Transradial versus Transfemoral Approach in Peripheral Arterial Interventions

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Abstract

This study aims to compare the clinical and procedural characteristics, including iatrogenic complications, of transradial versus transfemoral approach in patients who underwent peripheral arterial interventions.

We retrospectively analyzed data of 72 patients who had undergone interventions of peripheral arteries in the preceding 3 years. Of all the procedures, 39 were performed using the transfemoral approach and 33 using the transradial approach. We assessed baseline clinical factors as well as procedure-related parameters (volume of contrast media, the amount of radiation, and duration of radiation exposure), rates of primary success, and acute vascular, access-site, or neurological complications.

Patients whose interventions were done via transradial access had similar demographic characteristics to those who had transfemoral angioplasties. The presence of cardiovascular risk factors was similar in the two groups, but patients in the transradial subset were significantly more likely to have dyslipidemia (90.9 vs. 71.7%, p value = 0.04) and less likely to have baseline chronic kidney disease (3.0 vs. 23.0%, p value = 0.01). The length of admission was shorter for patients who underwent transradial interventions compared with the transfemoral approach (1.1 vs. 1.3 days, p value = 0.04). Fluoroscopy time, the amount of radiation, and the volume of contrast media were similar between the two groups. Rates of primary success and periprocedural complications did not differ between the two groups.

The transradial route appears to be a viable, safe, and noninferior alternative to the transfemoral approach for treatment of atherosclerotic stenosis in peripheral arterial territories. Prospective studies are needed.

Keywords

- atherosclerosis
- carotid stenosis
- internal carotid artery
- peripheral arterial disease
- percutaneous
- transradial coronary intervention
- subclavian stenosis

Over the past decade, interventional cardiologists have embraced the use of the transradial approach (TRA) in coronary procedures. In some countries, the TRA is now the predominant access site for diagnostic and therapeutic coronary catheterizations, but in the United States, it is still being employed in a minority of cases.^{1,2} Compared with the transfemoral approach (TFA), the TRA offers several important

advantages. It results in lower rates of access-site complications, which translates into decreased procedure-related mortality.^{3–5} It leads to shorter time to ambulation and shortens the length of hospital stay. It also enhances patient comfort. Further advantages are expected as technological improvements facilitate the miniaturization of equipments, allowing stenting of smaller, more delicate arterial beds.

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Endovascular interventions using the TRA could benefit more than the coronary territory. TRA may enable better and more natural procedures of the peripheral circulation. In most of the cases, the transradial anatomy and catheter support are ideal when approaching the vertebral, subclavian, and right carotid artery. Accessing the renal and mesenteric vessels is more favorable using the TRA due to the superior orienting origin of those arteries. In addition, TRA is crucial when the common femoral artery is extensively diseased, thus enabling alternative means of access.⁶

Indeed, several trials have demonstrated the feasibility of TRA for stenting of the aortoiliac, renal, and carotid arteries.⁷⁻⁹ Those studies have shown that percutaneous treatment of these vessels is a safe and feasible alternative to TFA. Patients with specific anatomic characteristics were described in those trials: Patients with severe bilateral iliac artery disease or absent femoral pulses were included in a trial that assessed instrumentation of the iliac and femoral arteries. Similarly, stenting of the renal artery via the TRA was done in patients with acute aortorenal angles or severe peripheral arterial obstructions. Despite the encouraging results, there is still a paucity of data regarding the utility and outcomes of TRA, compared with TFA, for the standard, undifferentiated patient with peripheral arterial disease.

In our study, we report our experience with peripheral interventions using the TRA compared with the TFA, in patients with a variety of atherosclerotic pathologies.

Methods

Study Population

We retrospectively reviewed our database for all patients who had undergone peripheral arterial interventions at our institution from 2012 to 2014. All patients had symptoms that correlated with their angiographic findings. Patients with the interventions of the carotid, subclavian, vertebral, renal, aortoiliac, and superficial femoral arteries were included. All patients had baseline stenosis of greater than 70% defined by angiogram and most had comorbid conditions. All patients were on chronic aspirin therapy. Clopidogrel was started before the procedure and maintained for exactly 1 month after the procedure. Aspirin was continued indefinitely. Patients with mild or greater degrees of renal impairments were given intravascular fluids and *N*-acetyl cysteine before the procedure.

We analyzed the demographic factors and clinical characteristics of the patients. Pertinent procedural data were collected, including fluoroscopy time, the amount of radiation, and the volume of administered contrast. The incidence and nature of intraprocedural complications, vascular, access-site (local or systemic), and in-hospital adverse events was assessed. Neurological assessments were performed by certified neurologists, in suspected cases. Procedural success was defined as less than 30% of visual residual stenosis. Procedures that required a switch from one access site to the other were considered a failure.

Technique and Vascular Access

Each of the participating cardiologists had to perform at least 200 TRA percutaneous procedures of peripheral arteries by

2012, to increase the likelihood that they reach the plateau phase of their learning curve at the beginning of the study.

Patients with kidney impairment (baseline creatinine >1.5), nonpalpable radial artery pulse, or previous radial interventions, had their procedure done through the TFA. The remaining patients had their radial artery used as a port of entry. Switching between the transfemoral and the transradial route was permitted at any point, at the physician's discretion. The radial and femoral arteries were palpated manually and Allen test was done before each intervention. Radial sheaths for diagnostic and interventional procedures had a diameter of 5 to 6F in the TRA and 6F in the TFA. After placement of the Terumo introducer sheath (Terumo Radiofocus Introducer II, manufactured by Terumo Medical Corporation, Somerset, NJ) in the radial artery (but not in the femoral artery), a mixture of unfractionated heparin (5,000 IU) and isosorbide dinitrate (200 µg) was administered.

Cervical diagnostic procedures were undertaken using a 5F JR4, JL4, LIMA or Simmon 2 catheters (Cordis, Johnson and Johnson, Miami, FL) and long Multipurpose (125 cm) catheter for peripheral diagnostic procedure allowing a 300 cm, 0.035" or 0.018" wire into the descending aorta.

Interventions of infra-diaphragmatic vessels, as well as those of the left vertebral/subclavian arteries, were performed via the left TRA. Interventions of the right vertebral/subclavian and right/left carotid arteries were done through the right TRA. For carotid interventions, we used shuttle sheath, 6F (MPA1 J & J or Terumo destination).^{10,11}

Subclavian, vertebral, and renal procedures were done with coronary equipment. Aortoiliac and superficial femoral artery (SFA) procedures were performed by TRA without a guiding catheter using stiff SV-18, 0018", or Emerald 035" long wires. SFA procedures by TRA were only PTA (percutaneous transluminal angioplasty)-based using 180 cm long shaft Invatec Pacific Xtreme (Medtronic, Mexico) 5 to 6-mm, 120 to 150-mm long balloons. We used balloon expandable or self-expandable stents; according to the standard indications.¹² We did not use any homeostatic device.

Postprocedure Management

The femoral sheath was removed 2 hours after procedures, when activated clotting time (ACT) was less than 250 seconds, and a radial sheath was removed immediately following the procedure. Ambulation was allowed 8 to 12 hours after transfemoral procedures and 30 minutes after transradial procedures.

Angiographic records were studied offline. Mean percent diameter stenosis, at baseline and postprocedure, was calculated.

Statistical Analysis

Categorical variables are expressed as absolute or relative frequencies and are compared using the chi-square analysis or the Fisher exact test. Continuous variables are presented as mean ± standard deviation (SD). Differences between continuous variables were assessed by the Student *t*-test or the Wilcoxon two-sample test. A *p* value less than 0.05 was considered to be of statistical significance. The statistical

analyses were performed with SAS 9.2 software (SAS Institute Inc., Cary, NC).

Results

A total of 72 patients underwent percutaneous interventions of peripheral arteries at our institution during the 2012 to 2014 time period. Of those patients, 39 had procedures using TFA, while 33 were performed via TRA. The mean age of the patients (19 females, 53 males) was 64.2 years (range, 42–64.5 years). The patients had the following cardiovascular risk factors: dyslipidemia (80.5%), coronary heart disease (79.1%), hypertension (76.3%), diabetes mellitus (43.0%), current nicotine use (41.6%), and chronic kidney disease (13.8%).

Patients in the two groups had similar rates of cardiovascular risk factors (►Table 1). The prevalence of diabetes mellitus in the two groups was similar (38.4% transradial, 48.4% transfemoral), as were the rates of hypertension (71.7, 81.8%), smoking (41.0, 42.4%), and coronary heart disease (82.0, 75.7%). However, patients who underwent interventions via the TRA were less likely to have chronic kidney disease (3.0vs.23.0%, p value = 0.01) and more likely to have dyslipidemia (90.9vs.71.7%, p value = 0.04) compared with patients who had procedures using the TFA.

Stenting of the common iliac artery (or its branches) was performed in 22 patients (30.5%). Subclavian interventions were done in 11 patients (15.2%) while 9 patients (12.5%) each were treated for renal and vertebral atherosclerotic disease. Smaller numbers of patients were treated for disease of the internal carotid artery (right and left: 7 patients, 9.7%) and SFA (7 patients; 9.7%) (►Table 2).

Patients' preprocedure stenosis ranged from 70 to 100% (mean, 84.8%), with most patients having 80 to 90% stenosis. Following the procedure, stenosis ranged from 0 to 100% (mean, 8.2%;SD, 16.33), with most patients having less than 20% residual arterial stenosis. Calcification in the occluded vessel was seen in 11.0% of patients during fluoroscopy.

Table 1 Patient clinical data

Characteristic	Transradial approach: number of patients (%)	Transfemoral approach: number of patients (%)
Age (>65 y)	17 (51.5)	15 (38.4)
Gender (female)	7 (21.2)	12 (30.7)
Hypertension	27 (81.8)	28 (71.7)
Dyslipidemia ^a	30 (90.9)	28 (71.7)
Diabetes mellitus	16 (48.4)	15 (38.4)
Current smoking	14 (42.4)	16 (41.0)
Coronary artery disease	25 (75.7)	32 (82.0)
Chronic kidney disease ^a	1 (3.0)	9 (23.0)

Note: The mean age was 64.8 y for patients in transfemoral group and 63.3 y for patients in transradial group.

^aCharacteristics had a statistically significant between-group difference.

The mean amount of radiation used was 70.2 International System of Units (IS) (range, 4–260; SD, 53.9). Patients in the TRA group were exposed to 74.4 IS units of radiation, whereas those in the TFA group required a mean of 65.4 IS units (p value = 0.86). Duration of radiation exposure ranged from 3 to 40.2 minutes (mean, 12.6 minutes) in all patients. It was 13.3 minutes (mean) for patients in the TRA group and 11.8 minutes (mean) for patients in the TFA group (p value = 0.725). The volume of contrast media used ranged from 15 to 300 mL (mean, 104.6 mL). Mean values for contrast media volume were 105 and 104.3 mL, for patients in the TRA and TFA groups, respectively (p value = 0.85). Mean number of stents deployed was 1.2 in each group, ranging from 1 to 3 stents per intervention.

Acute vascular complications occurred in one patient (3.0%) in the TRA group and did not occur in the TFA group (p value = 0.20). During a TRA procedure on a 58-year-old man with an occluded common iliac artery, the 0.0014" coronary wire coiled in the aorta, resulting in stent migration to the axillary artery. Vascular surgical intervention was needed. Access-site complications were encountered in two patients in the TFA subset and in one patient in the TRA group (6.0 and 2.5% of patients, respectively; p value = 1.0). In the TFA subset, a 66-year-old man who underwent SFA instrumentation had an acute dissection that led to procedural failure. Another patient, an 83-year-old female, developed acute dissection after instrumentation of her iliac artery. Subsequent use of protamine sulfate led to symptom resolution and procedural success. Dissection occurred in one patient in the TRA group: A 70-year-old female who had a POBA (plain old balloon angioplasty)-based procedure of her SFA developed dissection following completion of the intervention. The procedure was completed successfully after prolonged balloon dilatation. Neurological complications (either local or systemic) did not occur in any patient in the two groups (►Table 3).

We were able to successfully complete interventions in 87.1% of the patients who had the TFA and 93.9% of those who had a TRA approach (p value = 0.44). Two patients in the TFA group and one in the TRA group whose initial procedure failed eventually had their intervention successfully done through the other route (TRA after TFA, or vice-versa). The most common reasons for procedural failure (in both access sites) were vessel tortuosity, calcification, or dissection. Most patients (76.3%) stayed at the hospital for a total duration of 1 day. Four patients (5.5%) stayed for 2 days, while six patients (8.3%) required more than 2 days before discharge. The mean length of hospital stay was 1.3 days (range, 1–5 days;SD, 0.9) for patients who had transfemoral interventions and 1.1 days (range, 0–5 days;SD, 1.1) for patients who had transradial interventions (p value = 0.04).

Discussion

Since the pivotal report by Campeau in 1989, the TRA has become an increasingly used standard for coronary angiographies.¹³ Numerous clinical trials have validated the feasibility and safety of this approach for diagnosis and

Table 2 Vessels of intervention

	Carotid	Subclavian	Vertebral	Renal	Aortoiliac	SFA
Transfemoral	8	5	4	7	11	4
Transradial	6	6	5	2	11	3

Abbreviation: SFA, superficial femoral artery.

Note: Chronic total occlusion was present in 3.0% of the patients in the transfemoral group and in 10.2% of the patients in the transradial group.

intervention of coronary vessels.^{3,14} Compared with the traditional femoral route, the TRA confers lower rates of access-site complications and overall in-hospital major adverse cardiac events.¹⁵ The TRA improves patient comfort and allows almost immediate ambulation. Of interest, the TRA has also been associated with a cost reduction, probably owing to shorter length of stay, diminished rates of local complications, and the sparing of closure devices.¹⁶ In a recent landmark study, the Matrix trial, the radial approach has been shown to decrease all-cause mortality, compared with the femoral route, in patients with acute coronary syndrome undergoing an invasive procedure.¹⁷

The data on the use of the TRA for the intervention of peripheral arteries, however, are much less extensive. Most of the information is derived from observational studies or case reports, and large-cohort studies are scarce. However, the few scientifically rigorous studies that have been published thus far did show encouraging results. One of these, the RADCAR (RADial access for CARotid artery stenting) study, was a prospective randomized trial that compared TRA and TFA for carotid artery stenting.¹⁸ A total of 260 patients at high risk for carotid endarterectomy were randomized into carotid artery stenting using one of the two access sites. No differences were seen in the total duration of the procedure or in fluoroscopy time, but the length of the hospitalization was shorter and the radiation dose higher in the TRA group. No difference in major adverse events was found. Another study assessed TRA for renal artery stenting.⁸ Overall, 18 patients with hemodynamically significant unilateral renal artery stenosis had stent implantation using radial access. All patients had acute aortorenal aneurysms or high-grade peripheral arterial occlusions. The primary success rate (defined as residual stenosis, lower than 30%) was achieved in all patients, and no periprocedural complications were encountered. A third study focused on patients with iliac and SFA disease.¹⁹ A total of 15 patients with occlusions of the mentioned vessels—and superimposed absence of femoral pulses or severe bilateral

iliac artery disease – had interventions via the TRA. The procedures were successful in 14 patients (93.7%), with no access-site complications or periprocedural morbidity. These studies, among several others, demonstrated the feasibility of TRA for treatment of carotid, renal, and iliac artery disease in carefully selected patients.

Our study examined the utility and safety of TRA for peripheral arterial disease in patients with a variety of pathology distributions. This heterogeneity in patients' disease and anatomy improves the generalizability of our study.

Our results show a predominance of males in both access-site groups, particularly middle-aged and elderly individuals. Most patients had traditional atherosclerotic risk factors, most commonly dyslipidemia, coronary artery disease, and hypertension. There was a proportionate representation of different vascular territories as the intervention target, although more patients had common iliac artery procedures (22 patients, 30.5%) compared with other interventions. The distribution of comorbidities among patients in the TRA versus the TFA group was similar. Nevertheless, patients in the TRA group tended to have lower rates of baseline renal impairment compared with the latter group. This is understandable, as proceduralists preferred to avoid the radial site in patients with a possible future need of radial graft for hemodialysis, and instead favored the TFA.

The primary success rate in the two groups was similar, with TRA achieving fluoroscopic outcomes as favorable as those of TFA. No change was found in the fluoroscopic time, the amount of radiation exposure or volume of contrast material between the two groups. We speculate that the reason why TRA was not associated with shorter radiation duration or contrast volume (compared with TFA) was our underutilization of preprocedure vascular imaging. Some authorities recommend performing CTA and MRA upstream to the interventions of the carotid, subclavian, and vertebral arteries to better define the anatomy of the aortic arch and supra-aortic trunk.²⁰ We did not obtain prior targeted

Table 3 Postprocedure outcomes

Complication	Transradial approach: number of patients (%)	Transfemoral approach: number of patients (%)
Acute vascular complication	1 (3.0)	0 (0)
Access-site complication	2 (6.0)	1 (2.5)
Neurologic	0 (0)	0 (0)
Primary success	31 (93.9)	34 (87.1)

Note: None reached statistical significance.

imaging and that might have resulted in longer navigation intervals before formal stent implantation. We do not have data on the length of procedures which could have helped us answer that question. Another explanation for the relatively high use of contrast media in the TRA group might be the patients' kidney function: cardiologists may have been more liberal with the use of contrast agent in patients who underwent TRA procedures (as these patients had significantly lower rates of baseline renal impairment). In contrast, judicious use of contrast material was probably made in the case of renally impaired patients in the TFA group. The shorter time to discharge of patients in the TRA group is probably attributable to the quicker interval to ambulation in these patients. The rate of complications was very low in the two groups, which is consistent with previously published reports. The single patient who suffered a vascular complication during a TRA procedure underwent his intervention very early in our learning curve, at a time when we were not sufficiently aware of the need of stiff wires in peripheral intervention via TRA. Central nervous system complications did not occur at any approach, which may also be explained by the relatively low number of cervical vessel interventions. The likelihood of a type II error (failure to identify a significant difference; false-negative) was calculated for the various outcome measures, and was found to be in the standard range of 0.7 to 0.9.

There is still a significant learning experience to be gained with the TRA procedures. Several issues have to be resolved, particularly with the performance of mid-lower extremity interventions. The equipment necessary for performing diagnostic and therapeutic procedures of those vessels has to be optimized. That includes developing heavy-duty wires, long-enough shafts for stent implantation, and adequate support tools.

The limitations of our study include its nonrandomized, retrospective nature, which might have introduced confounding factors that might have biased the results. The sample size was relatively small and included 7 to 22 patients in each vascular subset. The grouping of heterogeneous procedures together could also have swayed the results in unforeseen patterns.

In summary, our study shows that, in both patients with trivial and unfavorable vessel anatomy, TRA angioplasty and stenting is a feasible and very low-risk procedure. It results in high technical success and carries very low morbidity. Although randomized, controlled trials are needed, TRA should be considered as a legitimate alternative to TFA in patients with a diverse range of peripheral arterial vascular pathologies.

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