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Distal radial secondary access for transcatheter aortic valve implantation: The minimalistic approach☆

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ABSTRACT

Background: Although not yet recommended by the guidelines, distal radial access, a new site for cardiovascular interventions, has been rapidly acknowledged and adopted by many centers due to its high rate of success, safety and fewer complications. We present our experience using secondary distal radial access during transcatheter aortic valve implantation (TAVI), proposing a new, even more minimal approach.
Methods: As of November 2020, a systematic distal radial approach as secondary access site for TAVI was adopted in our center. Primary endpoints were technical success and major adverse events (MAEs). Secondary endpoints: the access site complication rate, hemodynamic and clinical results of the intervention, procedural related factors, crossover rate to the femoral access site, and hospitalization duration (in days).
Results: From November 2020, 41 patients underwent TAVI using this strategy. Patients had a mean age of 76 ± 11.2 years, 41% were male. Six (14.63%) patients received a balloon-expandable valve and 35 (85.37%) received a self-expandable valve. TAVI was successful in all cases. No complications occurred due to transradial access. Puncture success, defined as completed sheath placement was maximum ($N = 41/41,100\%$) and emergent transfemoral secondary access was not required in any case. Primary transfemoral vascular access site complications occurred in 7 cases (17%) of which 4 (13.63%) were resolved through distal radial access: one occlusion, two flow-limiting stenoses and four perforations of the common femoral artery. There were no additional major vascular complications at 30 days. Overall MACE rate was 2.4%.
Conclusion: The use of the distal radial approach for secondary access in TAVI is safe, feasible and has several advantages over old access sites.

1. Introduction

Vascular complications (VCs) during transcatheter aortic valve replacement (TAVI) remain the most common procedural complications despite smaller delivery systems and improved operator experience. The transradial approach (TRA) as secondary access in TAVI has become the preferred access site due to its significant reduction in (overall and major) vascular and bleeding periprocedural events (approximately 25% of periprocedural access VCs are related to the transfemoral secondary access [1]). Distal radial access (dRA) at the anatomical snuffbox has been reported [2–4] as a safe and feasible unique alternative to TRA at the wrist [3]. The need for patent hemostasis with forearm radial access, to minimize the risk of radial artery occlusion (RAO) mandates close vigilance for bleeding to prevent forearm hematoma formation and requires prompt effective management if it develops, to stop progression to compartment syndrome. The latter risk may be lower with dRA as not only is the puncture site distal to the forearm, but it is more readily compressible. A typical complication of proximal radial access (pRA) is a chronic RAO caused by local hematoma, spasm, arterial wall damage or compression [4,5] and dRA was proven superior to proximal radial access in preventing proximal RAO at 24 h and 30 days after a diagnostic or interventional coronary procedure [6]; another important aspect is

Abbreviations: TAVI, transcatheter aortic valve implantation; MAEs, major adverse events; VCs, vascular complications; TRA, transradial approach; dRA, distal radial approach; pRA, proximal radial approach; RAO, radial artery occlusion; AoS, aortic stenosis; PTA, percutaneous transluminal angioplasty; PCI, percutaneous coronary intervention; COPD, chronic obstructive pulmonary disease; IDDM, insulin-dependent diabetes mellitus; NIDDM, noninsulin-dependent diabetes mellitus; LVEF, left ventricle ejection fraction.

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ipsilateral pRA patency even if dRA occludes after intervention, because dRA location is after the superficial palmar branch of the radial artery (Fig. 1), therefore flow is maintained through this branch and thrombus formation is stopped at this point. Lastly, hand position difficulties take place more often when performing pRA.

Putting forward these advantages, dRA competes with the conventional radial approach and may change our common access common in the near future. Several registries have been collected recently regarding dRA for coronary angiography and interventions [7–10] but there are no data regarding dRA as a secondary site for TAVI, although it may bring significant benefit in terms of VC reduction and patient-operator ergonomics. We aimed to prospectively analyze the procedural performance, outcomes, safety and efficacy of dRA as a new, minimalistic option during TAVI.

2. Methods

Clinical and angiographic data from 41 consecutive patients with severe, symptomatic aortic stenosis (AoS) were evaluated in a retrospective single-center study. Between November 2020 and April 2021 the patients were treated using dual access, one distal-radial and one femoral. Distal radial access was obtained using a 5 or 6 French Glidesheath (Terumo Medical Corporation, Somerset, NJ, USA). When 2 secondary access sites were needed (for periprocedural coronary protection), both distal radial arteries were cannulated. Access to the ascending aorta from the radial artery was typically obtained using a 5F pigtail on a 0.35″ guidewire (J-Tip Guidewire, Terumo Medical Corporation, Somerset, New Jersey, USA). Transfemoral TAVI cases were routinely performed under local and general anesthetic with transesophageal echocardiographic guidance unless clinical reasons required otherwise. Portico (St Jude Medical, MN, USA), Evolut (Medtronic, Inc., Minneapolis, Minn, USA), Acurate (Boston Scientific, Boston, MA, USA) and Myvalve (Meril Life Sciences Pvt. Ltd., Vapi, Gujarat, India) valves were used. TF primary access closure was performed with one ProGlide device (Abbott Vascular, Santa Clara, CA, USA) and one AngioSeal 8F (Terumo Medical Corporation, Somerset, NJ, USA). Our Insitutional Ethical Review Committee approved the study (OGYÉI/50275/2017), and all patients provided written informed consent prior to study inclusion.

2.1. Inclusion criteria

We included high risk patients with symptomatic significant AoS in the study after written informed consent was obtained.

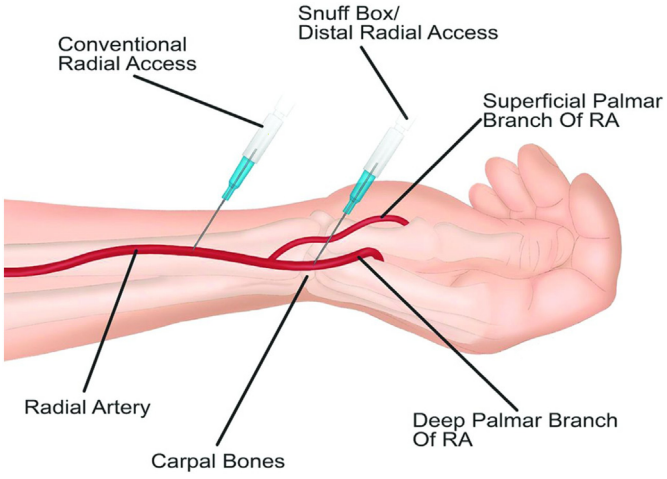

Fig. 1. *Curtesy of P. Patel* et al. Distal radial artery course through the anatomic snuffbox. Note that the superficial palmar artery branches take off before the radial artery enters the anatomic snuffbox.

2.2. Exclusion criteria

(1) hemodynamic Preexisting aortic prosthesis, recent myocardial infarction, left ventricular or atrial thrombus, severe aortic, mitral or tricuspid regurgitation (grade III-IV), recent cerebrovascular event (within 3 months), carotid or vertebral arterial stenosis (>80%), active internal bleeding, thrombocytopenia (platelet count <50,000/mm^3), (2) ethical: lack of written informed consent, severe mental disorder, drug/alcohol addiction, life expectancy <1/2 year, participation in another drug or device study, pregnancy, and (3) vascular: patients with occluded, severely diseased or small (<1.5) mm radial or ulnar arteries on both sides were not included.

Our primary endpoints were technical success and major adverse events (MAEs). *The secondary endpoints were* the access site complication rate, hemodynamic and clinical results of the intervention, procedural related factors, crossover rate, radial occlusion rate and hospitalization duration (in days).

2.3. Definitions

Major adverse events (MAEs): MAEs were assessed as the composite of death, stroke, myocardial infarction, and urgent major aortic valve replacement or implantation during the hospital stay and/or at the one-month follow-up.

Definition of vascular complications: Major vascular complications were defined as diminished or lost arterial pulse or the presence of any pseudoaneurysm or arteriovenous fistula during the clinical follow-up. Minor complications were defined as hematomas requiring no further treatment (EASY 1–2), measuring 2 cm in diameter over the radial or ulnar puncture area or measuring 5 cm in diameter over the femoral puncture site. Major bleeding was defined as a drop in the hemoglobin level of >3 g/dl, as well as any bleeding requiring blood transfusions. Major hematoma was defined as EASY 3–4 hematoma.

Technical success was defined as successful transcatheter aortic valve implantation over the native, stenotic aortic valve.

Hemodynamic success was defined as a 90% drop in the mean aortic gradient.

Clinical success: Primary clinical success was defined as an improvement of at least one clinical category in the NYHA classification.

2.4. Duplex ultrasound (US) protocol

Duplex US was used in the operating room to investigate all forearm arteries. RA, UA diameter and peak systolic velocity were measured at the wrist level. On the first postoperative day, all patients underwent control duplex US.

Access site selection: Two skilled operators trained in bilateral transradial access and TAVI performed all cases. The primary preferred access site was the right femoral artery, and for aortography the left radial artery was used. The left radial artery was punctured distally, with the arm flexed and pronated on the patient's abdomen, reproducing a natural positon, increasing the patient's comfort and minimizing operator discomfort during the procedure (Fig. 2). The alternative access site was the ulnar artery, which was used when a Doppler ultrasound showed a small radial artery (less than 1.5 mm) or was extremely calcified or occluded. For rapid pacing the access site was the femoral or the jugular vein or guidewire pacing approach.

2.5. Statistical analysis

Statistical analysis was performed using commercially available GraphPad Prism 8.0 software (USA). Continuous variables were expressed as the mean ± standard deviation or as the median with interquartile range. Categorical variables were tabulated as percentages. The different patient cohorts were compared using either the Mann-

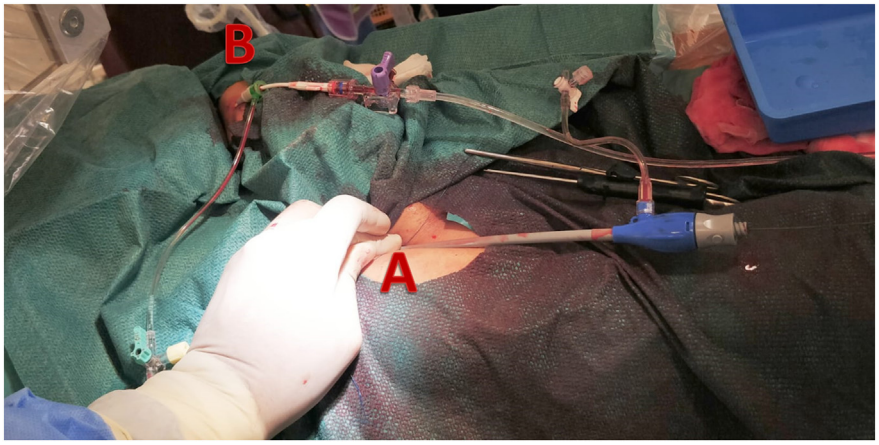

Fig. 2. Patient example, right femoral primary access (A) and left distal radial secondary access (B), both sheaths being in proximity of each other, enhancing better ergonomics and lowering the radiation dose.

Whitney *U* test or the Kruskal-Wallis test. Probability values lower than 0.05 were considered to be significant.

3. Results

The main baseline clinical and procedural characteristics of the global population and according to the secondary approach (transfemoral versus transradial) are shown in Table 1.

TAVI was successful in all cases. Procedural details are highlighted in Table 2. Technical success was achieved in all patients (100%). Clinical success was achieved in 40 patients (97,5%). Hemodynamic success was achieved in all patients (100%). By hemodynamic investigation, the peak-to-peak mean gradient decreased from 76.8 ± 27.2 to 10.7 ± 5.1 mmHg ($p = 0.001$). Balloon postdilatation was performed in 19 cases (46.3%), and the crossover to urgent surgical aortic valve implantation was 0%. Secondary access was achieved through the left dRA only (100%) and the crossover rate to the femoral access site was achieved in 3 cases (7.31%) of major primary femoral access perforation. Temporary pacing was performed either through the jugular vein ($n = 19$, 46.3%) or femoral vein ($n = 10$, 24.3%) or directly on the TAVI stiff wire ($n = 12$, 29.2%). The fluoroscopy time, X-ray dose, procedure time, and contrast consumption were 18.20 ± 7.6 min, 529.8 ± 484.6 mGy, 50.3 ± 28.1 min, and 64.9 ± 28.1 ml, respectively. Mean hospitalization duration over the cohort was 4 ± 2.5 days. Ultrasonography parameters before and after the procedure are summarized in Table 2.

No complications occurred due to transradial access. Transfemoral vascular access site complications occurred in 7 cases (17.07%): 1 occlusion, 2 flow-limiting stenoses and 4 perforations of the common femoral artery. Three complications were successfully managed using balloon dilatation and balloon tamponade from the transradial access (Fig. 3). The cases of major perforation (9.75%) were successfully treated with a covered stent delivered via direct ipsilateral superficial femoral retrograde 6F access and stent delivery with angiographic control from dRA (Fig. 4). There were no additional major vascular complications at 30 days. Five cases of PCI (12.19%) and one case of left subclavian artery PTA (2.43%) were successfully performed through dRA, in the same session. Hemostasis of the primary transfemoral access was achieved percutaneously (vs surgical cut-down) in all patients, using two ProGlide devices (Abbott Vascular, Santa Clara, California) in 31.82% and one ProGlide plus one Angioseal 8F device (Terumo Medical Corporation, Somerset, NJ, USA) in 68.18% of the cohort. Sheath size for secondary

Table 1
Demographic and clinical data.

		n (%)
Demographic data	Age (years)	76.0 ± 11.2
	Male	17 (41)
	Hypertension	34 (82.9)
	Current smokers	11 (26.8)
	Diabetes mellitus	15 (36.5)
	IDDM	4 (9.7)
	NIDDM	11 (26.8)
	Weight (kg)	79.4 ± 16.7
	Height (cm)	167.1 ± 9.9
	COPD	9 (21.9)
	Renal insufficiency	15 (36.5)
	Family history	9 (21.9)
	Dyslipidemia	26 (63.4)
	Atrial fibrillation	17 (41.4)
Cardiac and vascular history	Coronary artery disease	13 (31.7)
	Peripheral artery disease	7 (17.07)
	Previous PCI or coronary bypass	10 (24.3)
	Previous valve surgery	3 (7.31)
	Symptoms	
	- Angina	34 (82.9)
	- Dyspnoea	41 (100)
	- Syncope	2 (4.87)

Table 2
Procedural results.

	Pre-interventional	Post-interventional
Clinical status (dyspnoe)		
NYHA 1	0	1
NYHA 2	1	30
NYHA 3	30	10
NYHA 4	9	0
Vascular ultrasound (radial site)		
- Radial artery (mm)	1.8 ± 0.5	1.8 ± 0.5
- Hematoma (EASY 1–2)	0	1
- Hematoma (EASY 3–4)	0	0
- Radial artery occlusion	0	0
- Pseudoaneurysm	0	0
Transthoracal ultrasound		
LVEF		
- 50–70%	34 (82.92)	37 (90.24)
- 30–50%	6 (14.63)	4 (9.75)
- <30%	1 (2.43)	0 (0)
Aortic gradient (peak)	76.8 ± 27.2	10.7 ± 5.1
Aortic gradient (mean)	50.9 ± 18.7	12.6 ± 9.3
AVA (mm^2)	0,67 ± 0.13	2.4 ± 0.27
Aortic regurgitation		
- 0–2	24 (58.5)	10 (24.39)
- 3–4	0 (0)	0 (0)

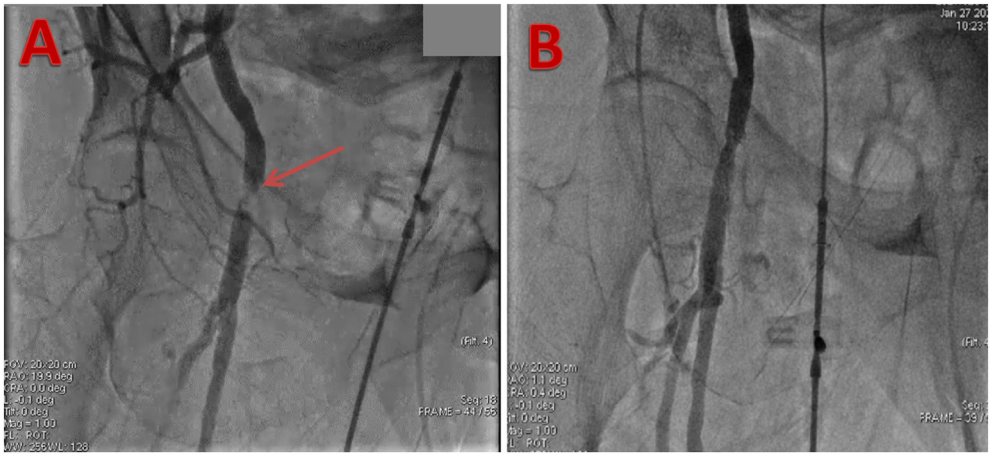

Fig. 3. Thrombotic subocclusion of femoral artery treated percutaneously.
A - Angiography via MPA guide catheter in the iliac artery, showing extensive thrombus and poor flow. B - Angiography showing restoration of distal flow following balloon dilatation. Technical details: 7.5 F sheatless guiding catether, V18 0.14″ guidewire (Boston Scientific, Natick, MA, USA), Passeo 6 × 40 mm balloon (Biotronik AG, Buelach, Switzerland), 2 min inflation at 8 atm.

access in the transradial group was 5 French (F), 6 F, and 7 F in 20 (48.7%), 19 (46.3%) and 2 (4.87%) patients, respectively. Hemostasis of the radial access was achieved via compression in all cases, using a combination of one StatSeal Disc (Biolife, LLC, USA) with gauze compression. Standard hemostasis time was 3 h. The need of repeating the hemostasis was not needed in any cases. Data regarding radial occlusion were collected 24 h after puncture and Doppler ultrasound revealed no artery occlusion. All-cause 30-day mortality was 2.4% %, one patient suffered esophageal and tracheal bleeding after extubation with hemorrhagic shock (autopsy report revealed bleeding from the esophageal vein). No stroke or myocardial infarction was observed.

4. Discussion

Our case series shows that TAVI can be performed safely using dRA secondary access with no increase in radiation dose, screening time or procedural duration. The occlusion rate proved to be non-existent. This is of particular importance in order to keep access available. We also show that with appropriate equipment major vascular complications related to femoral primary access can be managed entirely via the TR approach (Fig. 3).

TRA for TAVI secondary access sites has been introduced to guide valve implantation, to treat coronary lesions, and to control or treat vascular access site complications. Coronary angioplasties, even complexs such as LM-stenting could be simply and elegantly completed using dRA. Puncturing the left dRA brings the left hand very close to the primary femoral access, thus keeping the radiation dose low and enhancing the comfort of the operator. Easy closure shortens the procedural time and keeps the pRA available for emergency second-look at any time. A total of 13.63% of our patients necessitated pre- or post-PCI during TAVI, which was performed via dRA only. It has been reported that up to a quarter of vascular complications during TAVI result from the use of femoral secondary arterial access [1]. The introduction of TRA for coronary angiography and angioplasty has reduced bleeding and access site complications in coronary interventions [11]. Logically, the same may be true during TAVI procedures, especially as the elderly patient cohort currently eligible for TAVI is at high risk of developing femoral arterial complications. Because old and frail adults often present with limited arm motion, our approach demonstrated greater patient tolerability and resulted in short hospital stays. Additionally, the procedural time was shorter than that in other reports [1,12].

Transradial secondary access readily allows aortography to guide valve implantation. For non-TF TAVI cases, this is the sole purpose of secondary arterial access and thus TR access can be considered the default approach. Changing from conventional pRA to dRA, thus heading toward an even more minimally invasive approach, can achieve further VC reduction and longer radial lumen patency for possible future interventions. Various small observational studies have shown similar radiation doses between pRA and dRA on coronary interventions [6,9,10], because the two access sites are very close to each other. However, we believe this concept could be different in TAVI, as in this case the operator could receive the “femoral” radiation dose, lower than the radial dose,

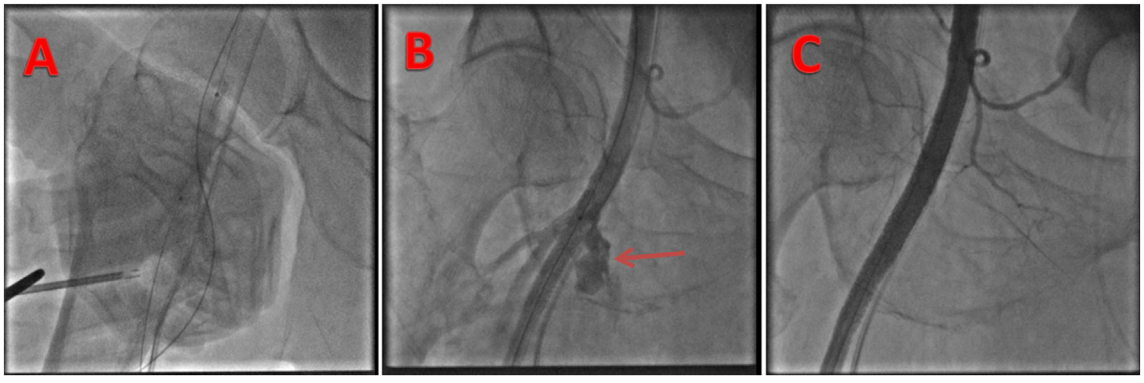

Fig. 4. Stent graft placement from direct femoral access route.
Balloon tamponade via dRA route (A), with unsuccessful hemostasis and active bleeding (B, arrow) and final stent graft implantation over the common and superficial right femoral artery, with subsequent deep femoral artery occlusion (C).

by bringing the left hand very close to the femoral access. Won-Keun Kim et al. recently described a novel technique using only a single arterial access technique [12] (valve deployment without contrast injection but using a guiding wire for valve positioning that is introduced through the same femoral access but outside the large bore sheath), heading for the same minimalistic approach and stating that secondary access complications were eliminated together with the whole secondary access concept but we believe aortography is necessary for the valve positioning and further postdilatation decisions or ad-hoc PCI; therefore, secondary access should be kept and dRA may be the solution for minimizing all possible secondary access complications.

dRA for coronary angioplasty is becoming the primary access site in many catheterization laboratories. The main advantage of this access site is the low rate of radial artery occlusion and the better comfort for the patient during left transradial cases [3–10]. The main disadvantage of this access site is the small size of the RA in this location, the angulated course of the RA and the need of ultrasonography for the puncture. It is essential to know that the dRA diameter is 80% less than the proximal diameter, which may affect suitable French sheaths that can be used, and it varies according to sex, race, and other factors. The diameter of the dRA in females tends to be smaller than that in males. Some studies have shown that hypertensive patients have larger radial artery diameters than normal patients. Other studies show that the diameter of dRA is positively correlated with both body weight and basal metabolic index. Ulnar arteries were slightly larger than radial arteries and may be used as an alternative to dRA [8,13,14]. We did not find a correlation between body weight and vessel diameter in our group. A blind puncture increases the risk of tendon damage. At the same time, the double-wall technique can irritate the underlying periosteum and increase the risk of hematoma formation. Ultrasound (US) allows the identification of anatomical landmarks, and enables accurate vessel access, especially in impalpable dRA. The probe can be used to perform a compressibility test to confirm that the target vessel corresponds to the radial artery rather than the cephalic vein. Accurate scanning can identify the superficial branch of the radial nerve, thus avoiding potential injury. A further benefit of US guidance is that the operator can measure the vessel size before puncturing. A vessel diameter under 2.0 mm was associated with higher occlusion rate, spasm and patient pain [13,14,15]. The success rate of sheath placement was found to be 100% (41/41), without differences between the side (left dRA or right dRA) or site (anatomical snuffbox or distal dorsal of the tendon of the extensor pollicis longus) of the dRA. However, we must admit that an adequately powered randomized trial is necessary to confirm this success rate, as our study was a single-center study; moreover, it was a relatively small study and we did not include acute, unstable patients requiring emergency TAVI.

dRA for iliac and femoral angioplasty has been published recently with high technical success and a very low complication rate [16]. Our center is a dedicated dRA center; thus most of our operators are trained to perform this puncture procedure. The limitation of the dRA for the treatment of access site complications is the distance between the dRA and the common femoral artery, therefore small bleedings or dissections can be treated from this access site with available devices (sheaths, balloons, stents) (Fig. 3), but perforations need distal access if stent graft implantation is needed. In this case series, stent graft placement was needed in two cases and both were implanted from direct superficial femoral artery access (Fig. 4). Spasm was infrequent because of the use of a long transradial slender sheath, although we did not administer any intraarterial nitroglycerine due to aortic stenosis.

4.1. Limitations

This registry included neither a randomization nor a control group and although we used uniformly prespecified endpoints for the analysis it was a retrospective data collection. It is therefore possible that some patients with complications or crossover may have been overlooked. We tried to counter this problem by double rechecking all cath lab protocols in the participating centers during the period of data acquisition. The lack of a control group with proximal access certainly limits our conclusions; our goal was to implement this promising new access site in other cardiac interventions. Additionally, no data were collected regarding the occurrence of radial occlusion. Although this is usually a silent complication with no clinical consequences, future studies will have to evaluate the impact of this complication in the TAVI population.

More and more positive data on (left) distal radial access are being published [10–17]. In fairness, the more publications appear, the more local complications will be described as well. Simultaneously, many of the benefits associated with distal access are becoming less and less theoretical at this point of time and as more practitioners adopt this technique, new nuances, indications, and technical aspects will assuredly continue to emerge.

5. Conclusion

The initial results of this novel, minimalistic approach demonstrate its feasibility and potential beneficial effects without compromising procedural safety. The main advantages are less arterial obstruction and short hemostasis. Larger randomized trials are needed to further evaluate the advantages of dRA over pRA.

CRediT authorship contribution statement

Alexandru Achim MD: Contributing Author, Writing- Original Draft and Editing, Conceptualization **Tamás Szűcsborus MD**: Data Curating, Software, Validation **Viktor Sasi MD PhD**: Data Curating, Validation **Ferenc Nagy MD PhD**: Project Administration, Data Curation **Zoltán Jambrik MD PhD**: Methodology, Conceptualization **Attila Nemes MD DsC**: Data Validation, Reviewing, Software **Albert Varga MD DsC**: Conceptualization **Olivier F Bertrand MD PhD**: Resources, Formal Analysis **Zoltán Ruzsa MD PhD**: Supervision, Writing- Reviewing and Editing, Investigation.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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