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ORIGINAL STUDIES

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Propensity matched analysis of vascular complications using integrated or expandable sheaths for TAVR

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Abstract

Objectives: Vascular access site complications increase morbidity and mortality in transcatheter aortic valve replacement (TAVR).

Background: Medtronic's EnVeo PRO® low-profile sheath concept and Edwards' expandable eSheath® aim to lower vascular trauma and access site complications. This study aims to compare Valve Academic Research Consortium (VARC)-3 defined access-related vascular complications using the two different transcatheter heart valve (THV) delivery concepts.

Methods: We performed a retrospective, propensity-matched study to compare access site vascular complications in 756 consecutive patients who underwent a transfemoral TAVR using a Medtronic Evolut-R®/Evolut-PRO® or an Edwards Sapien3®/Sapien3ultra® THV.

Results: Propensity score matching resulted in 275 patient pairs. The primary endpoint of major VARC-3 vascular complication was 7.6% in the Medtronic group and 12.7% in the Edwards group ($p = 0.066$). Minor VARC-3 vascular complications were 9.1% and 8%, respectively ($p = 0.76$). VARC-3 bleeding complications (8.4% vs. 12.7%, $p = 0.129$) length of hospital stay (7.6 ± 5.4 vs. 7.5 ± 3.7 days, $p = 0.783$) and in-hospital mortality (1.1% vs. 0.4%, $p = 0.624$) were comparable between both groups.

Conclusions: In a propensity-matched TAVR population, patients treated with the integrated sheath showed a trend towards fewer major vascular complications than patients treated with an expandable sheath, however, the difference was not statistically significant.

KEYWORDS

aortic valve disease, ascular access, complicationsv, percutaneous intervention, transcatheter valve implantation

Abbreviations: BMI, body mass index; RCT, randomized clinical trial; SFAR, sheath to femoral artery ratio; TAVR, transcatheter aortic valve replacement; THV, transcatheter heart valve; VARC, Valve Academic Research Consortium; VCD, vascular closure device.

1 | INTRODUCTION

Vascular complications are still of concern in transfemoral transcatheter aortic valve replacement (TAVR) and increase patients' morbidity and mortality.[1–3]

Third-generation transcatheter heart valve (THV) systems are designed to reduce vascular trauma. They offer smaller bore-size integrated or expandable delivery sheaths. The integrated EnVeo PRO® sheath provides a 14 French shaft diameter for the Evolut R® THV and a 16 French shaft diameter for the Evolut R® 34 THV and the Evolut PRO® THV. Aortic valve predilatation and postdilatation of the THV require an exchange for large bore sheaths (Figure 1). The 14 and 16 French eSheath® provides an expandable shaft intended to ease sheath and THV insertion. The proximal, nonexpandable part of the shaft measures 22 and 24 French, respectively, for the 29 mm Sapien 3 THV (Figure 2).

Randomized clinical trials (RCTs) report Valve Academic Research Consortium (VARC)-2 defined major vascular complications with third-generation THV ranging from 6% to 7.9% in intermediate-risk and from 2% to 3.8% in low-risk patients, respectively.[4–8] However, a head-to-head comparison of vascular complications with either the integrated sheath or the expandable sheath has not been conducted yet. This study aims to compare VARC-3 vascular and bleeding complications and their underlying mechanism in transfemoral TAVR with either the Medtronic R/PRO® THV using the EnVeo PRO® delivery catheter or with the Edwards Sapien 3®/3 ultra® THV using the eSheath® in a propensity-matched cohort.

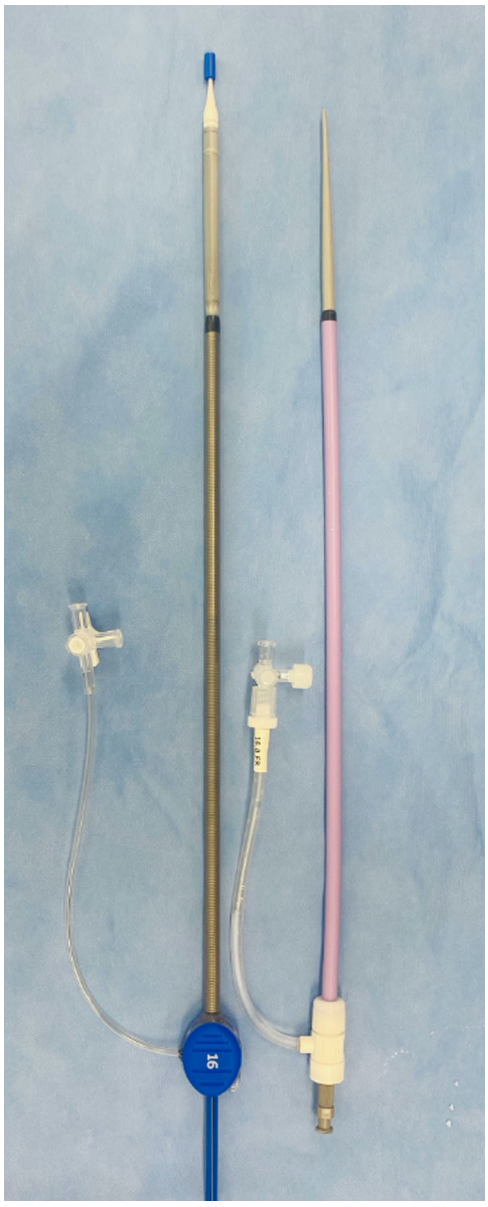

FIGURE 1 The Medtronic integrated EnVeo PRO® sheath provides a 14 or 16 French catheter. Exchange for a large-bore sheath is required for aortic valve predilatation or transcatheter heart valve postdilatation [Color figure can be viewed at wileyonlinelibrary.com]

2 | MATERIALS AND METHODS

All patients who underwent TAVR with a third generation THV (Medtronic Evolut R®, Evolut PRO®, and Edwards Sapien 3®, Sapien 3 ultra®) were identified in our institutional TAVR database. Of these, patients with non-femoral access and utilization of a vascular closure device (VCD) other than Perclose ProGlide® or utilization of an 18 or 20 French large-bore sheath were excluded. The choice of using the Medtronic Evolut THV system or the Edwards Sapien THV system was to the operator's discretion focusing on the aortic root anatomy.

The local ethics committee approved the study (118/20 S).

2.1 | Vascular access and closure

Puncture of the common femoral artery for TAVR access was guided by contralateral angiography with an 18 G needle positioned in the subcutaneous tissue serving as a reference for the puncture height. Ultra-sound guidance or micro-puncture equipment were not used. Two Perclose ProGlide® were placed in the standard preclose technique. In none of the cases, ileo-femoral access required pretreatment with percutaneous transluminal angioplasty or intravascular lithotripsy. A Medtronic THV was implanted with either the 14 or 16 French (for Evolut R 34 or Evolut Pro THV) EnVeo PRO® delivery system. The company's guidelines required vessel predilatation with a 14 or 16 French sheath before insertion of the EnVeo PRO® system. This initial sheath also facilitated potential aortic valve predilatation. If postdilatation of the Evolut valve was performed, a second exchange of large-bore sheaths was required. For implantation of an Edwards Sapien THV, either a 14 or 16 French eSheath® or 14 French Axela® sheath was advanced over an extra stiff wire.

After removal of the large bore sheath over a guidewire, the puncture hole was closed with the two Perclose ProGlide®. If required, manual compression was applied to achieve full hemostasis. No plug-based VCD was used in addition to the suture-based systems. The need

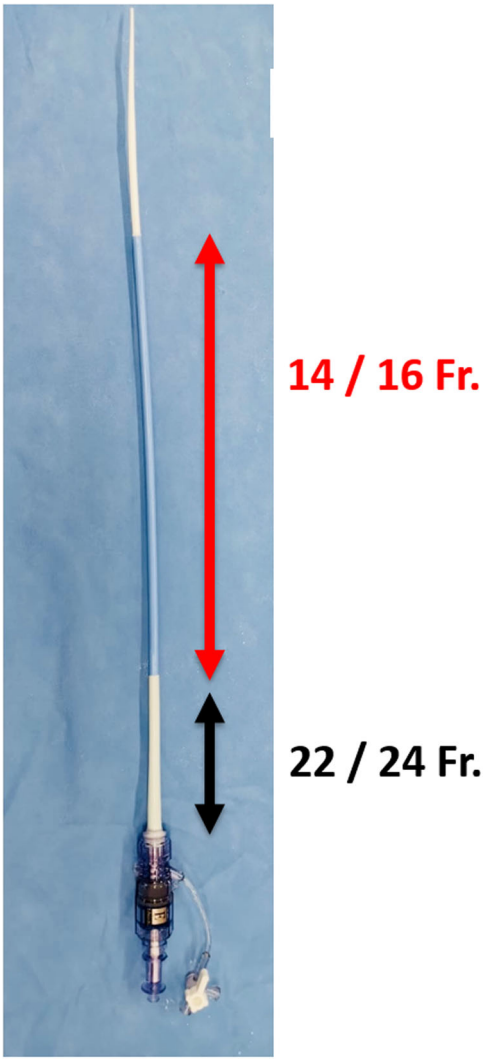

FIGURE 2 The Edwards eSheath® provides a 14 or 16 French expandable shaft with 22 or 24 French large-bore proximal part at the vascular access site [Color figure can be viewed at wileyonlinelibrary.com]

for interventional or surgical interventions to achieve hemostasis was reported according to VARC-3 criteria. Administration of half-dose or full-dose of protamine was to the operator's discretion. In patients with dual antiplatelet therapy for recent coronary stent-graft implantation and adequate hemostasis, no protamine was given in selected cases. All patients were clinically followed and underwent Doppler sonography of the femoral vessels before discharge as the standard of care.

2.2 | Endpoints

The primary endpoints were VARC-3-defined major and minor vascular complications at the femoral access site during hospitalization. Secondary endpoints included VARC-3 defined bleeding complications at the access site, blood transfusion requirements, length of hospital stay, and intra-hospital mortality.

2.3 | Data collection

Demographics, procedural details, intra-hospital course, and adverse events were prospectively recorded according to the VARC-3 recommendations[9] in our dedicated TAVR database. The underlying mechanism of vascular complications was categorized.

For the purpose of the current study, all data were validated by reviewing operative reports, medical records, and intra-procedural angiography studies. To determine femoral artery diameter and calcification, all available preoperative computerized tomographies underwent reassessment by the same examiner, unaware of the performed procedure and patient outcome. Vessel wall calcification at the access site region between femoral bifurcation and cranial margin of the femoral head was graded as none, minimal, moderate, or severe based on visual assessment. Calcification grade was determined for anterior, posterior, lateral, and medial vessel walls separately. Adequate vessel diameter and absence of severe tortuosity of the iliac arteries to allow transfemoral access was confirmed. Each procedure with Evolut R/Evolut PRO was categorized into one or two exchanges of large-bore sheaths. The outer diameter of the utilized large-bore sheaths allowed for sheath-to-femoral-artery-ratio (SFAR) calculations.

2.4 | Statistical analysis

Statistical analysis was conducted using R statistical software language (version 3.6.1, R Foundation for Statistical Computing). Continuous variables are presented as mean ± standard deviation or as median (interquartile range), categorical variables are expressed as percentages. Comparison between groups was performed using either a Fisher exact test for binominal variables, *t* test for normally distributed variables, and a Wilcox rank-sum test for the remaining variables. A p value of <0.05 was considered significant.

A 1:1 nearest neighbor propensity score matching using the R package MatchIt was applied for imbalanced baseline characteristics: age, gender, femoral artery diameter and calcification (anterior and posterior calcification), and aortic valve diameter.

3 | RESULTS

3.1 | Baseline and procedural characteristics

Seven hundred and fifty-six patients met the inclusion criteria (Figure 3). Preoperative computerized tomography studies were available for secondary assessment in 719 patients (95.1%). Table 1 displays the demographic data of the Medtronic and the Edwards group before and after propensity score matching. Differences in the Medtronic and Edwards group before matching included gender (57% vs. 42% female, $p < 0.001$), mean aortic valve diameter (23.2 vs. 24.6 mm, $p < 0.001$) and presence of ≥moderate vessel wall calcification at the anterior (7.8% vs. 12.4%, $p = 0.042$) and posterior site (38.7% vs. 49.7%, $p = 0.003$).

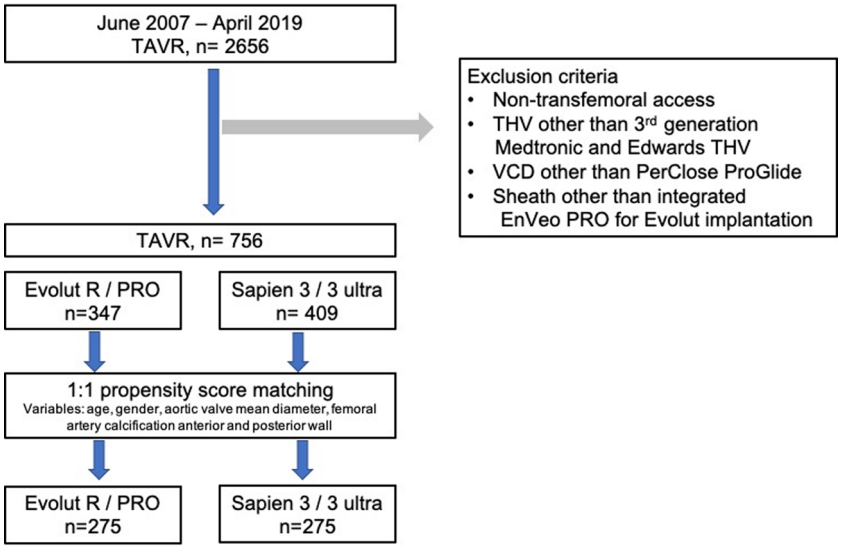

FIGURE 3 Study flow and variables for propensity score matching. TAVR, transcatheter aortic valve replacement; THV, transcatheter heart valve; VCD, vascular closure device [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 1 Baseline characteristics

	Entire cohort (*n* = 756)			Matched cohort (*n* = 550)		
	EnVeo PRO (Evolut THV)	eSheath (Sapien 3 THV)		EnVeo PRO (Evolut THV)	eSheath (Sapien 3 THV)	
n	347	409	*p* value	275	275	*p* value
Age (years)	79.3 ± 8.1	80.0 ± 6.8	0.196	80.1 ± 7.5	79.8 ± 7.2	0.606
Gender (female)	199 (57.3%)	173 (42.3%)	**<0.001**	145 (52.7%)	145 (52.7%)	1.0
Body mass index (kg/m^2)	26.6 ± 5.0	26.7 ± 4.7	0.844	26.6 ± 4.9	26.8 ± 4.7	0.632
Euroscore 2	6.0 ± 6.5	5.5 ± 5.9	0.324	6.0 ± 6.4	5.6 ± 6.1	0.473
Log. Euroscore	17.4 ± 13.1	17.2 ± 12.5	0.823	17.3 ± 12.6	17.7 ± 12.5	0.745
STS predicted risk of mortality	4.4 ± 4.3	4.1 ± 3.3	0.276	4.3 ± 4.4	4.1 ± 3.6	0.493
Coronary artery disease	180 (52.2%)	226 (55.3%)	0.420	145 (53.1%)	152 (55.3%)	0.668
Peripheral artery disease	36 (10.4%)	56 (13.7%)	0.181	29 (10.6%)	34 (12.4%)	0.592
COPD	45 (13.0%)	51 (12.7%)	0.913	34 (12.4%)	33 (12.2%)	1.0
Prepoerative hemoglobin (mg/dl)	12.4 ± 1.8	12.3 ± 1.9	0.283	12.5 ± 1.8	12.2 ± 1.8	0.078
Glomerular filtration rate (ml/min)	59.8 ± 22.4	57.4 ± 23.8	0.155	60.6 ± 22.4	57.9 ± 23.9	0.178
NT-Pro-BNP (ng/ml)	4390 ± 6405	5047 ± 7383	0.279	4175 ± 5808	5146 ± 7356	0.156
Mean aortic valve diameter (mm)	23.2± 2.4	24.6 ± 2.5	**<0.001**	23.6 ± 2.2	24.7 ± 2.5	**<0.001**
Access site CFA diameter (mm)	7.9 ± 1.2	8.0 ± 1.3	0.164	8.0 ± 1.3	8.0 ± 1.3	0.995
Illio-femoral tortuosity	82 (24.33%)	98 (24.50%)	1.0	65 (24.34%)	70 (25.93%)	0.692
CFA anterior wall calcification ≥moderate	26 (7.8%)	48 (12.4%)	**0.049**	24 (8.7%)	24 (8.7%)	1.0
CFA posterior wall calcification ≥moderate	129 (38.7%)	192 (49.7%)	**0.003**	120 (43.6%)	120 (43.6%)	1.0

Note: Variables included in propensity score matching are highlighted in bold.

Abbreviations: CFA, common femoral artery; COPD, chronic obstructive pulmonary disease; STS, Society of Thoracic Surgeons.

TABLE 2 Procedural data and outcome after transcatheter aortic valve replacement with Evolut and Sapien 3 transcatheter heart valve (THV)

	Evolut THV	Sapien 3 THV	*p* value
Patients, *n*	275	275	
Procedural data			
THV			
Evolut PRO	34 (12.4%)	0	
Evolut R	241 (87.6%)	0	
Sapien 3	0	264 (96%)	
Sapien 3 ultra	0	11 (4%)	
THV size (mm)			
20	0	1 (0.36%)	
23	12 (4.4%)	104 (37.8%)	
26	96 (34.9%)	92 (33.5%)	
29	118 (42.9%)	78 (28.4%)	
34	49 (17.8%)	0	
Number of sheath exchange			
0	0	274 (99.6%)	
1	134 (48.7%)	1 (0.4%)	
2	133 (48.4%)	0	
>2	8 (2.9%)	0	
Outer sheath mean diameter (mm)	6.25 ± 0.40	7.81 ± 0.22	<0.001
Access site CFA mean diameter (mm)	7.96 ± 1.25	7.96 ± 1.28	0.995
Sheath to femoral artery ratio	0.80 ± 0.12	1.00 ± 0.15	<0.001
Outcome			
Major vascular complication	21 (7.6%)	35 (12.7%)	0.066
Minor vascular complication	25 (9.1%)	22 (8%)	0.761
Bleeding complication	23 (8.4%)	35 (12.7%)	0.129
Typ 1	5	5	
Typ 2	6	15	
Typ 3	11	15	
Typ 4	1	0	
Hemoglobin at discharge (g/dl)	11.1 ± 1.4	11.0 ± 1.3	0.188
Red blood cell transfusion (units)			0.495
0	188 (68.4%)	179 (65.3%)	
1–2	54 (19.6%)	61 (22.3%)	
>2	33 (12%)	34 (12.4%)	
Length of hospital stay	7.6 ± 5.4	7.5 ± 3.7	0.783
In-hospital mortality	3 (1.1%)	1 (0.4%)	0.624

Abbreviation: CFA, common femoral artery.

TABLE 3 Procedural sheaths details

Sheath	Outer diameter (mm)	Evolut THV	Sapien THV
14 French EnVeo PRO	6	184	0
16 French EnVeo PRO	6.67	84	0
14 French eSheath	7.67	1	200
16 French eSheath	8.17	0	75
18 French Cook	7.33	3	0
20 French Cook	8	3	0

Abbreviation: THV, transcatheter heart valve.

TABLE 4 Transcatheter heart valve size distribution

Evolut R/pro	#23	12 (4.4%)	Sapien 3/ultra	#20	1 (0.4%)
	#26	96 (34.9%)		#23	104 (37.8%)
	#29	118 (42.9%)		#26	92 (33.5)
	#34	49 (17.8%)		#29	78 (28.4)

3.2 | Propensity score matching and procedural outcome

Propensity score matching for age, gender, aortic valve diameter, access vessel diameter, and calcification resulted in 275 matched patient pairs (Table 2).

Details of procedural sheaths are displayed in Table 3. Distribution of THV sizes is displayed in Table 4. With the Evolut, 134 implantations were performed with one sheath exchange, 133 implantations were performed with two sheath exchanges. For all Sapien implantations, the eSheath® or the Axela® sheath was used.

The larger outer sheath diameter of the eSheath resulted in a higher SFAR in the Edwards group (0.8 ± 0.12 vs. 1.0 ± 0.15, $p < 0.001$).

3.3 | Primary endpoint

Major VARC-3 vascular complications show a trend towards difference in favor of the integrated sheath (7.6% vs. 12.7%, $p = 0.066$) (Figure 4), not meeting the pre-specified threshold for statistical

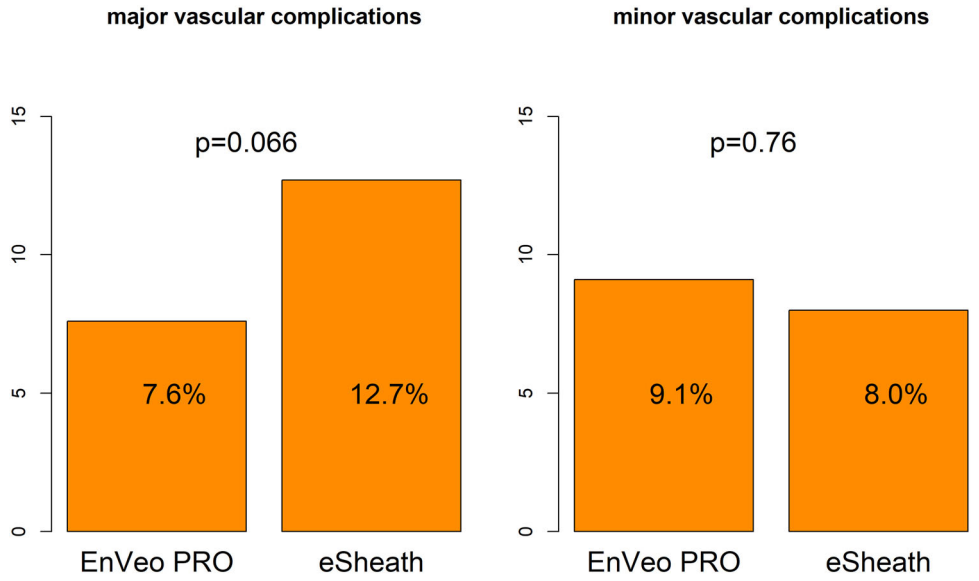

FIGURE 4 Major and minor Valve Academic Research Consortium-3 defined vascular complications with the Evolut and Sapien transcatheter heart valve [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 5 Details of Valve Academic Research Consortium-3 defined access-related vascular complications and consecutive treatment

	Evolut THV (%)	Sapien THV (%)	*p* value
Vascular complication			
Bleeding	25 (52)	32 (57)	0.55
Vessel stenosis, occlusion, dissection	17 (37)	16 (29)	0.52
False aneurysm therapy	5 (11)	8 (14)	1.0
Conservative	15 (32)	27 (48)	0.070
Interventional	20 (43)	16 (28)	0.092
Surgical	12 (26)	13 (23)	1.0

Abbreviation: THV, transcatheter heart valve.

significance. Minor VARC-3 vascular complications were 9.1% in the Medtronic and 8% in the Sapien group ($p = 0.76$).

The most common cause of vascular complications was bleeding for VCD failure (Evolut 52%, Sapien 57%, $p = 0.55$). The second most common cause was vessel stenosis, occlusion or dissection in both groups (Evolut 37%, Sapien 29%, $p = 0.52$). Table 5 displays the treatment for vascular complications.

3.4 | Secondary endpoints

VARC-3 bleeding complications (8.4% vs. 12.7%, $p = 0.129$), transfusion requirements, length of stay (7.6 ± 5.4 vs. 7.5 ± 3.7 days, $p = 0.783$) and in-hospital mortality (1.1% vs. 0.4%, $p = 0.624$) were comparable between both groups.

4 | DISCUSSION

The present study is a retrospective, propensity-matched comparison of vascular complications after TAVR with Evolut R/PRO using the EnVeo PRO system and Sapien3/3 ultra using the eSheath. Major VARC-3 vascular complications occurred less frequently in the Medtronic group, but the difference was not statistically significant. The most common cause for vascular complications was bleeding for VCD failure. Secondary endpoints, bleeding complications, transfusion requirement, hospital length of stay, and in-hospital mortality did not differ between the groups.

4.1 | Risk factors for vascular complications

Previous studies have identified female gender,[3,10] vessel calcification,[11,12] and high SFAR[2,10,12] as risk factors for vascular complications. Previously we have shown that an exchange of a large-bore sheath is also a risk factor for vascular complications in transfemoral TAVR.[2] So far, different delivery sheath concepts and their influence on vascular complications have not been compared. In our intermediate- to high-risk patient cohort, we observed 7.6% major vascular complications with the integrated sheath and 12.7% with the expandable sheath. This is comparable to RCTs including intermediate-risk TAVR patients, which report major vascular complication rates of 6% with the Evolut valve and 8.5% with the Sapien 3 valve.[4,8] In a recent monocenter study, 11%–12% of major vascular complications were reported with the expandable sheath.[13] The design of the PARTNER 2 trial with two parallel arms for transfemoral and transapical THV placement may have led to a positive selection of patients in the transfemoral arm explaining the lower vascular complication rates found in all-comers cohorts.

4.2 | Specifications of integrated and expandable sheaths

The specific design of third generation THV systems intends to reduce vessel trauma by two different mechanisms. The low-profile sheath concept from Medtronic, for example, the Medtronic EnVeo PRO® utilizes 14–16 French sheaths. We showed that the lower outer sheath diameter of the Medtronic system results in a lower SFAR compared to the Sapien group. However, an exchange of large-bore sheaths is required to perform pre- and/or postdilatation and THV implantation, respectively.

In contrast, the expandable sheath concept from Edwards, for example, Edwards Lifescience® eSheath requires only one vessel entry with a large bore sheath. A drawback of this strategy is the larger 22–24.5 French outer diameter of the sheath causing an effectively larger puncture hole and leading to the higher SFAR. In our study, the Medtronic concept showed a trend towards less major vascular complications, but the difference was not statistically significant. In the current versions, both concepts are not able to sufficiently reduce major vascular complication rates. Of note, we saw a significantly higher rate of vascular calcifications in the Sapien group before propensity score matching. The influence of vascular calcifications on THV selection is unclear. In general, the choice of a specific THV usually focuses on the aortic valve/aortic root anatomy aiming for optimal hemodynamic results. With TAVR being predominantly a fully percutaneous transfemoral procedure, differences in vascular complications between different THV systems offering different sheath technologies have not been analyzed yet and a potential impact of choosing a specific THV has not been reported yet. For patients with heavily calcified or small femoral arteries, surgical cutdown increases the safety of the transfemoral access.[14] Future technical development could be either a further reduction of the effective size of the puncture hole with expandable sheaths or an integrated sheath that allows insertion of dilatation balloons to avoid sheath exchange.

4.3 | Limitations

The study is limited to our single-center experience and the retrospective study design. The data have not been reviewed by an independent adjudication committee. Despite propensity score matching, the influence of unknown confounders cannot be excluded.

5 | CONCLUSION

In a propensity-matched TAVR population, patients treated with the integrated sheaths showed a trend towards fewer major vascular complications than patients treated with an expandable sheath, however, the difference was not statistically significant. Based on this result, we cannot conclude which delivery concept is superior.

CONFLICT OF INTERESTS

Dr. Ruge and Dr. Erlebach report personal fees from Medtronic, outside the submitted work. Dr. Lange is a consultant of Medtronic, outside the submitted work. Furthermore, he receives royalties from Medtronic.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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