Percutaneous radial access for peripheral transluminal angioplasty

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Objective: The radial approach is currently gaining popularity in the setting of coronary percutaneous transluminal angioplasty (PTA) because it decreases the incidence of vascular complications. This study reports our initial results with radial access for peripheral PTA.

Methods: Between November 2011 and January 2014, we performed peripheral PTA in 526 patients. PTA was performed through left radial access in 24 ambulatory patients (4.6%) presenting with TransAtlantic Inter-Society Consensus A or B lesions on preoperative computed tomography angiography. Materials included a 110-cm-long introducer, a 0.018-inch 400-cm-long wire, 150-cm-long angiography catheters, 180-cm-long shaft balloons and stents. Data were prospectively collected.

Results: There were 22 men (92%), median age was 65 years (range, 45-88 years), and 38 target lesions were treated. Indication for revascularization was disabling claudication in 22 patients (92%) and critical ischemia in two (8%). Indication for choosing the radial approach was bilateral hostile groins in 12 patients (50%), bilateral infrainguinal lesions in 4 (17%), need for a contralateral femoral approach in the setting of kissing iliac stents or bifurcated surgical aortic grafts in 3 (13%), and elective in 5 (21%). Radial puncture failed in one patient (4%), and PTA was performed through brachial access. Technical success was 91% (20 of 22 patients). Thirty-seven stents were implanted. Total procedure duration was 45 minutes (range, 30-120 minutes). Fluoroscopy time was 9 minutes (range, 5-35 minutes), and 40 mL (range, 20-90 mL) of contrast was necessary. Radial artery rupture secondary to spasm was noted at the end of the procedure in two patients (8%). All patients could ambulate 2 hours after the procedure. No patient died. Median follow-up was 8 months (range, 1-23 months). Three radial arteries (13%) were occluded at the last follow-up. At 6 months, freedom from target lesion revascularization and target vessel revascularization were 91% and 91%, respectively, for iliac lesions and 93% and 86%, respectively, for infrainguinal lesions.

Conclusions: This study demonstrates the feasibility of radial access for peripheral PTA. Radial access could represent an alternative to brachial access for peripheral and visceral interventions. Although complication rates of the present series are concerning, larger studies are needed to determine the role of transradial PTA once the learning curve is overcome. A wider diffusion of the technique mandates (1) smaller-diameter sheaths, (2) longer shaft devices, and (3) the development of specifically designed rescue devices such as covered stents and thromboaspiration catheters. (J Vasc Surg 2015;61:463-8.)

In the current period, the main vascular access for peripheral percutaneous transluminal angioplasty (PTA) is the common femoral artery (CFA). In some situations, the CFA can be inappropriate or unavailable for puncture, such as in the absence of palpable femoral pulses, the presence of CFA calcifications, obesity, a history of femoral surgery (particularly with prosthetic materials), or the need for a contralateral femoral approach in the setting of previous kissing iliac stents or a bifurcated aortic graft.

Access through the upper limb, especially from the brachial artery, has been well described as an additional,[1,2] or main[1,3-5] access in these situations but is fraught with risks of local complications (pseudoaneurysm, brachial artery thrombosis, median nerve injury) in up to 11% cases.[1,3-5] The radial approach is currently gaining popularity in the setting of coronary PTA.[6,7] It is associated with fewer vascular complications compared with femoral access.[6-11] A recent meta-analysis[8] of randomized controlled trials comparing radial vs femoral access for primary percutaneous coronary interventions (PCIs) revealed that the radial approach was significantly associated with a decreased risk of major bleeding (1.4% vs 2.9%) and access site bleeding (2.1% vs 5.6%). Scant data are available regarding the use of this alternative approach in peripheral PTA.[12-16] The aim of this study was to report our initial results with radial access for peripheral PTA.

METHODS

Ethics Committee approval was not necessary for this study because the study only involved Conformité Européene-approved medical devices, no new implantable materials, and already described access techniques. The

study followed the principles outlined in the Declaration of Helsinki.

Patient selection and preoperative assessment. Between November 2011 and January 2014, we performed 526 peripheral PTAs. Of these, 24 nonconsecutive ambulatory patients (4.6%) presenting with TransAtlantic Inter-Society Consensus (TASC) A or B lesions on preoperative computed tomography angiography (CTA) underwent a PTA through left radial access (LRA). During the same period, we used brachial access in six patients (1.1%) and axillary access in three (0.6%).

Decision making to perform transradial access was at each senior surgeon's discretion and usually depended on material availability, patient choice, and the surgeon's expertise. Patients with a history of aortic arch atheroembolism and stage ≥3 chronic kidney disease (glomerular filtration rate <60 mL/min) were not offered a radial approach.

Preoperatively, the left arm was examined and the presence of ulnar and radial pulses was verified. An Allen test was systematically performed, and an alternative access (femoral or brachial) was used if the Allen test result was negative. All patients gave informed consent for the procedure.

Operative technique. The procedure took place in the operating room. The patient was placed supine with the right upper limb along the body and the left upper limb perpendicular to the body axis. The mobile C-arm (Veradius Neo; Philips Healthcare, Best, The Netherlands) was placed at the patient's right side. The operator and the assistant stood at the level of the left wrist, and the fluoroscopic screen was positioned in front of them. The left upper limb and both groins were draped.

Retrograde puncture of the radial artery was performed using a 21-gauge needle from a transpedal puncture kit (Cook Inc, Bloomington, Ind). Heparin was administered intravenously (50 IU/kg). A short 4F introducer (Terumo Europe, Leuven, Belgium) was introduced in the radial artery. A 0.035-inch 260-cm-long hydrophilic guidewire (Terumo Europe) was pushed to the level of the left subclavian ostium. A C2 or a pigtail catheter (Cook Inc) was used to catheterize the descending aorta, and the wire was exchanged for a 0.035-inch 260-cm-long Amplatz super stiff wire (Boston Scientific, Natick, Mass). This allowed changing the introducer for a 110-cm-long sheath (Cook Inc), which was pushed down to the level of the aortic bifurcation.

When iliac angioplasty and stenting was planned, we used a 6F introducer, and a 5F introducer was used for superficial femoral artery (SFA) treatment. A 125-cm-long vertebral catheter (Cook Inc) was used to catheterize the ipsilateral common iliac artery. After this maneuver, the introducer was pushed into the ipsilateral common iliac artery and even into the external iliac artery, when possible. If the ipsilateral CIA presented a tight stenosis, balloon angioplasty was performed first.

Iliac angioplasty. Iliac angioplasty was performed using 135-cm-long shafts Express LD (Boston Scientific)

stents. When a stent diameter >8 mm was needed, we implanted 8-mm-diameter stents and then inflated them using a 9- or 10-mm-diameter 135-cm-long shaft Fox balloon (Abbott Vascular, Redwood City, Calif) because the Express LD stents >8 mm in diameter enter a 7F sheath.

SFA angioplasty. SFA angioplasty mandated even longer material. The 0.035-inch guidewire was exchanged for a 400-cm-long 0.018-inch Plywire guidewire (Optimed Global Care, Ettlingen Germany). Catheterization of the lesion could necessitate the use of 150-cm-long 4F straight or beacon tip Slip-cath angiography catheters (Cook Inc). Angioplasty was performed using a 180-cm-long shaft Pacific Xtreme angioplasty balloon (Medtronic Invatec, Frauenfeld, Switzerland). When a stent was needed, we used a 180-cm-long shaft Sinus-SuperFlex-518 stent (Optimed Global Care). Stent modeling was performed using the balloon previously described.

After completion angiography, the wires and the sheath were retrieved. Manual arterial compression was performed for 10 minutes. The TR Band radial artery compression device (Terumo Europe) was positioned and removed 6 hours later.

Postoperative management and follow-up. All patients were asked to walk 2 hours after the procedure. After removal of the radial artery compression device, radial pulse and hand coloration were verified, and patients were discharged home. An oral antiplatelet agent (aspirin [75-250 mg] or clopidogrel [75 mg], daily) and statin therapy were administered to all patients before the procedure and continued for life-long. Patients were examined at the 1-month visit with a duplex scan of the lower and the left upper limbs. Biannual follow-up visits were planned thereafter.

Data collection. Data were collected prospectively in a computerized database. Results are presented as median and range.

RESULTS

Study population. There were 22 men (92%) and two women (8%), aged 65 years (range, 45-88 years). Median patient height was 171 cm (range, 155-183 cm). Indication for revascularization was disabling claudication in 22 patients (92%) and critical limb ischemia in two (8%). All lesions were classified as TASC A or B on preoperative CTA. Risk factors and comorbidities are presented in Table I.

Indications for choosing a radial approach in these patients are reported in Table II. Bilateral hostile groins (obesity, history of bilateral femoral surgery) were noted in 12 patients (50%). After the 15 first cases, LRA was used electively in five patients (21%).

Technique. Radial puncture failed in one patient (4%) because of major refractory radial artery spasm (RAS), and the procedure was successfully performed through percutaneous brachial access. In another patient (4%), a 9-cm-long SFA occlusion could not be crossed, and the procedure was undertaken through femoral access. There were 38 target

Table I. Baseline characteristics of patients

Variables	Median (range) or No. (%) (n = 24)
Demographics	
Age, years	65 (45-88)
Male gender	22 (88)
Height, cm	171 (155-183)
Risk factors	
Tobacco use	19 (79)
Hypertension	18 (75)
Hyperlipidemia	18 (75)
Diabetes	6 (25)
Obesity (BMI >30 kg/m^2)	4 (17)
Patient characteristics	
Coronary artery disease	9 (38)
Bilateral hostile groins	12 (50)
ASA class 3 or 4	13 (54)
Indication and disease characteristics	
Disabling claudication	22 (92)
Critical limb ischemia	2 (8)
TASC A lesion	17 (71)
TASC B lesion	7 (29)

ASA class, American Society of Anesthesiologists Physical Status Classification; *BMI,* body mass index; *TASC,* TransAtlantic Inter-Society Consensus.

Table II. Indications for choosing a radial approach in the present series

Indication	No. (%)
Bilateral hostile groins, including	12 (50)
History of bilateral femoral surgery	9 (38)
Obesity	3 (13)
Bilateral infrainguinal lesions	4 (17)
Contralateral femoral approach needed in the setting of kissing iliac stents or bifurcated surgical aortic grafts	3 (13)
Elective	5 (21)

lesions, including 16 iliac arteries (42%), 2 CFAs (5%), 17 SFAs (45%), and 3 popliteal arteries (8%). Thirty-seven stents were implanted. Technical success was 91% (20 of 22 patients).

Total procedure duration was 45 minutes (range, 30-120 minutes). Fluoroscopy time was 9 minutes (range, 5-35 minutes), and 40 mL (range, 20-90 mL) of contrast was necessary. Of note, fluoroscopy time decreased through the study period, which highlights the importance of the learning curve process with this approach. Fluoroscopy time was 15 minutes (range, 8-35 minutes) for the first 12 patients and was 8 minutes (range 5-13 minutes) for the second half of the series.

Left radial artery rupture was noted at the end of the procedure in two patients (8%), mandating compression therapy. We tried to seal the rupture in both patients using a 6F introducer that was let in place in the artery for 15 minutes. After the device was removed, the rupture was still present in both patients, and we used manual compression for 10 minutes. A hemostatic band was then applied over the forearm for 2 hours.

All patients were able to walk 2 hours after the PTA. In total, 15 patients (63%) were discharged home the day of the procedure. The first five patients of the series stayed overnight in the hospital as a precaution. The two patients with radial artery rupture were also kept overnight in the hospital for surveillance. Two more patients had social issues precluding an early discharge.

Perioperative complications. An 87-year-old woman (4%) presented a minor right hemispheric postoperative stroke (Rankin score 2) at the first postoperative day, from which she recovered. No other complications were noted. Apart from the two patients with radial rupture, all patients had a left radial pulse at discharge. All early complications occurred in the first 12 patients of the series.

Follow-up. With a median 8 months of follow-up (range, 1-23 months), three patients underwent reoperations. The first patient presented 3 months after the procedure with recurrent claudication related to iliac stent thrombosis. He was successfully treated by percutaneous recanalization through femoral access. However, he finally developed diffuse iliac lesions and underwent laparoscopic aortobifemoral bypass at 21 months. The second patient underwent SFA angioplasty proximal to the last PTA because of a new symptomatic stenosis at 5 months. He also finally developed diffuse SFA lesions and underwent femoropopliteal bypass at 19 months. The third patient had redo-PTA at 6 months related to intrastent restenosis. At 6 months, freedom from target lesion revascularization and target vessel revascularization were 91% and 91%, respectively, for iliac lesions and 93% and 86%, respectively, for infrainguinal lesions.

In addition to the two patients who had intraoperative radial artery rupture and a subsequently occluded radial artery, one more patient was noted to have left radial artery thrombosis at the 1-month duplex scan examination. Therefore, three radial arteries (13%) were found to be occluded at the last follow-up. The other patients were alive and healthy, with satisfactory PTA patency on their last duplex scan examination.

DISCUSSION

This study demonstrates the feasibility of peripheral PTA through LRA and also highlights some drawbacks and limits of this technique. In the current era, the femoral artery is considered as the first-choice access site for peripheral PTA. Although this approach is usually simple and fast to perform, several issues remain. The femoral artery can be hard to puncture, even when using duplex scan guidance, especially in the setting of obese patients or antegrade access.[17] In some cases, femoral artery puncture can be deemed at increased risk of local complications or failure, such as in the absence of palpable femoral pulses, the presence of CFA calcifications, obesity, a history of femoral surgery (especially with prosthetic materials), or the need for a contralateral femoral approach in the setting of previous kissing iliac stents or a bifurcated aortic graft. Moreover, postoperative hematomas account for significant postoperative morbidity.[17,18]

Table III. Preferred lesions and indications for peripheral transluminal angioplasty (PTA) through a radial approach

Lesions	Indications	Contraindications
TASC A or B	History of bilateral femoral surgery (prosthetic grafts)	Negative Allen test
Stenosis rather than occlusion	Cross-over needed in the setting of previous iliac kissing stents or bifurcated aortic graft	Aortic arch atherothrombosis
Short-length lesion	Bilateral SFA lesions	Functional arteriovenous fistula
Above-knee lesion	Obesity	Hemodialysis vascular access needed
	No palpable femoral pulses	Long height/amplitude
	Need for high dose of antithrombotic therapy	

SFA, Superficial femoral artery; *TASC,* TransAtlantic Inter-Society Consensus.

The largest amount prospective data regarding access site complications derive from the coronary literature.[6-11] In the prospective multicenter RIVAL (Radial vs Femoral Access for Coronary Angiography and Intervention in Patients With Acute Coronary Syndromes) study,[11] rates of major vascular complications (large hematomas, pseudoaneurysm needing closure, arteriovenous fistula) and minor bleeding with femoral access were 3.7% and 3.4%, respectively.

Another issue with femoral access is the need for patients to stay supine several hours after the procedure.[19,20] Early ambulation after femoral artery puncture is feasible,[20-24] especially when using vascular closure devices. In our study, we kept our patients supine for 2 hours after the procedure as a precaution. No patient had any access site bleeding complication during this time. Therefore, we think that LRA allows ambulation with totally normal walking activities immediately after the procedure. This aspect may facilitate outpatient procedures and simplify postoperative surveillance.

Radial access is gaining popularity for PCIs.[6,7] In France, more than half of PCIs are performed through radial access.[25] In the United States, radial access represented 16% of PCI by the end of 2012 but was used in <2% of PCI in 2007.[7] Although reasons for this modification of practice can be multiple, the decrease in local complications[6,7] and the ability to simplify outpatient procedures might explain the rise of radial access in PCI. Whether results of transradial coronary interventions can be transferred to peripheral PTA remains uncertain.[12-16] In the coronary literature, sizes of sheaths, transarterial navigation, and antithrombotic regimen are different compared with peripheral PTA. For these reasons, we designed this study to assess the feasibility and evaluate the results of radial access for peripheral PTA.

Our results allowed us to improve patient selection for transradial peripheral PTA. We recommend systematically performing a preoperative Allen test. During the study period, we excluded two patients due to a negative Allen test. It could be of great interest to consider the use of a vascular laboratory to perform the Allen test and map the course of the radial artery before the intervention.

Patients with stage ≥3 chronic kidney disease (glomerular filtration rate <60 mL/min) who might need a Cimino-Brescia fistula in the future were logically excluded from our study. Also, patients who already had a functional arteriovenous fistula were not offered a radial approach to avoid compromising fistula patency.

Patients with a history of ischemic stroke secondary to aortic arch atheroembolism were also excluded because they might be at higher risk for navigation through the aortic arch. The systematic use of the left radial artery had the goal to avoid arch navigation. Despite this precaution, a minor right hemispheric postoperative stroke developed in one patient after recanalization of a short SFA occlusion. From the anatomic considerations, the reasons for a right hemispheric stroke after LRA seem unclear. We hypothesized that the long introducer formed a loop in the aortic arch while trying to recanalize the SFA occlusion. On the basis of this case, we now recommend a CTA of the aortic arch before the procedure.

As have others, this case highlights the lack of axial force when trying to cross an occlusion through transradial access. At this time, we consider that transradial peripheral PTA should be reserved for TASC A and B lesions and stenosis rather than occlusion. Our preferred indications for transradial peripheral PTA are summarized in Table III.

RAS was noted after the arterial puncture, in four patients, including two patients with intraoperative radial artery rupture. On the basis of our experience, RAS must be suspected when the operator feels resistance while introducing the first sheath or when there is no backflow in the sidearm of the introducer. The exact incidence of RAS during PCI is unclear,[26] and depends on spasm definition, diagnostic methods, and pharmacologic premedication. A literature review found the incidence of RAS was evaluated to be as high as 14.7% altogether.[26]

As others,[27] we did not routinely use intra-arterial injections of vasodilators at the beginning of our experience (first 13 patients). Two patients presented subsequent arterial rupture and lost radial artery patency. Another patient with intraoperative spasm treated by intra-arterial injections of vasodilators was found to have an occluded left radial artery at the 1-month visit. Although the two arterial ruptures might be related to our learning curve with this technique, preserving radial artery patency is paramount for vascular patients. Some might need radial blood pressure monitoring for a major surgery in the future.

For these reasons, we now systematically perform a 2-mL isosorbide dinitrate (Risordan 10 mg/10 mL; Sanofi, Paris, France) intra-arterial injection after radial artery

puncture. If intraoperative RAS persists despite this treatment, a second 2-mL isosorbide dinitrate injection can be used and possibly associated with a 2.5-mg verapamil intra-arterial injection.[26,28] In the future, smaller-profile devices specifically designed for LRA could decrease RAS and its consequences.

We generally used LRA in our practice when the femoral approach was precluded (Table II). We perceived LRA as an alternative to brachial and axillary artery access in the setting of some challenging patients where the femoral artery was deemed inaccessible or inappropriate. In fact, axillary artery access can necessitate a surgical cutdown,[29] and brachial access carries a certain risk of local complications.[1-5] In the largest series reporting on the use of brachial access for aortic and peripheral procedure,[1] the Cleveland Clinic team reported a 6.5% rate of access site-related complications (pseudoaneurysm, brachial artery thrombosis, hematoma), including a 4.0% rate of surgical correction. Of note, conversion to open surgical closure was needed in 2.3% cases when the artery was initially punctured percutaneously in that series. LRA could therefore represent an interesting option for patients mandating a procedure through the upper limb. Although this series focused on lower limb PTA through LRA, the LRA could represent an attractive option for visceral interventions[30] that are often performed through the upper limb.[31]

Material improvements are needed to allow the wide diffusion of this technique. To our knowledge, 110 cm is the longest currently available introducer sheaths length. This generally allowed landing distally within the distal common iliac artery or the proximal external iliac artery. However, the introducer sheath did not reach the iliac axis in tall patients. Moreover, below-the-knee lesions remain currently inaccessible through LRA. These points underline the need for longer introducer sheaths and angiography catheters to improve the results of PTA through the radial artery. Anatomic studies correlating patient's height with the distance between vascular accesses and target lesions could help better defining material needed. Another limit with radial access is the lack of specifically designed rescue devices such as long-shaft covered stents or thromboaspiration catheters.

Finally, cost-effectiveness of the technique remains to be demonstrated. The current costs of the materials and devices we used for transradial peripheral PTA seemed higher than those used for femoral access. In our institution, performing a SFA angioplasty through a LRA was associated with €393.64 (taxes excluded) extra cost for materials compared with a femoral approach with vascular closure device.

CONCLUSIONS

This study demonstrates the feasibility of radial access for peripheral PTA. Radial artery access could represent an alternative to brachial artery access for peripheral and visceral interventions. Although complication rates of the present series are concerning, larger series would be necessary to determine the results of PTA through a radial

approach once the learning curve is overcome. Arch navigation remains an issue to be solved to avoid postoperative stroke. A wider diffusion of the technique mandates material improvements with smaller-diameter sheaths, longer shaft devices, and the development of specifically designed rescue devices.

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