A Randomized Comparison of Percutaneous Transluminal Coronary Angioplasty by the Radial, Brachial and Femoral Approaches: The Access Study

FERDINAND KIEMENEIJ, MD, PHD, GERT JAN LAARMAN, MD, PHD,
DIEGO ODEKERKEN, MD, TON SLAGBOOM, MD, RON VAN DER WIEKEN, MD

Amsterdam, The Netherlands

Objectives. **This study sought to compare procedural and clinical outcomes of percutaneous transluminal coronary angioplasty (PTCA) performed with 6F guiding catheters introduced through the radial, brachial or femoral arteries.**

Background. **Transradial PTCA has been demonstrated to be an effective and safe alternative to transfemoral PTCA; however, no randomized data are currently available.**

Methods. **A randomized comparison between transradial, transbrachial and transfemoral PTCA with 6F guiding catheters was performed in 900 patients. Primary end points were entry site and angioplasty related. Secondary end points were quantitative coronary analysis after PTCA, procedural and fluoroscopy times, consumption of angioplasty equipment and length of hospital stay.**

Results. **Successful coronary cannulation was achieved in 279 (93.0%), 287 (95.7%) and 299 (99.7%) patients randomized to undergo PTCA by the radial, brachial and femoral approaches, respectively. PTCA success was achieved in 91.7%, 90.7% and 90.7% (p = NS) of patients, with 88.0%, 87.7% and 90.0% event free at 1-month follow-up, respectively (p = NS). Major entry site complications were encountered in seven patients (2.3%) in the transbrachial group, six (2.0%) in the transfemoral group and none in the transradial group (p = 0.035). Transradial PTCA led to asymptomatic loss of radial pulsations in nine patients (3%). Procedural and fluoroscopy times were similar, as were consumption of guiding and balloon catheters and length of hospital stay ([mean ± SD] 1.5 ± 2.5, 1.8 ± 3.8 and 1.8 ± 4.2 days, respectively).**

Conclusions. **With experience, procedural and clinical outcomes of PTCA were similar for the three subgroups, but access failure is more common during transradial PTCA. Major access site complications were more frequently encountered after transbrachial and transfemoral PTCA.**

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Safety of transradial coronary catheterization is mainly determined by the favorable anatomic relations of the radial artery to its surrounding structures. No major veins or nerves are located near the artery, minimizing the chance of injury of these structures. Because of the superficial course of the radial artery, hemostasis easily can be obtained by local compression. Thrombotic or traumatic arterial occlusion does not endanger the viability of the hand if adequate collateral blood supply from the ulnar artery is present. We modified the technique of transradial coronary catheterization, as described by Campeau in 1989 (1), to perform transradial percutaneous transluminal coronary angioplasty (PTCA), with 6F guiding catheters and miniaturized balloon catheters. In 1992, when these catheters became commercially available, we initiated a feasibility study of transradial artery PTCA. In a series of 100 patients, PTCA could be performed through the radial artery in 94 patients; procedural success was 98% (2). No major bleeding complications were encountered.

Little is known about the incidence of access failure and vascular complications after insertion of 6F guiding catheters in the femoral and brachial arteries, and no randomized data are available comparing these approaches. The present study was designed to prospectively evaluate procedural success and complication rates in patients randomly assigned to undergo PTCA by means of one of three catheterization routes.

Methods

Patient selection. Patients with stable and unstable angina were included in the study and were selected for single- or multivessel PTCA of lesions in native coronary arteries and venous bypass grafts. Suitability for participation in the study was assessed by one of the investigators (F.K., G.J.L., T.S. or R.v.d.W.). On arrival of the patient in the catheterization laboratory, femoral, brachial, radial and ulnar artery pulse rates were measured, and the Allen test was performed. If the patient fulfilled the enrollment criteria, he or she provided

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Address for correspondence: Dr. Ferdinand Kiemeneij, Amsterdam Department of Interventional Cardiology (ADIC)-OLVG, 1e Oosterparkstraat 279, 1090 HM Amsterdam, The Netherlands.

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Abbreviations and Acronyms

ID = inner diameter
LAD = left anterior descending coronary artery
PTCA = percutaneous transluminal coronary angioplasty
QCA = quantitative coronary analysis

written informed consent to participate in the study. The study was approved by the ethics committee of the hospital.

Exclusion criteria, detailed in Table 1, were based on vascular and cardiac status, the intended type of angioplasty and availability of consent. If no exclusion criteria were encountered, each patient was randomized to undergo PTCA by the radial, brachial or femoral artery approach.

End points. Primary end points were recorded from the start of the procedure to 1-month follow-up and were divided into access site- and PTCA-related end points. Follow-up was performed at 1 month instead of in the hospital because patients are routinely discharged the day after PTCA to their homes or to the referring hospitals, where additional complications may occur.

An *access site-related end point* was defined as either the necessity to puncture a second access site due to any procedural failure or a major access site complication. A *complication* was considered to be *major* if associated with hemoglobin loss of at least 2 mmol/liter, administration of blood transfusions or vascular repair, alone or in combination. After a failed attempt to cannulate the coronary artery, the operator was free to select any other entry site. This site could be the same artery at the contralateral side or any other artery.

PTCA-related end points were defined as a residual stenosis >50% or the occurrence of any *major cardiac event*: death, myocardial infarction, coronary artery bypass graft surgery or repeat PTCA.

Secondary end points were defined as change in minimal lumen diameter and percent diameter stenosis (DS) as assessed by quantitative coronary analysis (QCA), procedural time, fluoroscopy time, consumption of angioplasty equipment and hospital stay.

Table 1. Exclusion Criteria

Vascular status
Absence of pulse in femoral, brachial or radial arteries
Abnormal Allen test results
Failed previous arterial access
Cardiac status
Chronic total occlusion
Acute myocardial infarction
Expected severe hemodynamic deterioration during balloon inflation or after PTCA failure, leading to intraaortic pumping or right heart catheterization for hemodynamic monitoring
Expected need for a temporary pacemaker
Procedural
Ad hoc PTCA after transfemoral diagnostic catheterization
Indwelling sheath from previous arterial puncture
Planned primary stent implantation
Planned coronary atherectomy
No consent

PTCA = percutaneous transluminal coronary angioplasty.

Medical preparation. At the start of the procedure, patients received diazepam (5 mg orally) and aspegic (900 mg intravenously). The puncture site was infiltrated with 2% xylocaine (2 to 10 ml). Heparin (5,000 IU) was administered after insertion of the introducer sheath and every hour during prolonged angioplasty procedures. No activated clotting time was measured during or after intervention. After sheath removal and local hemostasis, heparin infusion was continued "overnight" in case of evidence of intracoronary thrombus or dissection. Heparin could be continued at the discretion of the operators in those patients who had a heparin infusion for unstable angina that commenced before the procedure. Nitroglycerin (100 to 300 μg) was administered before the first and final coronary angiogram and repeated if necessary.

Femoral and brachial artery cannulation. The percutaneous transluminal technique was used in all patients. After appearance of pulsatile blood from the arterial needle, an 0.035-in. guide wire was advanced, followed by insertion of a 6F arterial introducer, 10 cm in length.

Radial artery cannulation. The right arm, supported by an extension of the catheterization table was abducted (45°), and the wrist was hyperextended. After local anesthesia with 2% xylocaine, the radial artery was punctured with an Arrow, 20-gauge radial artery catheterization set or an 18-gauge arterial needle at 1 cm proximal from the styloid process. To reduce spasm and discomfort, an intraarterial injection was given containing 200 μg of nitroglycerin and 2 ml of 2% xylocaine after the appearance of pulsatile flow from the needle. A Schneider 0.025-in. 260-cm long guide wire was introduced through this system, followed by insertion of a 6F, 23-cm long arterial introducer, after a skin incision with a No. 11 surgical blade was made.

Coronary artery cannulation. Six-French guiding catheters manufactured by Scimed (inner diameter [ID] 0.060 in.), Schneider (ID 0.061 in.) and Cordis (ID 0.062 in.) were used. A 6F guiding catheter was selected with an appropriate curve, providing maximal backup support during angioplasty. Rapid-exchange balloon catheters were used (Scimed Express) in combination with an ACS 0.014-in. High Torque Floppy guide wire.

Sheath removal, immobilization and discharge. In all instances, the arterial sheath was removed directly after withdrawal of the guiding catheter. Hemostasis of the radial puncture site was obtained by application of two occlusive tourniquets, one at and one proximal to the puncture site, over a pile of gauze. Over the course of 30 min, the occlusive pressure of both tourniquets was gradually decreased, followed by application of a pressure bandage, during simultaneous digital compression of the puncture site. The brachial and femoral puncture sites were manually compressed. In the three subgroups, a pressure bandage over the punctured artery was applied for 4 h. After femoral entry, patients had bed rest for

6 h. After brachial and radial entry, patients were not restricted to bed rest but were advised to restrict movements of the elbow and wrist joint, respectively. If no complications were encountered, the patient was discharged on the following day.

Coronary analysis. Preprocedural lesion morphology was classified as defined by the American College of Cardiology/ American Heart Association (3) from films read by two cardiologists (F.K., G.J.L., T.S. or R.v.d.W.). The X-ray equipment used was the Philips Poly Diagnost C2, equipped with a Digital Cardiac Imaging System (DCI). Qualitative and quantitative analysis of coronary segments was performed with this system before angioplasty and after the final balloon inflation under standardized conditions by the operating cardiologist or a technician. Postprocedural coronary artery dissections were described according to the classification of Dorros et al. (4).

Assessments and examinations. An electrocardiogram was recorded before and after the procedure and at 1 month follow-up. Laboratory assessments were hemoglobin and hematocrit before PTCA and at discharge and creatine kinase (with MB fraction) before discharge. Physical examination of the puncture site was performed to determine the presence of a complication, followed by two-dimensional echocardiographic and Doppler ultrasound examination.

Follow-up evaluation. One month after the procedure, patients were screened for the occurrence of end points.

Statistical analysis. The sample size was based on an estimated incidence of major bleeding complications of 1% in patients undergoing PTCA through the radial artery and 5% after transfemoral and transbrachial PTCA with 6F guiding catheters under low dose heparin. With an alpha error of 0.05 and a power of 0.80, a sample size was calculated of 840 patients. To compensate for a loss of power due to a planned interim analysis, the sample was increased from 280 to 300 for each study group.

Randomization was performed by opening a sealed envelope containing a code for either transradial (R), transbrachial (B) or transfemoral (F) angioplasty. These envelopes were ordered at random and included a registration number from 1 to 900.

Continuous variables are expressed as mean value $\pm$ SD and were compared by unpaired analysis of variance. Proportions were compared using the chi-square test (3×2 tables).

Definitions. *Allen test.* Results are considered positive (normal) when, after compression of both radial and ulnar arteries, the return of normal color to the hand occurs within 10 s after release of pressure over the ulnar or radial artery (reversed Allen test).

Bypass surgery. Coronary artery bypass graft surgery involving the previously dilated segment.

Cardiac death. All deaths, unless an unequivocal other cause could be established.

Canadian Cardiovascular Society classification. class 0 = no exertional angina; class 1 = no angina on ordinary physical activity; class 2 = slight limitation of ordinary activity; class 3 = marked limitation of ordinary activity; class 4 = inability to carry on any physical activity without discomfort.

Myocardial infarction. The presence of at least two of the following: 1) occlusion of a previously patent coronary artery; 2) prolonged chest pain; 3) serial enzyme pattern typical of myocardial infarction, with at least one enzyme exceeding twice the upper limit of normal; 4) new Q waves.

Radial artery occlusion. Absence of radial artery pulse confirmed by a negative reversed Allen test or by a visible obstruction with two-dimensional ultrasound or absence of a positive Doppler signal, alone or in combination.

Repeat PTCA. PTCA involving the same segment after the guiding catheter has been removed from the arterial sheath.

Successful PTCA. Residual post-PTCA diameter stenosis $<50\%$, as assessed by QCA, irrespective of PTCA technique or device used, without major cardiac events within 1 month.

Results

Study cohort. Between November 1993 and August 1995, 1,899 patients underwent PTCA at our department, of whom 900 patients (47.4%) were included in the trial. The most important exclusion criteria in the remaining 999 patients (52.6%) were nonelective procedures (acute myocardial infarction, severe unstable angina) in patients with previous placement of a sheath in the femoral artery (31%); elective, intended nonballoon techniques (28%); and local vascular exclusion criteria (18%). Angioplasty of chronic total occlusions (11%), no consent (6%) and poor cardiac condition with expected need for right heart catheterization or intraaortic balloon pumping (2%) were less frequently encountered contraindications. Physician preference and logistic circumstances led to the exclusion of 4% of patients.

From the 900 randomized patients, 3 (1 in the brachial group, 2 in the femoral group) had no significant stenosis during direct preprocedural angiography, whereas a significant lesion was present on the previous diagnostic angiogram. As a consequence, PTCA was not attempted in these three patients. Baseline clinical characteristics, detailed in Table 2, were not significantly different among the study subgroups. Angiographic and QCA data are detailed in Tables 3 and 4. Most patients were referred for single-vessel PTCA, although multivessel PTCA was not a contraindication to participation in the study. Because venous bypass graft disease was considered a primary indication for stenting, and patients undergoing primary stenting participated in other study protocols, the incidence of venous bypass graft disease in the three study groups was low.

Procedural results. *Coronary cannulation.* All patients had a right-sided arterial puncture. Successful coronary cannulation was achieved in 279 (93.0%), 287 (95.7%) and in 299 (99.7%) patients randomized to undergo PTCA through the radial, brachial or femoral artery, respectively ($p < 0.001$). In 21 patients from the radial group and 13 from the brachial group, coronary cannulation failed because of inability to puncture the artery (n = 14 [4.6%] vs. n = 7 [2.3%], respectively) and to advance the 6F sheath (n = 2 [0.7%] vs. n = 0, respectively) and the 0.025-in. guide wire toward the ascending

Table 2. Baseline Clinical Characteristics

	Radial Group	Brachial Group	Femoral Group	p Value
Male	221 (73.6)	207 (69.0)	220 (73.3)	0.365
Age (yr)	61 ± 11	61 ± 10	62 ± 10	0.393
Height (cm)	172 ± 9	172 ± 9	173 ± 9	0.291
Weight (kg)	78 ± 13	78 ± 12	79 ± 12	0.519
CCS I	4 (1.3)	6 (2.0)	5 (1.7)	0.816
CCS II	34 (11.3)	29 (9.7)	28 (9.3)	0.685
CCS III	137 (45.7)	144 (48.0)	140 (46.7)	0.848
CCS IV	98 (32.7)	96 (32.0)	108 (36.0)	0.539
NEA	27 (9.0)	25 (8.3)	19 (6.3)	0.452
MI	122 (40.7)	123 (41.0)	136 (45.3)	0.435
CABG	28 (9.3)	17 (5.7)	17 (5.7)	0.123
PTCA	76 (25.3)	73 (24.3)	68 (22.7)	0.743

Data presented are mean value ± SD or number (%) of patients. CABG = coronary artery bypass graft surgery; CCS = Canadian Cardiovascular Society angina pectoris classification; MI = myocardial infarction; NEA = nonexertional angina; PTCA = percutaneous transluminal coronary angioplasty.

aorta (n = 5 [1.7%] vs. n = 4 [1.3%]). During brachial and femoral PTCA, no adequate guiding position could be obtained in two (0.7%) and one (0.3%) patients, respectively. This problem was not encountered during transradial PTCA. Twenty patients were crossed over from PTCA through the radial to the femoral artery and one to the left radial artery, followed by successful coronary cannulation. In the brachial artery group, 12 patients were crossed over to PTCA through the femoral and 1 to the radial artery, also with successful outcomes. The failed femoral attempt was redone successfully through the radial artery. All second attempts took place during the same angioplasty session.

Coronary angioplasty. Of the 897 patients undergoing PTCA, 49 (5.5%) received one or more Palmaz-Schatz stents because of a suboptimal PTCA result (radial group, n = 14 [4.7%]; brachial group, n = 21 [7.0%]; femoral group, n = 14 [4.7%], p = 0.347). Successful PTCA (with or without stenting) was achieved in 91.7%, 90.7% and 90.7% of patients randomized to the radial, brachial or femoral approach, respectively (p = 0.885).

The reasons for failed PTCA (radial group, n = 25 [8.3%]; brachial group, n = 27 [9.0%]; femoral group, n = 26 [8.6%]), and ensuing events are shown in Table 5. No significant differences were noted between the reasons for PTCA failure

Table 3. Angiographic Characteristics

	Radial Group	Brachial Group	Femoral Group	p Value
Vessel	n = 325	n = 319	n = 337	
LAD	140 (43.1)	136 (42.6)	141 (41.8)	0.948
LCx	89 (27.4)	85 (26.6)	88 (26.1)	0.933
RCA	82 (25.2)	84 (26.3)	95 (28.1)	0.684
AL	11 (3.4)	12 (3.8)	12 (3.6)	0.967
VBG	3 (0.9)	1 (0.3)	1 (0.3)	0.441
LMCA	0 (0.0)	1 (0.3)	0 (0.0)	0.354
Lesion*	n = 377	n = 362	n = 385	
A	154 (40.8)	160 (44.2)	161 (41.8)	0.639
B	139 (36.9)	120 (33.1)	121 (31.4)	0.269
C	84 (22.3)	82 (22.7)	103 (26.8)	0.276

*Ambrose et al. (3). Data presented are number (%) of vessels or lesions. AL = anterolateral branch; LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery; LMCA = left main coronary artery; RCA = right coronary artery; VBG = venous bypass graft.

Table 4. Quantitative and Qualitative Coronary Analysis

	Radial Group	Brachial Group	Femoral Group	p Value
Pre-PTCA QCA				
RD (mm)	2.74 ± 0.64	2.73 ± 0.62	2.67 ± 0.63	0.339
MLD (mm)	0.78 ± 0.42	0.80 ± 0.41	0.73 ± 0.4	0.099
DS (%)	71 ± 14	70 ± 14	73 ± 14	0.072
PTCA QCA				
RD (mm)	2.83 ± 0.68	2.80 ± 0.64	2.77 ± 0.6	0.518
MLD (mm)	2.19 ± 0.76	2.18 ± 0.74	2.19 ± 0.9	0.985
DS (%)	23 ± 20	22 ± 19	22 ± 20	0.988
Post-PTCA dissection				
lesion*	n = 377	n = 362	n =385	
A	30 (8.0)	27 (7.5)	40 (10.3)	0.308
B	68 (18.0)	76 (21.0)	66 (17.1)	0.372
C	10 (2.7)	8 (2.2)	7 (1.8)	0.737
D	0 (0)	0 (0)	2 (0.5)	0.146
E	0 (0)	2 (0.6)	2 (0.5)	0.362
F	6 (1.6)	2 (0.6)	5 (1.3)	0.397
Total	114 (30.2)	115 (31.8)	124 (32.2)	0.829
Total no. of pts	108 (36.0)	107 (35.8)	124 (38.5)	0.275

*Dorros et al. (4). Data presented are mean value ± SD or number (%) of dissections. DS = diameter stenosis; MLD = minimal lumen diameter; QCA = quantitative coronary analysis; PTCA = percutaneous transluminal angioplasty; pts = patients; RD = reference diameter.

Table 5. Procedural Outcome and Events*

	Radial Group (n = 300)	Brachial Group (n = 300)	Femoral Group (n = 300)	p Value
Procedural success	275 (91.7)	272 (90.7)	272 (90.7)	0.885
No stenosis	0 (0)	1 (0.3)	2 (0.7)	0.367
Procedural failure	25 (8.3)	27 (9.0)	26 (8.6)	0.959
Inability to cross stenosis	13 (4.3)	10 (3.3)	10 (3.3)	0.753
MI	1 (0.3)	0 (0)	2 (0.7)	0.367
CABG	0 (0)	3 (1.0)	1 (0.3)	0.172
PTCA	3 (1.0)	1 (0.3)	0 (0)	0.172
Suboptimal result	9 (3.0)	10 (3.3)	9 (3.0)	0.964
Death	0 (0)	1 (0.3)	0 (0)	0.367
MI	4 (1.3)	2 (0.7)	1 (0.3)	0.365
CABG	2 (0.7)	6 (2.0)	5 (1.7)	0.363
PTCA	1 (0.3)	1 (0.3)	0 (0)	0.606
Sidebranch occlusion	0 (0)	3 (1.0)	2 (0.7)	0.245
MI	0 (0)	3 (1.0)	2 (0.7)	0.245
Partial success in MVD	3 (1)	4 (1.3)	4 (1.3)	0.912
PTCA	0 (0)	1 (0.3)	0 (0)	0.367
Coronary spasm	0 (0)	0 (0)	1 (0.3)	0.367
MI	0 (0)	0 (0)	1 (0.3)	0.367

*All events are counted; thus, a myocardial infarction (MI) after repeat percutaneous transluminal coronary angiography (PTCA) and coronary artery bypass graft surgery (CABG) is counted as three events. Data presented are number (%) of patients. MVD = multivessel disease.

Table 6. All Major Adverse Cardiac Events and Their Ranking From PTCA Coronary Angioplasty to 1-Month Follow-Up (intention to treat)

	Radial Group (n = 300)	Brachial Group (n = 300)	Femoral Group (n = 300)	p Value
Total no. of events				
Death	1 (0.3)	3 (1.0)	0 (0)	0.172
Infarction	10 (3.3)	8 (2.7)	9 (3.0)	0.892
CABG	5 (1.7)	12 (4.0)	6 (2.0)	0.147
PTCA	13 (4.3)	9 (3.0)	4 (1.3)	0.089
Total	30 (10)	32 (10.7)	19 (6.3)	0.136
Total no. of pts with event ranked to most serious complication				
Death	1 (0.3)	3 (1.0)	0 (0)	0.172
Infarction	10 (3.3)	8 (2.7)	9 (3.0)	0.892
CABG	3 (1.0)	10 (3.3)	5 (1.7)	0.110
PTCA	6 (2.0)	4 (1.3)	2 (0.7)	0.363
Total	20 (6.7)	25 (8.3)	16 (5.3)	0.342
Free of MACE	280 (93.3)	275 (91.7)	284 (94.7)	0.342

Data presented are number (%) of patients. MACE = major adverse cardiac event; other abbreviations as in Tables 1 and 4.

and subsequent outcome among the three groups. Results of final quantitative and qualitative coronary analysis (Table 4) were also similar.

Equipment consumption. The consumption of guiding catheters (1.3/procedure) and dilation catheters (1.3/procedure) was similar for the three approaches.

Procedural time. Procedural time (recorded from the moment of the start of the first attempt to puncture the artery to the moment of sheath withdrawal) of transradial PTCA (40 ± 24 min) was similar to transbrachial (39 ± 25 min) and transfemoral PTCA (38 ± 24 min, p = 0.603). Fluoroscopy time was also similar in the three groups (13 ± 11, 12 ± 10 and 11 ± 10 min, p = 0.061).

Clinical outcome at 1-month follow-up. *Cardiac events.* Successful PTCA with an uncomplicated clinical course was achieved in 264 (88.0%), 263 (87.7%) and 269 (90.0%) patients in the radial, brachial and femoral groups, respectively (p = 0.714). Freedom from major events was seen in 280 (93.3%), 275 (91.7%) and 284 patients (94.7%) in the three respective study groups (p = 0.342) (Table 6). No significant differences in incidence and distribution of major events at 1-month follow-up was noted. The total study mortality rate was 0.4%. Four patients died—one in the radial group (sudden death 26 days after PTCA of the LAD) and three in the brachial group (p = 0.172). One patient died within 1 week of a cerebral hemorrhage after rescue stent implantation followed by Coumadin treatment. Another patient died in cardiogenic shock after emergent coronary artery bypass graft surgery for procedural abrupt LAD occlusion. One patient, with triple-vessel disease, had signs of abrupt occlusion of the LAD, hours after successful PTCA, with rapid progression to irreversible cardiogenic shock, before attempts could be undertaken to recanalize the artery.

Entry site complications. No major entry site-related bleeding complications were encountered in the radial group, whereas seven patients (2.3%) had a major complication in the brachial group and six patients (2.0%) in the femoral group (p = 0.035).

BRACHIAL ARTERY GROUP. After brachial artery cannulation, of three patients who developed a local hematoma with a decrease in hemoglobin ≥2 mmol/liter, one required a blood transfusion, one required local infiltration with xylocaine for median nerve compression, and one was treated conservatively. Of another four patients who developed a pseudoaneurysm, three underwent operation, with one of the three requiring a transfusion. One patient was treated by prolonged compression under ultrasound guidance.

FEMORAL ARTERY GROUP. In the femoral group, four patients had a major bleeding event, followed by vascular surgery in two and a transfusion in two. Of three patients with a pseudoaneurysm, one underwent surgical correction. One pseudoaneurysm was treated by compression under ultrasound guidance, and one pseudoaneurysm was left untreated.

RADIAL ARTERY GROUP. Radial artery occlusion was found in 15 patients (5.0%) at hospital discharge. At 1-month follow-up, occlusion was still present in nine patients (3.0%). No ischemic complications were noted after transradial PTCA at follow-up. No vascular occlusions were encountered after brachial and femoral artery cannulation.

Hospital stay. The hospital stay after transradial, transbrachial and transfemoral PTCA was 1.5 ± 2.5 days (median 1, range 0 to 15), 1.8 ± 3.8 days (median 1, range 0 to 29) and 1.8 ± 4.2 days (median 1, range 0 to 39, p = 0.49), respectively.

Discussion

Promise and limitations of 6F guiding catheters. Procedural success rates with 6F guiding catheters were high: 91.7%, 90.7% and 90.7% for transradial, transbrachial and transfemoral PTCA, respectively. In only three cases (0.3%) did an attempt with 8F systems have to be undertaken because lack of catheter support was considered to be the main reason for failure. Nevertheless, PTCA with 6F guiding catheters is associated with less interventional flexibility because bifurcational lesions of large coronary arteries are hard to address with small-sized guiding catheters. Directional atherectomy cannot be used, and small-sized rotational atherectomy catheters are not without severe compromise of distal visualization. However, with the new generation of guiding catheters (ID 0.064 in.) and low profile balloons and stents, a wide range of coronary pathology can be addressed with maintenance of adequate visualization. Interventional flexibility and visualization can be increased if 7F guiding catheters are used, which, in our experience, is also possible through the radial artery.

Because coronary stenting has become an essential part of the PTCA technique to improve PTCA results (in this study, 49 patients [5.5%]), it is important to note that 6F guiding catheters do not preclude the use of a variety of stents. The use of stents (5–12) and perfusion balloons (7,13) through 6F catheters has been reported.

Although not the focus of the present study, the hazard of loss of "unsheathed" stents in combination with the use of 6F guiding catheters is underscored if proper precautions are not taken. Optimal guiding catheter selection with regard to coaxial alignment and backup support is of paramount importance. The stent should be well crimped and fixed on the balloon catheter, and the target lesion should be well predilated before attempts to cross the stenosis. One of the merits of 6F guiding catheters is the ability to advance the catheter deep in the coronary artery. The guiding catheter then serves as a protective sheath, increasing safety of passage of the stent over proximal tortuosities and irregularities. Obviously, this maneuver should be carried out with delicacy and requires the use of atraumatic soft-tipped guiding catheters that can be advanced over the intracoronary guide wire or over the shaft of the balloon catheter.

Promise and limitations of the transradial approach. The present study demonstrates that the outcome of PTCA with 6F guiding catheters is similar for the three study groups. However, coronary cannulation failure occurred more frequently during the arm procedures. Most coronary cannulation failures during the transradial and brachial techniques were due to inability to puncture the artery (4.6% and 2.3%, respectively). In the present study, coronary cannulation through the radial artery failed more frequently than transfemoral coronary cannulation because of smaller arterial size and the occurrence of radial artery spasm. Coronary cannulation was successful in 99.7% of patients in the femoral group. This favorable outcome is partially explained by the fact that patients with a previous entry site problem were excluded from this study. Because almost all patients underwent diagnostic catheterization through the femoral artery, bias toward a successful transfemoral catheterization was present.

No procedure performed through the right radial artery was associated with inadequate support of the guiding catheter despite the fact that most guiding catheters are not designed for the right radial approach. Good backup support for the right coronary artery can be achieved with multipurpose, Amplatz right and left and Kimny Radial (a curve designed for the transradial approach [Schneider, Bülach, Switzerland]) guiding catheters. For the left main coronary artery, Voda (Scimed Life System) curved guiding catheters, Kimny Radial or Amplatz left guiding catheters are recommended. Venous bypass grafts can usually be cannulated with multipurpose, Judkins right and Kimny Radial catheters. The left internal mammary artery can only be approached from the femoral arteries or from the left arm.

At the interim analysis, procedural and fluoroscopy times were longer for transradial PTCA, and more guiding catheters were consumed during arm procedures. At completion of the trial, procedural and fluoroscopy times were similar in the three treatment groups. The number of guiding catheters used (1.3/procedure) was also equal, reflecting the completion of a learning curve for the transradial technique.

In our experience, transradial interventions can be repeated, provided that the artery remained patent. In those patients with loss of distal radial artery pulse but with maintenance of a more proximal pulse, a second puncture may be successful more proximally. However, more proximally, the radial artery takes a less superficial course, complicating correct puncturing and achievement of hemostasis. In the case of loss of distal radial artery pulse, we therefore recommend selection of another entry site.

Vascular complications. Major vascular complications occurred more frequently after transbrachial and transfemoral angioplasty and were absent after transradial PTCA. However, the incidence of major bleeding complications (2.0%) after use of 6F guiding catheters by the femoral approach was still low.

Johnson et al. (14) recently reported an incidence of vascular complications of 2.4% of 1,579 PTCA procedures performed by the femoral and brachial techniques. Popma et al. (15) reported a 5.9% incidence of vascular complications after 1,413 coronary angioplasty procedures with different techniques, the highest incidence found after coronary stenting (14%).

Factors probably contributing to the low incidence of vascular complications at our center are small-sized sheaths, use of 5,000 IU of heparin during uncomplicated procedures and immediate sheath removal, even in patients who have heparinzation "overnight."

Radial artery occlusion occurred in nine patients (3.0%). There were no clinical symptoms in association with these occlusions, which is due to the selection of patients with collateral blood supply through the ulnar artery.

On the basis of data from large series of patients who underwent radial artery blood pressure monitoring (16,17), radial artery occlusion is not considered to be a major event. Compared with a 30% and 38% incidence of radial artery occlusion reported by Davis et al. (16) and Bedfort et al. (17), respectively, after prolonged cannulations of the radial artery for blood pressure monitoring, the incidence is low in the present study and in the feasibility studies on transradial PTCA (100 patients) and on transradial stenting (100 patients) (2,8).

Clinical implications. From the present study we conclude that compared with transbrachial and transfemoral PTCA, in experienced hands, the transradial technique yields comparable results. However, coronary cannulation failure is more frequently encountered during right-arm procedures. The near elimination of bleeding complications makes the radial artery a safe entry site for PTCA in patients with normal Allen test results.

The safety of the transradial approach with regard to bleeding complications allows immediate postprocedural ambulation, which is usually appreciated by the patients. Analysis of a recent survey of patients who underwent transradial PTCA after transfemoral diagnostic catheterization at our center, showed that 75% of patients preferred the radial approach because of postprocedural ambulation (unpublished data).

An additional advantage of this approach is the passive achievement of hemostasis by a pressure device or by a pressure bandage, reducing the workload of nursing and medical staff.

Safe, immediate mobilization of the patient opens the way to safe outpatient coronary angioplasty strategies. Outpatient treatment is a powerful tool for coping with an increasing patient load in an unchanging hospital environment and for reducing long waiting lists for coronary angioplasty. The feasibility of transradial coronary stenting on an outpatient basis has been demonstrated by our group in 100 patients (18) an has been accepted as routine in our hospital, where >70% of patients for elective stenting are discharged on the day of treatment. With an increasing number of 6F guiding catheter-compatible stent types, this percentage may increase in the future.

After having evaluated the risks of outpatient transradial balloon angioplasty in patients who fulfill a set of preprocedural, procedural and postprocedural criteria (19), we are currently performing a feasibility study of actual outpatient transradial PTCA that will be followed by a randomized study. The study will also include a cost-effectiveness and a quality-of-life analysis to clarify the socioeconomic consequences of the transradial technique.

Because outpatient femoral diagnostic coronary angiography seems straightforward with 5F or smaller catheters, the only reasons to select the radial approach for diagnostic purposes are increased patient comfort, associated with immediate mobilization, and situations for which ad hoc PTCA is considered.

The safety and efficacy of transradial coronary angiography and angioplasty in the same setting have been demonstrated by Barbeau et al. (20) in a group of 250 consecutive patients with normal Allen test results, of whom 129 (51.6%) had subsequent balloon angioplasty and 27 (10.8%) coronary stent implantation. Barbeau et al. conclude that this approach could be ideal for outpatient ad hoc invasive coronary interventions. This patient-friendly strategy additionally decreases the costs of health delivery.

Thus, despite the higher incidence of transradial coronary cannulation failure than with the 6F transfemoral approach, the transradial approach is the routine technique for PTCA in our practice because of high procedural success rates and PTCA outcomes similar to those for 6F transfemoral PTCA, together with nearly complete elimination of major bleeding complications. Major additional arguments are increased patient comfort and preference, reduced postprocedural workload associated with the achievement of hemostasis and the potential for outpatient treatment.

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