediT authorship contribution statement

**Ana Rita Pereira:** Writing – review & editing, Writing – original draft, Visualization, Software, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation. **Ahmed A. M. al Jaff:** Writing – review & editing, Writing – original draft, Visualization, Software, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation. **Jose Montero-Cabezas:** Writing – review & editing, Validation, Supervision, Project administration, Methodology, Investigation, Formal analysis, Conceptualization. **Arend de Weger:** Writing – review & editing, Data curation. **Dario Candura:** Writing – review & editing, Data curation. **Johan Wouter Jukema:** Writing – review & editing, Resources, Project administration. **Fatih Arslan:** Writing – review & editing, Data curation. **Madelien V. Regeer:** Writing – review & editing, Data curation. **Nina Ajmone Marsan:** Writing – review & editing, Data curation. **Frank van-der-Kley:** Writing – review & editing, Validation, Supervision, Project administration, Methodology, Investigation, Formal analysis, Conceptualization.

## Declaration of competing interest

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## Appendix A. Supplementary data

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