Vascular complications and access crossover in 10,676 transradial percutaneous coronary procedures

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Background Randomized trials have shown that transradial approach, compared with transfemoral, reduces vascular complications (VCs) of coronary procedures in selected patients. Yet, radial approach is associated to a variety of access-site VC as well as to a higher failure rate compared with femoral access.

Methods At our institution, from May 2005 to May 2010, we prospectively assessed the occurrence and outcome of VC in consecutive patients undergoing transradial percutaneous coronary procedures performed by trained radial operators. The need of access crossover to complete the procedure was also prospectively investigated. Vascular complications were classified as "radial related" or "nonradial related" (in the case of access crossover). Vascular complications were also classified "major" if requiring surgery and/or blood transfusions or causing hemoglobin drop >3 g/dL.

Results Ten thousand six hundred seventy-six procedures were performed using a right radial (87.5%), left radial (12.4%), or ulnar (0.1%) artery as primary access. A total of 53 VCs (0.5%) were observed: 44 (83%) radial related and 9 (17%) nonradial related. Major VCs occurred in 16 patients only (0.2%) and were radial related in 10 (62.5%) and nonradial related in 6 (37.5%) patients. Vascular complications rate was stable during the study and independent of operator's experience. Access crossover rate was 4.9%, differed according to the operator radial experience and significantly decreased over time.

Conclusions The present study, conducted in a center with high volume of radial procedures, shows that transradial approach is associated with a very low rate of VC, which is stable over time. On the contrary, access crossover rate decreased over time and differed according to operator (radial) experience. (Am Heart J 2012;163:230-8.)

Transradial approach has been developed, as an alternative to transfemoral access, to reduce vascular complications (VCs) for percutaneous coronary diagnostic and interventional procedures. A growing body of evidence (including several meta-analyses[1,2] and a large trial[3]) suggests that the adoption of radial access is associated to a significant reduction in entry site and hemorrhagic complications compared with transfemoral approach. As a consequence, transradial approach has been proposed as a promising strategy to increase the safety of percutaneous coronary procedures especially in the setting of high bleeding risk and acute coronary syndromes.[4,5] Although not frequent, various radial-related VC have been described, and their occurrence deserves attention, as the clinical consequences may not be trivial.

So far, data regarding the specific types of VC potentially occurring after transradial approach have not been systematically investigated in large populations and may have been underreported in many of the randomized studies published so far (which were mainly focused on selected patients and major VC). Thus, we performed the present prospective study aimed at assessing the incidence and predictors of VC in a large population of consecutive patients undergoing transradial percutaneous coronary procedures. Moreover, to assess the efficacy of transradial approach, the need of access crossover to complete the procedure was prospectively investigated.

Methods

From May 2005 to May 2010, consecutive patients admitted at our institution undergoing percutaneous coronary diagnostic or interventional procedures with attempt to use the transradial

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0002-8703/$ - see front matter

doi:10.1016/j.ahj.2011.10.019

(or transulnar) approach as a first access were prospectively enrolled in the present registry. Procedures were defined "urgent" when performed in patients with cardiogenic shock or with ST-elevation acute myocardial infarction within 12 hours from symptom onset and "elective" in all the other cases. The study was conceived and approved by our internal board to monitor the clinical impact of the introduction of the radial approach as the routine approach in our catheterization laboratory.

Demographic, clinical, and procedural data were prospectively collected on a dedicated database agreed on by all the operators of the center. To ensure the highest possible quality of data entry, all data were double checked. Indeed, the completeness and accuracy of the data were verified first at the end of the procedure (executive operator) and then at the end of each month (research fellow).

Recorded procedural data included the need of access crossover defined as failure to successfully complete the procedure by the first attempted approach. In patients with access crossover, the selection of contralateral radial, femoral, or brachial approach varied according to the individual operator's attitude.

In keeping with the agreed internal guidelines, all patients undergoing percutaneous coronary procedures were treated, unless contraindicated, with double antiplatelet therapy (aspirin and clopidogrel) before catheterization. Glycoprotein IIb/IIIa inhibitors were routinely administered, in the absence of specific contraindications, in patients with ST-elevation acute myocardial infarction, whereas in the remaining patients, their use was chosen by the operator according to clinical presentation and complexity of the target lesion.

After the procedure, the occurrence of a possible VC was prospectively recorded in the database after its suspect arose. Patients with suspected VC underwent an instrumental investigation, which, according to our standard protocol, included peripheral angiography if the suspect was intraprocedural and ultrasound evaluation if the suspect was postprocedural. All ultrasound evaluations were performed or reviewed by a vascular surgeon (GT). Other types of instrumental investigations were eventually performed if deemed necessary. According to our internal guidelines, conservative management of hemorrhagic complications of the upper arm included compressive bandage after diagnosis, followed by Doppler reevaluation.

All patients with VC were followed up from diagnosis to hospital discharge. The clinical consequences related to VC were evaluated after discharge by clinical visit or telephone interview at 3 months from the index procedure or from surgery.

Radial approach technique

The Allen test was routinely used to screen the patient suitable for radial artery catheterization. In the case of abnormal Allen test, the Barbeau test[6] was performed. A dedicated arterial puncture kit (with plastic cannula and hydrophilic wire) and long (25 cm) hydrophilic sheath (Radifocus, Terumo, Japan) were used for radial artery catheterization. Diagnostic procedures were performed by a 5F or 6F catheter sheaths, whereas 6F catheter sheaths were adopted for coronary interventions. In diagnostic procedures, 5000 IU heparin bolus was administered through the sheath. In patients undergoing interventional procedures, weight-adjusted (100 IU/kg) bolus was administered through the sheath at procedure beginning and was eventually followed by further intravenous heparin boluses to maintain activated clotting time between 250 an 300 s. Vasodilator drugs were not routinely administered, and nitrates only were used in the case of documented or suspected radial artery spasm. The arterial sheath was always withdrawn after the procedure. A bandage made of a gauze pad and 3 adhesive elastic bands was used for compression. The bandage was slackened after 1 hour and kept on for 4 to 6 hours after procedures.

Vascular complications definitions

Vascular complications were defined as any vascular damage documented by specific instrumental investigations and included the following types:

1. vessel perforation,
2. arterial-venous fistula,
3. pseudoaneurysm,
4. arterial dissection,
5. compartmental syndrome,
6. retroperitoneal hematoma,
7. local hematoma in the absence of documented specific vessel damage, and
8. any other vessel damage or entry-site complication (access-site infections, peripheral ischemia, etc).

Asymptomatic postcatheterization radial artery occlusion was not considered a VC nor was prospectively evaluated.

Vascular complications were defined as radial related or nonradial related (in the case of crossover to femoral or brachial approach). In the case of the occurrence of both radial and (after access crossover) nonradial VCs in the same patient, both complications were considered separately.

Vascular complications were classified as

1. Major: requiring surgery and/or blood transfusions or causing a drop in hemoglobin levels >3 g/dL
2. Minor: requiring instrumental investigations but managed conservatively (no surgery, no blood transfusions) and not causing hemoglobin drop >3 g/dL.

All the medical records were reviewed by 2 senior interventional cardiologists (CT and FB) who were responsible for the final adjudication of VC occurrence and type definition.

Forearm access site selection and operators' experience with radial approach

All the procedures were performed by a senior operator familiar with the radial access (>60% of percutaneous coronary procedures performed by radial approach at study beginning) or by an interventional cardiology fellow with the senior operator aside.

The access site selection (right or left, radial or ulnar) was left to the operator's discretion. However, the following agreed rules were shared by all operators of our institutions:

- Patients with renal failure requiring dialysis were not considered for the radial or ulnar approach to avoid any damage to the forearm circulation;
- A normal Barbeau test[6];

- Right radial access was the default approach in unselected patients undergoing elective coronary angiography;
- Left radial approach was the default approach in patients with previous coronary surgery using a left internal mammary artery[7]; and
- Ulnar approach was considered only in patients with previous documentation of unfavorable radial anatomy and after confirmation of radial artery integrity by normal "reverse" Allen test.

Finally, in patients undergoing urgent interventions in the setting of ST-elevation myocardial infarction or in those undergoing elective complex coronary interventions (chronic total occlusions, bifurcations, calcific lesions, unprotected left main), the use of radial approach varied according to the individual operator's attitude. Accordingly, the operators were defined "dedicated radialists" if the rate of radial access was ≥90% at study begin (2 operators) and "standard radialists" if the rate of radial approach was <90% at study begin (6 operators).

To evaluate the possible impact of learning curve on the procedural success and VC, data were evaluated in the different study periods using the following 3 time intervals: (1) 2005 to 2006 (May 2005-December 2006), (2) 2007 to 2008 (January 2007-December 2008), and (3) 2009 to 2010 (January 2009-May 2010).

Statistical analysis

Continuous variables were checked for normality using the Kolmogorov-Smirnov test, presented as mean ± SD, and compared using the Student unpaired *t* test. Categorical variables are presented as counts and percentages and compared by means of χ^2 tests or Fisher exact test, as appropriate.

An intracluster correlation analysis was performed to explore the possible impact of including multiple procedures from the same patients.

Multivariate analysis, using a binary logistic regression, was performed to identify predictive variables of VC, and C-statistic was used to explore the overall performance of the model. To avoid overfitting, bootstrapping analysis with 1000 bootstrap samples was performed. The logistic regression model was built by inserting the 3 clinical variables associated at univariate analysis with VC (age, sex, previous coronary surgery). Adjusted odds ratio (with 95% CIs) was calculated.

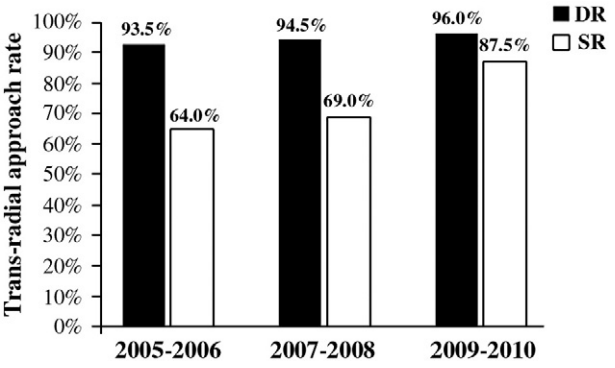
A 2-tailed *P* value <.05 was established as the level of statistical significance for all tests. Statistical analyses were carried out using IBM-SPSS Statistics software package for Windows (version 19.0; Chicago, IL).

No extramural funding was used to support this work. The authors are solely responsible for the design and conduct of this study, all study analyses, the drafting and editing of the manuscript, and its final contents.

Results

During the study period, 13,485 percutaneous coronary diagnostic or interventional procedures were performed at our institution. Among these, 10,676 procedures (79.2%) (on 8,577 patients) were performed using the radial (right or left) or the ulnar artery as the first approach being the object of the present study. Such procedures represented 80.4% of the elective procedures (10,078/12,521) and 62.0% (598/964) of the urgent procedures performed at our institution.

Figure 1



Rate of transradial approach for percutaneous coronary diagnostic or interventional procedures during the 3 study periods in operators with >90% radial access rate at study beginning (dedicated radialists) or in those with <90% radial access rate at study beginning (standard radialists). Dedicated radialists versus standard radialists: $P < .0001$ at all the 3 study periods. The rate of TRA significantly increased over time in both dedicated radialists ($P = .023$) and standard radialists ($P < .0001$) operators. *DR*, Dedicated radialists; *SR*, standard radialists.

A progressive increase in the radial access rate was observed during the study: 2005 to 2006, 73.1%; 2007 to 2008, 76.9%; and 2009 to 2010, 90.0% ($P < .001$). As shown in Figure 1, all the operators significantly increased their radial access rate during the study, dedicated radialists (4,057 procedures performed) having persistently a significantly higher rate of transradial approach to standard radialists (6,619 procedures performed).

The demographic and clinical characteristics of the study population are reported in Table I. The first attempted approach was the right radial in 9,339 cases (87.5%), the left radial in 1,319 cases (12.4%), and the ulnar (right or left) in 19 (0.1%). A double arterial access was electively adopted in 93 patients (0.9%) and consisted of contralateral radial injection in 49 cases of chronic total occlusion interventions and 44 transfemoral intraaortic balloon pump insertions. Concomitant transvenous right heart catheterization or temporary pacing was needed in 127 cases (1.2%) and was performed by the femoral vein or the arm vein approach. Procedural details and procedural non-VCs are reported in Table II.

Access crossover and impact of operator's radial volume

The overall access crossover rate was 4.9% and was significantly lower in dedicated radialists versus standard radialists (2.1% vs 6.6%, $P < .0001$).

Table I. Preprocedural clinical characteristics in the overall study population and in patients with or without VCs

Characteristic	All	VC	Absence of VC	P
No. of procedures	10676	53	10623	
Urgent	598 (5.6%)	1 (1.9%)	597 (5.6%)	.24
Diagnostic only	7204 (65.7%)	30 (56.5%)	7174 (67.5%)	.09
PCI	3664 (34.3%)	23 (43.5%)	3449 (32.5%)	.09
No. of patients	8577	51	8526	
Age (mean ± SD)	65.7 ± 10.8	70.5 ± 9.8	65.7 ± 10.8	.001
Female gender	2941 (27.5%)	23 (43.4%)	2918 (27.5%)	.01
Risk factors				
Family history of ischemic heart disease	2884 (27%)	15 (28.1%)	3261 (30.5%)	.85
Diabetes mellitus	2762 (25.9%)	16 (29.4%)	2762 (25.9%)	.49
Hypertension	7823 (73.3%)	40 (75.0%)	7823 (73.3%)	.76
Hypercholesterolemia	5898 (55.2%)	32 (59.5%)	5898 (55.2%)	.48
Active smoking	3261 (30.7%)	18 (34.0%)	3261 (30.5%)	.61
Clinical presentation				
Stable angina and/or inducible ischemia	5174 (48.5%)	32 (60.4%)	5142 (48.4%)	.08
Non–ST-elevation ACS	1903 (17.8%)	10 (18.9%)	1893 (17.8%)	.84
Previous myocardial infarction	1301 (12.2%)	6 (11.3%)	1295 (12.2%)	.85
ST-elevation myocardial infarction	1043 (9.8%)	4 (7.6%)	1039 (9.8%)	.59
Cardiogenic shock	23 (0.2%)	0	23 (0.2%)	.74
Previous PCI	2133 (20.0%)	11 (20.8%)	2122 (20.0%)	.89
Previous coronary surgery	944 (8.8%)	11 (20.8%)	933 (8.8%)	.002
Heart failure/cardiomyopathy	669 (6.3%)	3 (5.7%)	666 (6.3%)	.88
Valvulopathy	1072 (10.1%)	3 (5.7%)	1069 (10.1%)	.29

ACS, Acute coronary syndrome; *PCI*, percutaneous coronary intervention; *CTO*, chronic total occlusion.

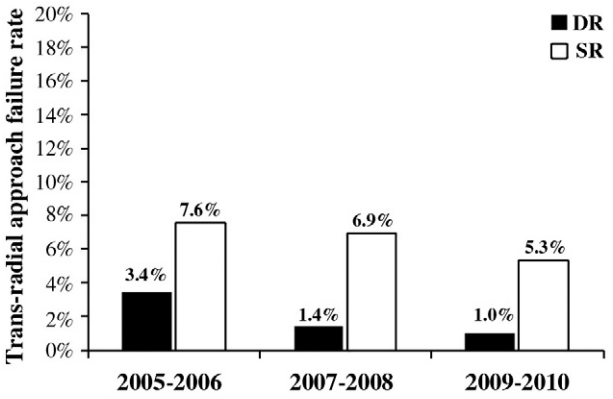
Table II. Vascular accesses, procedure failures, and non-VCs in the overall study population and in patients with or without VCs

Vascular access characteristics	All	VC	Absence of VC	P
Primary arterial vascular access				
Right radial	9338 (87.5%)	42 (79.2%)	9296 (87.5%)	
Left radial	1319 (12.4%)	11 (20.8%)	1308 (12.3%)	.17
Right or left ulnar	19 (0.2%)	0	19 (0.2%)	
Elective secondary arterial vascular access	93 (0.9%)	1 (1.9%)	92 (0.9%)	.43
Contralateral radial (PCI for CTO)	49 (0.5%)	1 (1.9%)	48 (0.5%)	.12
Femoral (PCI for CTO or IABP)	44 (0.4%)	0	44 (0.4%)	.64
Need of venous access	127 (1.2%)	1 (1.9%)	126 (1.2%)	.64
Right heart cath from arm vein	45 (0.4%)	0	45 (0.4%)	.64
Right heart cath from femoral vein	82 (0.8%)	1 (1.9%)	81 (0.8%)	.35
Failure of primary access	523 (4.9%)	20 (37.7%)	503 (4.7%)	<.0001
With crossover to contralateral radial	46 (0.4%)	2 (3.8%)	44 (0.4%)	<.0001
With crossover to femoral	468 (4.4%)	17 (32.1%)	451 (4.2%)	<.0001
With crossover to brachial	9 (0.1%)	1 (1.9%)	8 (0.1%)	<.0001
Non-VCs				
Cardiac complication				
Death	7 (0.07%)	0	7 (0.07%)	.85
VF or VT requiring DC shock	35 (0.33%)	0	35 (0.33%)	.68
Cerebrovascular accident				
Transient ischemic attack	3 (0.03%)	0	3 (0.03%)	.90
Stroke	3 (0.03%)	0	3 (0.03%)	.90
Allergic reaction	5 (0.05%)	0	5 (0.05%)	.87

CTO, Chronic total occlusion; *IABP*, intraaortic balloon pump; *cath*, catheterization; *VF*, ventricular fibrillation; *VT*, ventricular tachycardia; *DC*, direct current.

Access crossover rate significantly declined during the study (2005-2006: 5.5%, 2007-2008: 5.2%, 2009-2010: 3.9%, $P = .011$). Interestingly, as shown in Figure 2, both dedicated radialists and standard radialists exhibited a progressive decrease of access crossover rate during the study, dedicated radialists having persistently lower crossover rates.

Figure 2



Rate of radial access failure causing access crossover for percutaneous coronary diagnostic or interventional procedures during the 3 study periods in operators with >90% radial access rate at study beginning (dedicated radialists) or in those with <90% radial access rate at study beginning (standard radialists). Dedicated radialists versus standard radialists: $P < .0001$ at all the three study periods. The rate of access crossover significantly decreased over time in both dedicated radialists ($P < .0001$) and standard radialists ($P = .005$) operators. *DR*, Dedicated radialists; *SR*, standard radialists.

Among the 523 procedures requiring access crossover, the second approach was a femoral artery in 468 cases (89.5%), the contralateral radial in 46 cases (8.8%), and a brachial artery in 9 cases (1.7%). In 7 cases (0.07%) only (6 femoral, 1 radial), the second approach was not successful so that a third arterial approach was needed to complete the procedure.

In the case of access crossover, dedicated radialists used more commonly the contralateral radial compared with the standard radialists: 21 (25.0%) of 84 versus 25 (5.7%) of 439; $P < .0001$. As a consequence of both reduced access crossover rate and higher use of contralateral approach, "dedicated" radial operators had an overall rate of procedures requiring nonradial approach of 1.6% (63/4057) versus 6.3% (414/6619) among standard radialists ($P < .0001$).

Vascular complications

Vascular complications were observed in 53 patients (0.5%) and were radial related in 44 cases (0.4%, 83.0% of all VC) and nonradial related in 9 cases (0.1%, 17.0% of all VC). No patient presented both radial-related and non–radial-related VC, and no appreciable intracluster correlation was observed (Cronbach $\alpha = .0001$). Non–radial-related VC included 6 major complications (1 retroperitoneal hematoma, 1 large groin hematoma, and 1 femoral pseudoaneurysm with hematoma causing hemoglobin drop >3 g/dL) and 3 minor complications (3 femoral pseudoaneurysm successfully managed by Doppler-guided compression). Radial-related VC are reported in details in Table III and included 10 major VCs (0.1%) and 34 minor VCs (0.4%). The radial-related major VC included 2 compartment syndromes requiring urgent surgery, 2 pseudoaneurysm treated by elective surgery, 2 mycotic aneurysms treated by antibacterial therapy followed by elective surgery, and 4 forearm hematomas causing hemoglobin drop >3 g/dL (and managed without blood transfusions). Interestingly, the 2 compartment syndromes occurred during the first and second study period, whereas no case was noted in the last study period.

As shown in Figure 3, the rate of VC was stable during the study period and did not differ significantly between dedicated radialists and standard radialists operators.

Vascular complication occurrence was similar according to the type of first arterial access and to the need of elective secondary arterial or venous vascular access (Table II). Similarly, VC rate was not significantly different among elective or urgent procedures (0.52% vs 0.17%, $P = .24$) among interventional or diagnostic only procedures (0.63% vs 0.42%, $P = .14$).

As shown in Table I, among the preprocedural characteristics, only age, female gender, and previous coronary surgery were significantly associated to the occurrence of VC. The multivariable analysis model with bootstrapping (P for the model = .001) showed that age ($P = .003$), female gender ($P = .008$), and previous coronary surgery ($P = .026$) were the factors independently predicting the occurrence of VC. The C-statistic was 0.68, and the estimated odds ratios (95% CIs) were the following: 1.05 (1.01-1.07) for age, 2.03 (1.16-3.5) for female gender, and 2.79 (1.41-5.52) for previous coronary surgery.

Finally, a strong association was found between VC and access crossovers (VC rate 3.83% in patients with access crossover vs 0.33% in procedures successfully completed by radial approach, $P < .0001$). Such association was largely due to the fact that the occurrence of VC caused access crossover and that access crossover exposed patients to nonradial VC. Indeed, among the 20 patients who had both VC and access crossover, 8 (40%) had VC diagnosis before (and causing) access crossover, 9 (45%) had non–radial-related VC after crossover to femoral access, and 3 (15%) only had diagnosis of radial-related VC after the procedure.

Discussion

The present large, prospective study assessing the impact of systematic adoption of radial access for percutaneous coronary procedures shows that

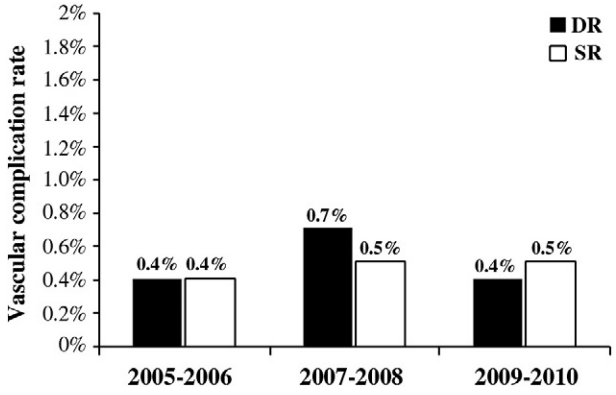
- Transradial approach is associated to high procedure success, which depends on operator's experience, and

Table III. Types and severity of radial-related VCs

	Total	Major: surgery	Major: blood transfusions	Major: Hb drop >3 g/dL	Minor
Radial-related VC	44 (0.41%)	6 (0.06%)	–	4 (0.04%)	34 (0.32%)
Vessel perforation	4 (0.04%)	–	–	–	4 (0.04%)
Arterial-venous fistula	9 (0.08%)	–	–	–	9 (0.08%)
Pseudoaneurysm	10 (0.09%)	2 (0.02%)	–	–	8 (0.08%)
Arterial dissection	4 (0.04%)	–	–	–	4 (0.04%)
Compartmental syndrome	2 (0.02%)	2 (0.02%)	–	–	–
Local hematoma in the absence of documented specific vessel damage	12 (0.11%)	–	–	4 (0.04%)	8 (0.08%)
Any other vessel damage or entry-site complication	3 (0.03%)	2* (0.02%)	–	–	1† (0.01%)

*Two patients with mycotic aneurysms.
†Possible hand ischemia (a patient who complained of hand pain with Doppler documentation of radial artery occlusion and concomitant atherosclerotic subocclusion of the ulnar artery).

Figure 3



Vascular complication rate after percutaneous coronary diagnostic or interventional procedures during the 3 study periods in operators with >90% radial access rate at study beginning (dedicated radialists) or in those with <90% radial access rate at study beginning (standard radialists). Vascular complication rate was stable during the study and did not differ significantly between dedicated radialists and standard radialists operators (all *P*, nonsignificant). *DR*, Dedicated radialists; *SR*, standard radialists.

- Transradial approach is associated to a very low rate of VC, which is stable over time and does not depend on the (radial) operator experience.

After its first reports,[8,9] transradial approach has gained progressively clinical attention finally being recognized as a promising strategy to increase the safety of percutaneous coronary procedures.[4,5,10,11] Such notion is supported by the results of meta-analyses of previous small studies[1,2] as well as by a large prospective randomized study,[3] which, overall, provided evidence of a strong reduction in (major) VC with transradial approach as compared with transfemoral. The relevance of this issue has recently been reinforced by the demonstration of the negative impact on the clinical outcome of hemorrhagic complications and of blood transfusions in acute coronary patients.[12] Yet, radial access is still by far underused in the clinical practice in many countries including the United States.[10,13] In addition to "historic" factors, the underuse of transradial approach is also due to technical complexities related to smaller caliber of the artery and to more difficult catheter manipulations due to (frequently encountered) anatomical variants of the upper arm arterial axis from the wrist to the aorta.[14] Such increased complexity is known to cause increased need of access crossover as compared with transfemoral approach[1] and to require a specific learning curve to be successfully overcome.[15] The present study confirms the relevance of operator's experience and extends its impact beyond the starting phase of the learning curve. Indeed, although all the operators were fully familiar with the radial access before study beginning, a significant difference was observed in the procedure failure rate between operators with different usage of transradial approach. Moreover, both dedicated radialists and standard radialists exhibited a reduction of access crossover over time, thus confirming the impact of operator's experience on procedure success. Procedure failure reduction was paralleled by increased operator's confidence in selecting radial access systematically so that the rate of transradial approach progressively increased at our institution during the study, thus resulting in a higher number of patients offered this procedure. Such observation suggests that operator education and continuous experience exchange are both pivotal for successful programs of radial adoption in transfemoral catheterization laboratories.

In the transition from femoral to transradial approach, the issue of the specific radial-related complications needs careful evaluation. Indeed, transradial approach is

Table IV. Incidence of some specific VCs in the radial arm of radial versus femoral trials

Study	Year	No. of patients	Local hematoma	Arterial-venous fistula	Pseudoaneurysm	Compartmental syndrome
ACCESS[17]	1997	279	0% major*	NR	NR	0%
Benit et al[18]	1997	50	0% major*	2%	0%	0%
Mann et al[19]	1998	74	0% major*	NR	NR	0%
Cooper et al[20]	1999	101	11.9%	NR	NR	0%
CARAFE[21]	2001	140	1.4%	NR	NR	0%
TEMPURA[22]	2003	77	0% major*	NR	NR	0%
Reddy et al[23]	2004	25	0% major*	NR	NR	0%
OCTOPLUS[24]	2004	192	3.5%	NR	0.5%	0%
Slagboom et al[25]	2005	322	0.9%	NR	NR	0%
RADIALAMI[26]	2005	25	9%	0%	8.7%	0%
Lange and von Boetticher[27]	2006	146	NR	NR	NR	NR
Li et al[28]	2007	184	1.1%	0%	0%	0%
Cruden et al[29]	2007	44	0%	0%	0%	0%
FARMI[30]	2007	57	3.5%	NR	0%	0%
Yan et al[31]	2008	57	0%	NR	0%	0%
Achenbach et al[32]	2008	152	0%	0%	0%	0%
RADIAMI[33]	2009	50	10%	0%	0%	0%
Santas et al[34]	2009	667	0.3%	NR	0%	0%
Brueck et al[35]	2009	512	0%	0%	0%	0%
Hou et al[36]	2010	100	2%	NR	0%	0%
RIVAL[3]	2011	3507	1.2%	0%	0.2%	0%
Present study	2011	10676	1.3%	0.08%	0.04%	0.02%

NR, Not reported.
*Only complications with major clinical consequences reported.

associated not only to the favorable reduction of VC but also to a change in their pattern with the introduction, in rare cases of specific types of major VC, such as the compartment syndrome,[16] which may impact on patient clinical status. A series of access-related specific complications have been described for radial access in previous trials[17-36] (see Table IV), but their typology and clinical impact have not been systematically investigated in appropriately powered studies. Thus, in the present study, we have not only prospectively assessed the occurrence of the different VC types but also investigated the clinical course after diagnosis. The observed findings support the safety of transradial approach as a preferred approach for percutaneous coronary procedures. Indeed, in this >10,000 procedure series, the rate of access crossover was 0.5%, the rate of VC needing surgery was 0.06%, whereas no patient needed blood transfusion caused by access-related bleedings. These remarkable results are probably the consequence of the combination of the intrinsic safety of the radial approach and an appropriate surveillance on and management of radial-related VCs. Indeed, our approach based on immediate angiography in the case of intraprocedural suspect and ultrasound assessment in the case of postprocedural suspect allowed an early recognition of VC.[37] This allowed us to solve with simple prolonged external compression most VCs so that surgery was rarely needed. The relevance of operative protocols for postprocedural management of patients who received transradial procedures has been suggested also by Bertrand[38] and deserves attention during the introduction of radial access in the catheterization laboratory practice. Of note, team approach and practice may be necessary to gain an optimal efficiency from operative protocols, as the 2 compartment syndromes occurred during the first and second study period but not in the last one.

Interestingly, operator attitude (systematic or nonsystematic use of transradial approach) was not associated to the occurrence of VCs, which indeed was mainly influenced by patient-related factors (such as age and gender). Again, this issue supports the safety of radial programs in transfemoral catheterization laboratories.

Study limitations

Despite the prospective nature of the study and the accurateness of data collection, we cannot exclude to have underestimated the radial-related VC, as some of them may be diagnosed after hospital discharge. Indeed, after discharge, no systematic follow-up was performed in patients without VC. Yet, according to recent data by our group, most radial access-related VCs (approximately 85%) are diagnosed during hospitalization so that a major underestimation can be excluded.[37] On the other hand, because a series of technical details (including shorter and smaller sheaths, routine vasodilator drug use, dedicated radial hemostasis devices, and perfused hemostasis) may theoretically reduce radial

artery trauma, radial-related vascular events may have been somewhat overestimated.

Another important limitation is related to the lack of prospective evaluation of the cause for crossover to a second access, as a procedure failure occurring during the procedure may be more troublesome and less acceptable for both the patient and the operator than a failure at procedure beginning.

Moreover, as our study was conducted in a single center with high-volume radial operators, the observed results need to be confirmed in multicenter studies conducted in centers with various case load. The relevance of this latter issue is underlined by the recent RIVAL trial showing that the radial approach benefit is strongly dependent on the transradial procedure volume of enrolling centers.[3]

Finally, postcatheterization radial artery occlusion has not been systematically investigated so that no information regarding the predictors and the clinical consequences of this (frequent) complication can be derived from the present study.

Conclusions

The present large registry describing the VC occurring in percutaneous coronary procedures performed by transradial approach in a high-volume European center shows that the clinical application of systematic radial access has a very promising safety profile and an efficacy, which is dependent on radial experience.

Acknowledgements

We thank all the nurses and the technicians of the catheterization laboratory of our institute for their invaluable help during the introduction of novel techniques in the daily practice.

Disclosures

Financial disclosures: The authors declare that they have no competing interests.

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