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The Leipzig Prospective Vascular Ultrasound Registry in Radial Artery Catheterization

Impact of Sheath Size on Vascular Complications

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Objectives This study investigated the impact of sheath size on the rate of radial artery occlusions (RAO) (primary objective) and other access site complications (hemorrhage, pseudoaneurysm, arteriovenous fistula) as secondary objectives after transradial coronary catheterization.

Background The number of vascular access complications in the published data ranges from 5% to 38% after transradial catheterization.

Methods Between November 2009 and August 2010, 455 patients 65.3 ± 10.9 years of age (62.2% male) with transradial access with 5-F (n = 153) or 6-F (n = 302) arterial sheaths were prospectively recruited. Duplex sonography was obtained in each patient before discharge. Patients with symptomatic RAO were treated with low-molecular-weight heparin (LMWH), and a follow-up was performed.

Results The incidence of access site complications was 14.4% with 5-F sheaths compared with 33.1% with 6-F sheaths ($p < 0.001$). Radial artery occlusion occurred in 13.7% with 5-F sheaths compared with 30.5% with 6-F sheaths ($p < 0.001$). There was no difference between groups with regard to hemorrhage, pseudoaneurysms, or arteriovenous fistulas. Female sex, larger sheath size, peripheral arterial occlusive disease, and younger age independently predicted RAO in multivariate analysis. In total, 42.5% of patients with RAO were immediately symptomatic; another 7% became symptomatic within a mean of 4 days. Of patients with RAO, 59% were treated with LMWH. The recanalization rates were significantly higher in patients receiving LMWH compared with conventional therapy (55.6% vs. 13.5%, $p < 0.001$) after a mean of 14 days.

Conclusions The incidence of RAO by vascular ultrasound was higher than expected from previous data, especially in patients who underwent the procedure with larger sheaths. (J Am Coll Cardiol Intv 2012;5:36–43) © 2012 by the American College of Cardiology Foundation

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Since the first successful diagnostic transradial coronary catheterization by Campeau in 1989 (1) and the first transradial percutaneous coronary intervention (PCI) by Kiemeneij in 1993 (2), the radial artery has been increasingly used as an access site for coronary procedures, because of lower rate of access site complications, shorter hospital stay, improved patient comfort, and safe hemostasis (3,4) compared with transfemoral access (5–7). Nonetheless, radial access still accounts for only 10% of coronary catheterizations worldwide and for <2% of coronary procedures in the United States (8). Bleeding at the vascular access site is an important predictor for post-interventional morbidity and mortality as demonstrated in several studies (7,9–15).

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The recently published multicenter RIVAL (radial versus femoral access for coronary intervention) trial (15) was conducted to compare radial with femoral access in the setting of acute coronary syndromes. The radial access was shown to reduce major vascular complications compared with the femoral access. Another interesting finding was the mortality reduction in favor of transradial access in patients with ST-segment elevation myocardial infarction.

The rate of post-procedural radial artery occlusion (RAO) and the increased radiation exposure (16,17) remain the primary concern of transradial access. Although radiation exposure mainly depends on operator training and experience with transradial coronary angiography (18), a number of factors might affect RAO rate. In the published data, RAO rates are surprisingly different, ranging from 5% to 38% (19–22). The large variance might be related to the fact that radial artery patency after catheterization was assessed by clinical forearm inspection and pulse palpation rather than vascular ultrasound in the vast majority of studies (23). To quantify the true rate and to elucidate risk factors for access site complications, we conducted the present prospective registry with high-resolution vascular ultrasound after transradial diagnostic angiography and PCI with 5-F and 6-F vascular sheaths.

Methods

Patient cohort. Between November 2009 and August 2010, 455 consecutive patients undergoing transradial cardiac catheterization at our high-volume tertiary care center were enrolled in this prospective registry. Informed consent for transradial coronary catheterization, including the follow-up Doppler examination, was obtained in all patients.

Vascular risk factors (hypertension, hyperlipoproteinemia, diabetes, and smoking) were assessed with standard definitions. The presence of coronary artery disease (CAD), peripheral arterial occlusive disease (PAOD), and cerebrovascular disease was recorded in all patients. An Allen test was not routinely performed, because there is no clear consensus with regard to the optimum cutoff time for a positive Allens test. As reported by Jarvis et al. (24), the use of Allen test for assessment of the ulnar collateral blood supply of the hands is unreliable and does not satisfactorily perform as a discriminatory test. Currently, criteria for an abnormal Allen test are clinically not well defined, and performing an Allen test is still not considered "standard care" (25,26).

Transradial coronary catheterization. Six-French sheaths (RADIFOCUS Introducer II, Terumo, Europe N.V, Leuven, Belgium) (outer diameter 2.10 mm, 7-cm length) were used in 302 patients, and 5-F sheaths (Engage TR Introducer, SJM TM, St. Jude Medical, Inc., St. Paul, Minnesota) (outer diameter 1.92 mm, 7-cm length) were employed in 153 patients. In the absence of large prospective trials we liberally used 6-F sheaths in patients with high risk for CAD. In particular, in patients presenting with acute coronary syndromes, a 6-F sheath was used more frequently because of the anticipated higher likelihood of PCI.

All sheaths were hydrophilic-coated. After local anesthesia with xylocaine 2% the right radial artery was punctured in 442 patients (97.1%), whereas in 13 patients (2.9%) the arterial access site was the left radial artery. Unfractionated heparin of 2,500 IU was administered for a diagnostic angiography, and in total 100 IU/kg body weight was given for PCI. An intra-arterial bolus of 0.2 mg nitroglycerin was routinely given to prevent arterial spasm. Verapamil was only administered in the occurrence of spasm of the radial artery. After completion of the cardiac catheterization procedure, sheaths were removed immediately and a compression device (RadiStop, St. Jude Medical Inc., or Terumo TR BAND, Terumo) was applied according to the instructions of the manufacturer to achieve hemostasis. The TR BAND was applied with occlusive compression, slow removal of air until bleeding occurred, and then re-insufflation of 1 to 2 ml of air. RadiStop compression devices were applied with palpation of the pulse of the radial artery distal to the compression site, and in case of an absent pulse, the device was loosened until the pulse was palpable again or bleeding occurred.

Abbreviations and Acronyms

CAD = coronary artery disease
CI = confidence interval
LMWH = low-molecular-weight-heparin
OR = odds ratio
PAOD = peripheral arterial occlusive disease
PCI = percutaneous coronary intervention
RAO = radial artery occlusion

Vascular ultrasound. Color Doppler ultrasound studies were performed by experienced sonographers in all 455 patients within 1.0 ± 1.3 days after the procedure to examine the radial, ulnar, and brachial arteries of the access forearm with a Vivid 7 ultrasonography system (General Electric Medical Systems, Andover, Massachusetts) featuring a 9- to 12-MHz multifrequency vascular probe.

Endpoints and definitions. The primary objective of the study was the incidence of post-procedural RAO as confirmed by absence of antegrade flow in vascular high-resolution ultrasound. Secondary objectives were other local access site complications (bleeding events, pseudoaneurysm, and arteriovenous fistula), respectively. Bleeding events were defined according to the Global Use of Strategies to Open Occluded Arteries bleeding definitions (mild, moderate, and severe bleeding events) (14).

Follow-up. Symptomatic patients with RAO were treated with low-molecular-weight heparin (LMWH) in body weight-adjusted dose for 7 to 14 days. Asymptomatic patients did not receive a specific therapy. In patients with RAO, a follow-up was conducted after 7 to 14 days after the transradial catheterization (clinical examination and vascular ultrasound examination).

Statistical analysis. All data were prospectively collected and entered into the registry. Dichotomous variables are reported as numbers and proportions. Continuous parameters are presented as mean ± SD. The 2 groups (5-F vs. 6-F) were compared by *t* tests for continuous variables. Nonparametric variables were compared by Fisher exact tests, and ordered proportions were compared by Armitage's test for trend. Potential risk factors for post-procedural RAO were investigated first by univariate logistic regression. A multivariate logistic regression model with all significant variables was established to estimate odds ratios (ORs) inclusive 95% confidence bounds. All tests were performed as 2-sided at significance level $\alpha = 5\%$.

Two separate analyses were performed to confirm that baseline group differences (e.g., frequency of PCI) do not confound our findings: first, we matched 2 × 153 patients by 1:1 propensity matching before analysis. Propensity scores were calculated by logistic regression model with variables like age and body mass index significantly associated with 5-F and 6-F sheaths.

Statistical analyses were performed with SPSS (version 19.0, SPSS. Inc., Chicago, Illinois).

Results

Patient characteristics. A total of 455 consecutive patients with a clinical indication for coronary catheterization who successfully underwent the transradial coronary procedure were included in the registry (Fig. 1).

In 302 patients (66.4%), a 6-F arterial sheath was used, whereas in 153 patients (33.6%), the procedure was performed with a 5-F arterial sheath. Baseline patient characteristics are displayed in Table 1. Both groups did not differ with regard to age, sex, cardiovascular risk factors, and oral medication. Patients with CAD, especially triple vessel disease, are over-represented in the 6-F sheaths group.

Procedural data. Procedural data are illustrated in Table 2. In total, 389 patients (85.5%) underwent diagnostic coronary angiography, and in 66 patients (14.5%) a PCI was performed. The rate of PCI differed significantly between the 2 groups (1.2% with 5-F sheaths vs. 21.2% with 6-F sheaths). The amount of contrast media was significantly higher in the 6-F group (55 ml vs. 87 ml, $p < 0.001$), and left ventriculographies were performed significantly more often in the 6-F group (38 vs. 114, $p = 0.006$). There was, however, no significant difference in fluoroscopic time between the 2 groups.

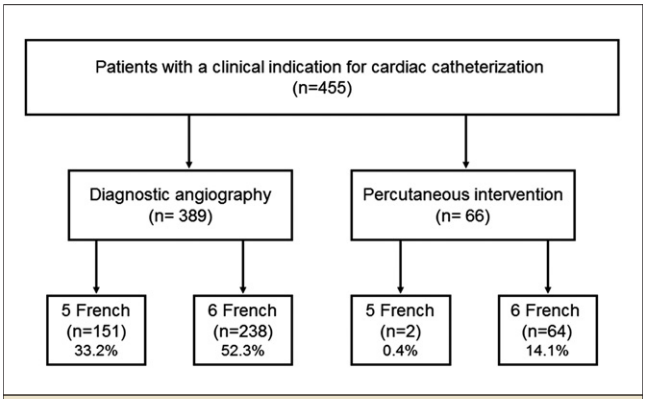

Figure 1. Study Flow Chart

A total of 455 patients were enrolled in the registry, of whom 389 patients underwent diagnostic coronary catheterization with 5-F and 6-F sheaths. A percutaneous coronary intervention was performed in 66 patients.

Vascular complication rates. Vascular access site complications are displayed in Tables 3 and 4.

The primary objective (RAO) occurred in 92 patients of the 6-F group and in 21 patients of the 5-F group (30.5% vs. 13.7%, $p < 0.001$). In 22 patients (19.5%) with ultrasonographic signs of RAO, the radial artery pulse was still palpable.

The secondary objective of the overall incidence of local access site complications was 33.1% (n= 100) in the 6-F group versus 14.4% (n = 22) in the 5-F group ($p < 0.001$). Three patients developed a pseudoaneurysm in the 6-F group (1.0%), whereas none was observed in the 5-F group (p = NS). Two of these patients were treated successfully with ultrasound-guided compression; however, 1 patient required a surgical repair. Arteriovenous fistulas were detected in 3 patients (1.0%) of the 6-F group and in 1 patient (0.7%) of the 5-F group (p = NS) with no need for further specific therapy.

There were no moderate or severe access site bleedings according to Global Use of Strategies to Open Occluded Arteries definitions requiring blood transfusions or surgical repair. Hematomas with a maximal size of 5 cm at the right forearm were noted in 6 patients (2.0%) of the 6-F group and in none of the 5-F group.

Predictors of RAO. The univariate analysis of predictors of post-procedural RAO is presented in Table 5. With 6-F sheaths, the presence of PAOD, younger age, and female sex were strong predictors of post-procedural RAO. There was a strong trend toward a higher occurrence of RAO in

Table 1. Baseline Patient Characteristics

	5-F Sheath (n = 153)	6-F Sheath (n = 302)	p Value
Age (yrs)	65.1 ± 10.8	64.9 ± 11.0	0.27
Male	97 (63.4%)	186 (61.6%)	0.76
Body mass index (kg/m^2)	30.8 ± 5.8	29.2 ± 5.8	0.005
Hypertension	145 (95.4%)	290 (96.0%)	0.81
Diabetes mellitus	53 (34.9%)	101 (33.4%)	0.83
Dyslipidemia	100 (65.8%)	214 (70.9%)	0.28
Current smoking	22 (14.5%)	52 (17.2%)	0.50
History of smoking	31 (20.4%)	78 (25.8%)	0.24
Coronary artery disease	61 (39.9%)	177 (58.6%)	<0.001
1-vessel disease	30 (19.6%)	76 (25.2%)	
2-vessel disease	21 (13.7%)	50 (16.6%)	
3-vessel disease	10 (6.5%)	51 (16.9%)	0.03
Acute coronary syndrome	6 (3.9%)	26 (8.6%)	0.08
Cerebrovascular disease	14 (9.2%)	26 (8.6%)	0.86
Peripheral arterial occlusive disease	10 (6.6%)	35 (11.6%)	0.10
Aspirin	93 (60.8%)	183 (60.6%)	1.00
Statins	81 (52.9%)	167 (55.7%)	0.62
Beta-blockers	99 (64.7%)	213 (71.0%)	0.20
ACE inhibitors	88 (57.5%)	169 (56.3%)	0.84
Angiotensin II receptor blockers	37 (24.2%)	83 (27.7%)	0.50
Calcium-channel blocker	40 (26.1%)	70 (23.3%)	0.56
LV ejection fraction (%)	57 ± 10	56 ± 11	0.58
Serum creatinine (mg/dl)	1.0 ± 0.3	1.0 ± 0.6	0.28
Platelets (×10^3/μl)	221 ± 64	230 ± 78	0.20
Hemoglobin (mg/dl)	13.8 ± 1.4	13.7 ± 1.7	0.46

Values are mean ± SD or n (%).
ACE = angiotensin-converting enzyme; LV = left ventricular.

patients with known cerebrovascular disease in univariate analysis.

In multivariate regression analysis, the use of 6-F sheaths (OR: 2.68, 95% confidence interval [CI]: 1.56 to 4.59, p < 0.001), female sex (OR: 2.36, 95% CI: 1.50 to 3.73, p < 0.001), age (OR: per-year 0.96, 95% CI: 0.94 to 0.98, p = 0.001), and the presence of PAOD (OR: 2.04, 95% CI: 1.02 to 4.22, p = 0.04) were significantly associated with post-procedural RAO in all patients. Independent predictors for post-procedural RAO are displayed in Figure 2.

Table 2. Procedural Data

	5-F Sheath (n = 153)	6-F Sheath (n = 302)	p Value
Percutaneous coronary intervention	2 (1.2%)	64 (21.2%)	<0.001
Fluoroscopy duration (min)	3.6 ± 3.3	4.1 ± 4.1	0.19
Amount of contrast media (ml)	55 ± 26	87 ± 56	<0.001
Left ventriculography	38 (24.8%)	114 (37.7%)	0.006
Right radial artery	151 (98.7%)	291 (96.4%)	0.24

Values are mean ± SD or n (%).

Table 3. Vascular Access Site Complications

	5-F Sheath (n = 152)	6-F Sheath (n = 303)	p Value
Total number of access site complications	22 (14.5%)	104 (34.3%)	<0.001
Radial artery occlusion	21 (13.7%)	92 (30.5%)	<0.001
Pseudoaneurysm	0 (0%)	3 (1.0%)	0.56
Arteriovenous fistula	1 (0.7%)	3 (1.0%)	1.00
Moderate/severe bleeding	0 (0%)	0 (0%)	—
Mild bleeding	0 (0%)	6 (2.0%)	0.19

Values are n (%).

Subgroup analyses were performed, including 389 patients who underwent diagnostic angiography only (151 patients with 5-F, 238 patients with 6-F). The univariate analysis of predictors of RAO in patients undergoing diagnostic catheterization only is presented in Table 6. With 6-F sheaths, the presence of PAOD, younger age, and female sex were again strong predictors of post-procedural RAO. Cerebrovascular disease was not associated with a higher occurrence of RAO in patients with diagnostic catheterization only (Tables 4 and 6).

In multivariate regression analysis all of our results remained unchanged in patients who underwent diagnostic catheterization only (Table 7).

PCI did not increase vascular access site complications in the present registry.

In propensity score analysis of 2 × 153 patients (5-F and 6-F), again, all main results remained unchanged. Only the presence of PAOD did not show a significant association with the occurrence of RAO in these 306 patients.

Body mass index was not associated with a higher occurrence of RAO (p = 0.335).

Clinical course of patients with RAO. Of all patients with RAO, 42.5% (n = 48) were symptomatic within 24 h after the transradial coronary procedure. Another 8 patients (7.1%) became symptomatic within a mean of 4.1 ± 2.1 days (2 to 8 days) after the coronary catheterization, when resuming physical activity at home. The most frequent symptoms were a painful forearm and thenar. Other symptoms were a loss of handgrip force and paresthesia. How-

Table 4. Vascular Access Site Complications in Patients With Diagnostic Catheterization Only (N = 389)

	5-F Sheath (n = 151)	6-F Sheath (n = 238)	p Value
Total number of access site complications	22 (14.6%)	82 (34.5%)	<0.001
Radial artery occlusion	21 (13.9%)	76 (31.9%)	<0.001
Pseudoaneurysm	0 (0%)	2 (0.8%)	0.524
Arteriovenous fistula	1 (0.7%)	3 (1.3%)	1.000
Moderate/severe bleeding	0 (0%)	0 (0%)	—
Mild bleeding	0 (0%)	5 (2.1%)	0.161

Values are n (%).

Table 5. Univariate Association of Different Risk Factors With Radial Artery Occlusion

	p Value	Odds Ratio	95% CI for Lower	Odds Ratio Upper
Female	0.001	2.110	1.370	3.247
Age*	0.005	0.973	0.954	0.992
6-F sheath	<0.001	2.754	1.635	4.639
Peripheral arterial disease	0.037	1.986	1.042	3.783
Cerebrovascular disease	0.056	1.941	0.984	3.827

*Age increase of 1 year is associated with a little lower risk. However, this results in an odds ratio of 1.67 for a 10-years-younger patient.
CI = confidence interval.

Table 6. Univariate Association of Different Risk Factors With Radial Artery Occlusion in Patients With Diagnostic Catheterization Only (N = 389)

	p Value	Odds Ratio	95% CI for Lower	Odds Ratio Upper
Female	<0.001	2.348	1.471	3.748
Age*	0.005	0.970	0.949	0.990
6-F sheath	<0.001	2.904	1.700	4.961
Peripheral arterial disease	0.018	2.424	1.165	5.043
Cerebrovascular disease	0.247	1.570	0.732	3.368

*Age increase of 1 year is associated with only a small relative decrease in risk of RAO. However, this difference results in an odds ratio of 1.67 for a 10-years-younger patient.
CI = confidence interval.

ever, critical limb ischemia did not occur in any patient. Of the 113 patients with RAO, 22 patients were lost to follow up. In 91 patients the first follow-up ultrasound examination was performed after a mean time interval of 9.3 ± 5 days (range 2 to 37 days). Fifty-four symptomatic patients were treated with LMWH in body weight-adjusted dose (n = 17) or in half-therapeutic dose in case of additional dual antiplatelet therapy (n = 37) over a mean time period of 6 ± 7 days. Asymptomatic patients (n = 37) were not treated with LMWH. At time of first follow-up, the recanalization rate of the radial artery was 31.5% (17 of 54) after treatment with LMWH, compared with 5.4% (2 of 37) in patients without an anticoagulatory therapy (p = 0.003).

In patients with persistent RAO at first follow-up, a second follow-up ultrasound study was conducted after a mean time interval of 14 days after catheterization. At this time, the final recanalization rate was 55.6% (30 of 54) in patients after treatment with LMWH compared with 13.5% (5 of 37) in patients without anticoagulation (p < 0.001).

Discussion

The present large prospective registry demonstrates that clinical assessment alone might miss clinically relevant RAO and might therefore underestimate the true risk of RAO. In addition, the present registry is, to the best of our knowledge, the first to compare radial access site complications between 5-F and 6-F sheaths. It confirms that 5-F sheaths reduce the rate of RAO by as much as 55%—a finding with significant implications for the routine use of transradial coronary catheterization.

Routine radial artery ultrasound and the true rate of RAO. The rate of vascular access site complications after transradial coronary catheterization as monitored by vascular high-resolution ultrasound examination was significantly higher in the present registry than expected from previous studies (27–30). This finding implies that routine clinical radial pulse checks might be inaccurate and insensitive in detect-

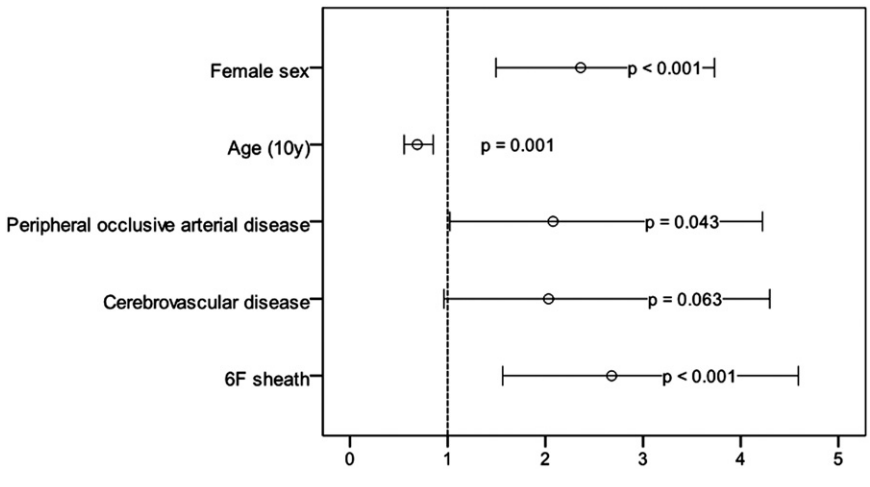

Figure 2. Odds Ratios for Potential Risk Factors for RAO in a Multivariate Model

In a multivariate model, the use of 6-F sheaths, female sex, younger age, and the presence of peripheral arterial occlusive disease were significantly associated with the occurrence of post-procedural radial artery occlusion (RAO).

Table 7. Odds Ratios for Potential Risk Factors for Radial Artery Occlusion in a Multivariate Model in Patients With Diagnostic Catheterization Only

	p Value	Odds Ratio	95% CI for Lower	Odds Ratio Upper
6-F sheath	<0.001	2.742	1.574	4.776
Age (10 yrs)	0.001	0.663	0.523	0.842
Female	<0.001	2.591	1.575	4.264
Peripheral arterial disease	0.010	2.936	1.300	6.632
Cerebrovascular disease	0.336	1.524	0.646	3.598

CI = confidence interval.

ing all RAO. As demonstrated by Bertrand et al. (31), the incidence of RAO before hospital discharge is not assessed in more than 50% of coronary procedures.

Interestingly, in the present study 22 patients showed RAO in ultrasound while the radial pulse was still palpable. This finding might be explained by the collateral circulation from the palmar arches (19,32). In the study by Kerawala et al. (32), the comparative blood pressure from the opposite artery ranged from 58 to 85 mm Hg (mean 70.4 mm Hg). This again underlines the necessity of performing vascular ultrasound examinations in each patient before discharge even if clinical assessment does not show abnormalities.

In addition, the unreliability of clinical pulse control might partly explain the large variation in the observed incidence of RAO reported in the published data (20).

Effect of sheath size on the RAO rate. In the present prospective registry the use of 6-F sheaths was independently associated with an increased rate of post-procedural RAO. As reported by Bertrand et al. (31), 5-F sheaths remain less frequently used, whereas 6-F is the standard sheath size in general practice. Although it might be obvious that larger sheath diameters lead to increased vascular trauma, the exact pathomechanism explaining this finding remains incompletely understood. There is an influence of the inner diameter of the radial artery and the outer diameter of the sheath on the rate of RAO (33). Because we did not measure pre-procedural radial artery diameter, we are unable to comment on the role of artery diameter-to-sheath diameter mismatch as a reason of RAO. Acute injuries of the radial artery after transradial coronary intervention might also be assessed by optical coherence tomography (34). The stretching effect of the sheath and the passage of the sheath as well as spasms of the radial artery might cause intimal flaps. Consequently, the mechanisms of RAO in relation to sheath size should be further studied in imaging studies with optical coherence tomography (arterial dissection vs. thrombotic occlusion).

Other patient-related risk factors for RAO. Transradial PCI did not increase the incidence of vascular access site complications compared with diagnostic angiographies. However, the number of interventional patients in the current registry might be too limited to draw definitive conclusions, and this will require larger sample sizes.

Younger patients and women are at a higher risk for RAO. These findings might be related to the smaller average radial artery diameter in women and the complex sympathetic autonomic innervations of the radial artery, which might increase the risk of vascular spasms. The exact mechanisms of post-procedural RAO remain unknown. Deftereos et al. (35) reported a significant univariate association between flow-mediated dilation of the radial artery and the occurrence of vascular spasm. In their study, female sex tended to be more prone to radial artery spasm.

Moreover, our study demonstrates that patients with known PAOD are at significantly higher risk of RAO. One potential explanation is the relationship between atherosclerosis and structural vascular changes (luminal narrowing, intimal hyperplasia) (36).

Procedure-related risk factors. The relatively high rate of RAO in the current study needs to be interpreted in the context of the unselected patients from routine coronary procedures. In contrast to a recently published study (37) reporting an incidence of RAO after transradial cardiac catheterization of only 10.5%, our registry represents a real world scenario with a pool of interventionalists having different degrees of experience with the transradial approach. The study by Zankl et al. (37) differs with regard to the sheath sizes used (4-F, 5-F, 6-F) and the exclusive selection of senior interventionalists (>10,000 interventions). Furthermore, the study was not designed to primarily investigate the potential relation between sheath size and RAO.

The optimal anticoagulatory therapy is regarded to play an important role for prevention of RAO, but data are still lacking about the optimal heparin dose. The influence of unfractionated heparin or LMWH on the incidence of RAO remains unclear with aspirin and clopidogrel pretreatment. A randomized study comparing a low dose (2,000 IU) versus a standard dose of unfractionated heparin (5,000 IU) in transradial diagnostic angiography did not show a difference in the rate of RAO between the 2 groups. Low-dose unfractionated heparin was reported to be safe and not inferior to standard dose (38). A study by Spaulding et al. (39) showed a rate of RAO of 24% in patients who received 2,000 to 3,000 IU of unfractionated heparin compared with 4.3% in patients who received 5,000 IU. As reported by Bertrand et al. (31), most interventional cardiologists use unfractionated heparin in a dose between 2,000 and 5,000 IU, whereas approximately 5% do not use heparin for diagnostic coronary angiography. In the present study, all patients with diagnostic angiography received 2,500 IU of unfractionated heparin and in total 100 IU/kg body weight when PCI was performed, resulting in a rate of

RAO of 13.7% with 5-F sheaths compared with 30.5% with 6-F sheaths.

Another important factor is the concept of achieving radial artery hemostasis. The patent hemostasis has been found to be highly effective in reducing RAO without compromising hemostatic efficacy (19). The optimal compression management is to aim just enough pressure to avoid bleeding while maintaining antegrade flow of the radial artery (40).

Clinical relevance of RAO. RAO might not be as harmless as previously thought (41). In the present registry 42.5% of patients with RAO became symptomatic immediately, and an additional 7% became symptomatic within a mean of 4 days after the catheterization. This finding could be confirmed by Zankl et al. (37), reporting a percentage of 58.8% of patients with RAO showing symptoms at the access site. Therefore, it is of important clinical relevance to detect all vascular access site complications before discharge to be able to initiate an appropriate treatment. This is also increasingly important, because of the potential future medical relevance of an open radial artery for repeat cardiac catheterizations, hemodialysis shunts, invasive hemodynamic monitoring, or arterial bypass grafting.

Study limitations. Some limitations of the current study need to be addressed. First, because the study design is a prospective registry and not a randomized study, a selection bias cannot be ruled out. Second, we did not perform a pre-procedural vascular ultrasound of the access site with measurement of the diameter of the radial artery. The third limitation is due to the lack of performance of a pre-procedural Allen test routinely. The fourth limitation results from the nonstandardized follow-up intervals when RAO was diagnosed (7 to 14 days). This was, however, not the primary endpoint of the present study. In consequence, this present study reflects a real world clinical setting of unselected consecutive patients and experienced yet unselected interventional cardiologists. Finally, our study represents a single-center experience with a limited number of patients, despite being 1 of the largest prospective vascular ultrasound registries in radial catheterization to date.

Conclusions

Radial access for catheterization did not show severe bleeding events in our registry, but the rate of RAO by ultrasound examination was higher than expected and reported previously. The use of 5-F sheaths for transradial access significantly decreased the rate of RAO by 55%, compared with 6-F sheaths.

The true rate of symptomatic RAO might be underestimated at discharge, because 7% of patients have shown a late onset of symptoms when resuming physical activity at home. To optimize the post-procedural management of patients with transradial coronary procedures, vascular ultrasound of the access site before discharge might be a valuable, objective, and noninvasive tool.

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Key Words: access site complications ■ radial artery occlusion ■ transradial coronary angiography and intervention ■ vascular ultrasound.