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Original Article

Safety of transradial compaired to transfemoral approach in interventional cardiology

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Abstract

Background
The femoral approach has been preferably used to access in interventional cardiology, being perceived as easy and facilitating quick access with relatively low risk. In the hands of experienced operators and high-volume centers, the radial approach offers improved patient comfort, decreased access-site complications, and decreased costs without compromising procedural success on long-term outcomes. Patients presenting with ST-elevation myocardial infarction, in particular, benefit from a transradial approach to coronary intervention. Owing to the results of the latest studies, the radial approach has become increasingly popular. Radial access is known to have a steep learning curve. The effect of this results in the hesitation of performing percutaneous coronary intervention through radial route by conventional femoral access operators. A growing body of evidence supports the adoption of transradial artery access to improve acute coronary syndrome-related outcomes, to improve healthcare quality, and to reduce cost. The purpose of this study was to propose and support a transradial strategy for patients with stable coronary artery disease as well as those presenting with acute coronary syndromes. The aim of this study was a safety analysis of coronary interventional procedures according to the access vessel.

Materials and methods
A total of 204 coronary interventions done in the Department of Interventional Cardiology were retrospectively analyzed. All the procedures were classified according to femoral or radial access. The incidence of local complications (e.g. major bleedings and hematomas) was assessed as well as the volume of contrast agent administered during the procedure and the fluoroscopy time of the procedure.

Results
It has been shown that radial approach, which is obviously more comfortable for patients, reduces the risk of local complications (0 vs 2.97% and 0 vs 3.96%). However, there could be a larger volume of contrast agent administered (P=0.029), which in some cases could increase the risk of contrast-induced nephropathy, and redial access has a longer fluoroscopy time.

Conclusion
The radial approach should be recommended as a first choice because it is safer than the classical femoral approach because it is associated with a lower incidence of complications, but one must be cautious in choosing radial-approach patients with renal insufficiency, especial in early learning because of the use of high contrast volume.

Keywords: Cardiac catheterization, femoral artery, percutaneous coronary intervention, radial artery

Background

Until recently, the femoral approach (FA) was preferably used method in interventional cardiology for diagnostics and therapeutic way of coronary artery disease. It has been perceived as being easy and facilitating quick access with relatively low risk. Owing to the results of the latest studies, however, the radial approach has become more popular. The use of the radial approach not only reduced the incidence of

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local and general operation-related complications but also proved to be preferred by patients [1–3].

Transradial artery access (TRA) for percutaneous coronary intervention (PCI) is associated with lower bleeding and vascular complications than transfemoral artery access (TFA), especially in patients with acute coronary syndromes (ACS). Use of TRA for coronary angiography and PCI may also be associated with improved measures of quality of life and reduced costs compared with TFA owing to shorter hospitalization time, especially in patients with ACS.

Despite the almost unequivocal results concerning the selection of the vessel approach, radial access continues to have its detractors. The most common arguments brought up are the relatively large proportion of permanent radial artery (RA) occlusions following the procedure and the need to learn a new method that is more difficult for the operator than the radial approach is. Thus, the largest opposition to this access is encountered in operator experienced in the FA. Attaining proficiency in TRA intervention, in practitioner experienced in TFA procedures, requires time and effort. TRA access has become the default mode of catheterization for a growing number of cardiologists and will undoubtedly continue to be increasingly performed.

This safety analysis was performed to assess the legitimacy of the radial approach experimentally. The analysis was performed in the department during the transition period from the femoral to the radial approach.

The aim of this paper was a retrospective comparison of safety between the femoral and radial approaches during coronary angiography procedures conducted in patients hospitalized between the years 2017 and 2018.

Materials and methods

A total of 204 coronary interventions done in the Department of Interventional Cardiology were retrospectively analyzed. All the procedures were divided according to the femoral or radial access. The analysis covered diagnostic and therapeutic coronary artery procedures in the year 2017 when the FA was preferred (90 patients) and in the year 2018 when the radial approach was introduced (114 patients). In 2017, all patients were subjected to the FA, but in the year 2018, 11 patients were subjected to the FA whereas 103 to the radial approach. Patients are divided into two groups with respect to the access site: the FA and the radial approach (RA). Two patients were switched from the TFA group to TRA procedure, and as a result, the tortuous aorta. The opposite process (a shift from the radial to the FA) was used in six patients. In the end, 204 patients were assessed (RA – 103 and FA – 101). The trial was approved by the national heart instute board.

Study procedure

The right RA was selected as the access in all cases of the study. RA access was achieved with transradial kit (AVANTI + of Cordis containing 21 G metal puncture needle with a compatible short metallic straight-tip guide-wire and introducer sheath of 6 F in diameter) under local anesthesia. Vasodilator cocktail in the form of 100 μg of nitroglycerine with 5000 units of unfractionated heparin along with 5 mg of Isoptin was used intra-arterially through the accessed RA to prevent RA spasm. This cocktail was readministered if the patient complained of forearm pain or if there was resistance to manipulation of the catheters. In all patients, the introductory sheath was removed immediately after the procedure, and hemostasis was achieved using an elastic compressor bandage, without using compression devices. The bandage was kept in place for at least 4 h. The patient was allowed to be ambulatory immediately following the procedure. All patients were evaluated 24 h after the procedure, and we noted the presence of palpable hematomas at the puncture point, hemorrhage, pain on palpation of the puncture area, and the presence of a distal radial pulse. Similarly, we performed an inverse Allen test, which was considered abnormal if normal color did not return to the hand with 10 s after removing the pressure to the RA. RA obstruction was considered present in the absence of a radial pulse distal to the puncture site or an abnormal inverse Allen test result.

Statistical analysis

All analyses were prepared using Statistica 10.0 with the medical set (Stat Soft Inc, Stat Soft Europe, Poßmoorweg 1, 22301 Hamburg, Germany). Continuous variables are expressed as medians with first to third percentile and qualitative variables as percentages. The normality of each continuous variable was at first tested with the Shapiro–Wilk W test. Because there were non-normal variables in further analyses, nonparametric, two-sided tests were used. Qualitative variables were analyzed with the Fisher exact test. *P* less than 0.05 was considered statistically significant.

Basic demographic data, the type of procedure, and indications to the coronary intervention were assessed (Tables 1, 2), and no differences between FA and RA groups were observed. Groups of patients were also analyzed concerning fluoroscopic time, the volume of administered contrast agent, and procedure-related complications, which were divided into hemorrhagic (major bleedings) and local (false aneurysm and large hematomas).

Results

The volume of contrast agent used and fluoroscopy time is presented in Table 1. The analysis shows that there are differences in the volumes of contrast used during between the TFA and TRA groups, as well as a difference in fluoroscopy time. Similar results were observed between the distinct subgroups of diagnostic and interventional percutaneous coronary angioplasty. Use of contrast agent was greater during the radial approach than in the FA in each studied group. The fluoroscopy time was longer for radial access.

Patients were also compared about complications, but no statistically significant differences were observed between the groups (Table 3). There was, however, a tendency to an increased number of complications in the TFA group, accompanied by a borderline value using the Fisher exact test ($P = 0.058$). It is noteworthy that despite there being no statistical differences

Table 1: Basic demographic and clinical data regarding the included patients

Demographic data	Radial access (%)	Femoral access (%)	*P*
Age	62.6±10.2	62.9±12.8	0.88 (NS)
Sex	38.8 (female)	27.7 (female)	0.09 (NS)
Patients' burdens			
Arterial hypertension	72.8	68.3	0.48 (NS)
Diabetes	27.2	30.7	0.58 (NS)
Hyperlipidemia	45.6	34.6	0.11 (NS)
Cardiac infarction	24.3	32.7	0.18 (NS)
Coronary artery bypass graft	5.8	5.9	0.97 (NS)
Aortic valve disease	3.9	4.0	0.74 (NS)
Indications			
STEMI	6.8	9.9	0.42 (NS)
NSTEMI	14.6	15.8	0.80 (NS)
Unstable angina	1.94	6.93	0.075 (NS)
Stable CAD	75.7	68.3	0.24 (NS)
Kind of intervention			
Coronarography	64.1	60.4	0.59 (NS)
Coronarography and PCI	35.9	39.6	

CAD, coronary artery disease; PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction.

Table 2: The comparison of fluoroscopy time and volume of contrast agent used in the analyzed groups

Procedure	Analyzed group		*P*
	Radial	Femoral	
n	103	101	-
Dose of radiation	1.218 (0.696-2.207)	1.199 (0.677-2.001)	0.88 (NS)
Contrast	100 (70-200)	80 (60-150)	0.029
Coronarography			
n	66	61	-
Dose of radiation	0.869 (0.613-1.450)	0.940 (0.607-1.374)	0.92 (NS)
Contrast	80 (60-100)	60 (50-80)	0.008
Angioplasty			
n	37	40	-
Dose of radiation	2.244 (1.689-3.0239)	1.800 (1.188-3.00)	0.41 (NS)
Contrast	200 (160-200)	190 (100-200)	0.044

in the TRA group, no complications were reported, whereas in the FA group, they did occur (Table 3). Subgroup analysis of patients patients presenting with ACS syndrome in TRA (24.3%) and TFA (21.7%) groups, the results were the same, with the use of contrast agent greater during the radial approach than in the FA in each studied group. The fluoroscopy time was longer for radial access. The crossover from redial to femoral access was in 5.5%, whereas crossover from femoral to radial access was 1.9%.

Discussion

Choice of arterial access site is an important debatable issue while performing percutaneous transluminal coronary angioplasty. Those practicing TFA feel to remain attached to it as they see no major advantage of TRA interventions. Moreover, the steep learning curve described for transradial interventions makes them comfortable with the FA. The major hurdles that have been considered as contributors toward steep learning curve for operators are difficulty in having access of RA, RA spasm, loops and bends in the course of the catheter, prolongation of procedure time, and associated increased radiation exposure. The major advantage of avoiding the transfemoral route is the freedom from local site complications, which may prolong hospitalization because of blood transfusion or some additional diagnostic and therapeutic procedures.

This work aimed to demonstrate the benefits and safety of the radial approach in comparison with the FA for patients with coronary interventions (diagnostic or therapeutic).

We selected from among factors that can be easily assessed by retrospective analysis and contribute to patient benefit in terms of the volume of applied contrast agent, fluoroscopy time, and incidence of complications. Between the compared groups, a statistically significant difference in fluoroscopy time was found. However, there are studies, which demonstrate a small but statistically significant difference in radiation dose, which was smaller in the FA [3,4].

Another aspect of the present comparison was used – the volume of contrast agent. A contrast agent is crucial for radiodiagnostics because the quality of obtained pictures depends on volume and quality of contrast agent. However, it should be remembered that some complications such as CIN (contrast-induced nephropathy) and hypersensitive reactions are connected with an excessive volume of contrast agent. In previous papers, there were no differences in the volume of contrast agent in terms of the vessel approach used [3], or the volume was greater in the radial approach [5]. Our results are in concordance with previous reports; they indicate that the volume of contrast agent is statistically greater in the radial approach procedure. It corresponds, however, to the results of 'the learning curve' in radial approach procedures [6,7].

In this study, the advantage of the radial approach to periprocedural complications was proven. About the observed tendency toward greater complications with TFA, a larger number of patients would be necessary to demonstrate the advantage of radial access.

Large clinical studies have demonstrated the advantages of the radial approach [1,3]. Use of contrast agent was greater during the radial approach than in the FA in each studied group. The fluoroscopy time was longer for radial access.

Vascular access complications

Most studies of patients with ACS demonstrated lower rates of vascular access site complications with TRA compared with TFA for angiography and PCI. These studies did not report RA occlusion (RAO) as a vascular complication, likely because

Table 3: Complications of a percutaneous procedure

	Analyzed group [*n* (%)]		*P*
	Radial	Femoral	
Catheterization			
Hemorrhagic complications	0	3 (2.97)	0.12 (NS)
Local complications (aneurysm + hematoma)	0	4 (3.96)	0.058 (NS)
Coronarography			
Hemorrhagic complications	0	0	NS
Local complications (aneurysm + hematoma)	0	2 (3.28)	0.23 (NS)
Angioplasty			
Hemorrhagic complications	0	3 (7.5)	0.24 (NS)
Local complications (aneurysm + hematoma)		2 (5.0)	0.49 (NS)

the clinical significance of RAO remains controversial. In the RIVAL trial, the incidence of major vascular access site complications was significantly lower in the TRA group [1.4 vs 3.7%; heart rate (HR): 0.37; 95% confidence interval (CI): 0.27–0.52], and the incidence of symptomatic RAO was extremely low (0.2%) [1].

In patients with ST-elevation myocardial infarction (STEMI), the incidence of major vascular access complications was 1.2% with TRA and 3.4% with TFA ($P = 0.002$) [8].

Although the overall incidence of major vascular complications in the MATRIX trial was low, patients randomized to TRA had a lower likelihood of complications that required surgical repair (0.1 vs 0.4%; relative risk: 0.27; 95% C:, 0.09–0.80) [2].

In the STEMI-RADIAL trial, vascular complications were uncommon and not significantly different between TRA and TFA (0.3 vs 0.8%; $P = 0.62$) [5].

Specific concerns about TRA in acute coronary syndrome (ACS) are reperfusion time and procedural success, as the two of the most important determinants of outcome for patients with ACS relate to the time to reperfusion of an occluded artery and overall procedural success. Although earlier studies reported a longer time to sheath placement or injection of the coronary artery and a longer door-to-balloon time with TRA, contemporary studies of TRA vs TFA have not demonstrated a significant difference in these times. There were also no differences in procedural success by access site among patients with ACS [9]. Data from the RIVAL and RIFLE-STEACS trials, In this study, the authors demonstrated that a substantial delay in STEMI reperfusion time (>20–80 min, depending on model assumptions) is required to offset the TRA-related mortality benefit demonstrated in clinical trials.[10]

Radiation exposure

Observational studies and randomized data have demonstrated longer fluoroscopy times with TRA procedures. However, assessments of radiation exposure as measured by the more accurate parameter of the dose-area product have reported mixed results. Some studies demonstrated a higher dose area product with TRA, whereas others reported no difference. Most recently, Radiation Substudy of MATRIX demonstrated greater radiation exposure with TRA even in this set of experienced TRA operators. Use of left vs right TRA also demonstrated mixed findings for radiation exposure.

Contrast volume

Most recent studies have demonstrated no difference or lower contrast volume with TRA compared with TFA [11–13]. Contrast volume appeared to be lower in procedures performed in centers with high-volume TRA operators [12]. A recent report from the MATRIX trial demonstrated that acute kidney injury occurred in 15.4% of patients who were randomized to TRA and in 17.4% of patients randomized to TFA (OR: 0.87; 95% CI: 0.77–0.98) [13]. Further investigation in this area is warranted.

Although the relative benefits of TRA over TFA are most pronounced in high-risk patient subgroups such as those with ACS, maintenance of adequate operator and center volume is important in realizing these benefits.

Analyses of the TRA learning curve suggest that operator proficiency may reduce concerns about access site crossover, radiation exposure, contrast volume, delay in reperfusion time, and procedural success [14].

Although the necessary procedures to achieve (>50 cases) and maintain (>80 procedures a year) proficiency have been proposed, many factors determine operator and center expertise in the TRA technique. Furthermore, the relationship between volume and procedural success does not appear to have a threshold [15]. Predictors of PCI failure with TRA catheterization include increasing age (≥75 years), female sex, previous CABG, cardiogenic shock, and short stature [16]. It is recommended that operators and centers pursue a radial-first strategy and a graduated exposure to case complexity with a transition plan for the ACS setting.

Plans to pursue TRA in STEMI and cardiogenic shock may need to be deferred until both the center and the operator have sufficient experience to ensure operator and staff comfort in achieving acceptable procedural time.

A recent update on RA Access and Best Practices for Transradial access in Coronary Angiography and Intervention in patients with ACS published by the American Heart Association stated that TRA should be considered the default strategy in the invasive management of patients with ACS. In the ACS population, TRA is associated with a significantly lower incidence of bleeding and vascular complications and potential mortality compared with TFA.

The mortality benefit is observed in patients with high predicted bleeding risk. The use of TRA in these patients requires an operator and institutional experience to optimize procedural outcomes. Compared with TFA, TRA is also associated with improved quality of life [17,20,21].

In the SAFARI-STEMI trial presented in March 2018 at ACC[16] in New Orleans, LA, patients with acute myocardial infarction who undergo PCI have the same 30-day mortality regardless of whether radial or femoral access is used for PCI, according to the results of this study. Michel Le May *et al*.[18] enrolled 2292 patients with STEMI from five medical centers across Canada. All patients underwent PCI; half were randomly assigned to radial access and the other half to femoral access. Most patients received bivalirudin and ticagrelor during and after PCI, respectively. According to the results, 30-day mortality was 1.5% in the radial access group vs 1.3% in the femoral access group. Rates of secondary outcomes, including subsequent acute myocardial infarction, blood clots, and bleeding complications, were not significantly different between the two groups. The researchers concluded that patients with STEMI should have similar results after PCI for either radial or femoral access. The operator stated that clinicians should be able to perform PCI using either approach because it is sometimes necessary to switch access sites for certain patients during the procedure. Despite advances in devices and technique, access site crossover remains an important limitation of TRA. Real world estimates of crossover rates have varied (4.6–10%), but operator experience consistently predicts rates of crossover. The RIVAL trial showed that the rate of access site crossover was higher in TRA compared with TFA (7.6 vs 2%; HR: 3.82; 95% CI: 2.93–4.97), but such crossover was lower in centers with higher PCI volume (4.4 vs 2.3%; HR: 1.92; 95% CI: 1.19–3.08). Some data suggest that the use of left (LRA) over the right RA (RRA) might help reduce crossover rates because of the lower prevalence of left-sided brachiocephalic tortuosity.[19]

Finally, crossover rates are also reduced with ultrasound guidance.

Conclusion

The increasingly frequently used and patient-preferred radial approach is safe as the classic FA with a trend toward lower periprocedural complications. However, it is associated with a longer fluoroscopy time. At sites where the radial approach is not routine, the risk of larger contrast agent volume usage increases. Thus, in patients at risk of CIN or who have a renal deficiency or hypersensitivity to the contrast agent in their medical history, the classical FA is recommended.

In patients with ACS, TRA is recommended, owing to lower incidence of bleeding and vascular complications and potential mortality compared with TFA. The mortality benefit is observed in patient s with high predicted bleeding risk. The use of TRA in these patients requires operator and institutional experience to optimize procedural outcomes. Compared with TFA, TRA is also associated with improved quality of life, reduced healthcare resource use, and reduced healthcare costs, owing to a shorter hospital stay and less bleeding complication.

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Conflicts of interest

There are no conflicts of interest.

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