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Transulnar Versus Transradial Artery Approach for Coronary Angioplasty: The PCVI-CUBA Study

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Objectives: To compare in terms of efficacy and safety the transulnar to the transradial approach for coronary angiography and angioplasty. **Background:** Opposite to the transradial approach, which is now widely used in catheterization laboratories worldwide, the ulnar artery approach is rarely used for cardiac catheterization. **Methods:** Diagnostic coronarography, followed or not by angioplasty, was performed by transulnar or transradial approach, chosen at random. A positive (normal) direct or reverse Allen's test was required before tempting the radial or the ulnar approach, respectively. MACE were recorded till 1-month follow-up. Doppler ultrasound assessment of the forearm vessels was scheduled for all the angioplastied patients. **Results:** Successful access was obtained in 93.1% of patients in the ulnar group (n = 216), and in 95.5% of patients in the radial group (n = 215), P = NS. One hundred and three and 105 angioplasty procedures were performed in 94 and 95 patients in ulnar and radial group, with success in 95.2% and 96.2% of procedures in ulnar and radial group, respectively (P = NS). Freedom from MACE at 1-month follow-up was observed in 93 patients in both groups (97.8% for ulnar group and 95.8% for radial group), P = NS.Asymptomatic access site artery occlusion occurred in 5.7% of patients after transulnar and in 4.7% of patients after transradial angioplasty. A big forearm hematoma, and a little A-V fistula were observed, each in one patient, in the ulnar group. **Conclusion:** The transulnar approach for diagnostic and therapeutic coronary interventions is a safe and effective alternative to the transradial approach, as both techniques share a high success rate and an extremely low incidence of entry site complications. The transulnar approach has the potential to spare injury to the radial artery in anticipation of its use as a coronary bypass conduit.

Key words: transulnar approach; cardiac catheterization; transradial approach

INTRODUCTION

The transradial approach for coronary diagnostic and therapeutic interventions is a highly safe and effective technique, now widely used in many catheterization laboratories worldwide. Although more challenging than the femoral or brachial approaches [1,2], its advantages over these two more classical approaches are now well established [3]. Major advantages to the transradial approach include relative freedom from local complications and ease of post-procedure patient management. Evaluation in all the clinical settings, ranging from elective diagnostic catheterization to elective percutaneous transluminal coronary angioplasty (PTCA) and stenting to urgent PTCA has shown to give comparable procedural success with significant reduction of access site bleeding and other complications, as compared to the transfemoral approach [4,5], even in patients treated with aggressive antithrombotic therapy, including oral anticoagulants [6] and glycoprotein IIb/IIIa inhibitors [7–9]. The transradial approach allows for earlier ambulation, more comfort, earlier patient discharge, and reduced costs of hospitalization [4,5,10,11].

The transulnar approach has received very little attention as a potential approach for cardiac catheterization. A few preliminary reports on small numbers of patients have suggested that the ulnar approach may be both feasible and safe for coronary angiography and PTCA in selected patients [12–14]. More recently, we and others showed in larger series of patients that the transulnar approach may be considered as a valuable alternative to the radial approach, with high rates of

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efficacy and very low rates of complications, similar to that reported for the radial approach [15,16].

The present prospective, randomized study was aimed to compare in terms of efficacy and safety the transulnar to the transradial approach for coronary angiography and angioplasty in nonselected patients.

METHODS

Patient Selection

Consecutive patients referred to our institutions for a diagnostic coronary angiography with or without subsequent coronary PTCA were randomized to ulnar or radial approach at arrival to the cathlab, before palpation of the forearm pulses and Allen's test were done.

Positive (normal) Allen's test was required to consider the randomized access site as suitable. The Allen's test is considered normal when, after compression of both radial and ulnar arteries, the open palm recover a normal color within 10 sec after release of pressure over the ulnar (classical Allen's test) or radial artery (reversed Allen's test) [17–19].

Randomization was performed by opening a sealed envelope containing a code for either transulnar (U) or transradial (R) approach.

Patients with known arterial circulatory disease in an upper limb, history of coronary revascularization surgery with left internal mammary artery grafting, need for simultaneous right heart catheterization, acute pulmonary edema, or cardiogenic shock were not screened for ulnar or radial access.

The study was approved by our local ethics committee, and a written informed consent was obtained from each patient.

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. The access site-related primary end point was defined as either the need to puncture a second access site due to any reason or the occurrence of a major access site complication. A complication was considered to be major if associated with hemoglobin loss of at least 2 mmol/l, administration of blood transfusions, vascular repair, or prolonged hospitalization. Minor bleeding was defined as insignificant subcutaneous bleeding or hematoma formation around the puncture site not requiring specific therapy. The other possible complications included ulnar or radial artery thrombosis, arterial effraction, arteriovenous fistula, pseudoaneurysm, and ulnar nerve injury.

PTCA-related end points were defined as more than 30% of residual stenosis or the occurrence of any major cardiac event including death, myocardial infarction, and urgent target vessel revascularization (re-PTCA or rescue bypass graft surgery).

Secondary end points included adequate opacification of both coronary arteries, and of the left ventricle cavity when required, allowing a diagnosis to be established, as judged by two independent and experienced operators. Procedural time, recorded from the moment of the start of the first attempt to puncture the artery to the end of the procedure, fluoroscopy time, and X-ray dose-area product (DAP) were also considered as secondary end points.

Ulnar and Radial Artery Cannulation

The right arm was abducted and placed on a rest attached to the catheterization table, with the wrist hyperextended. Local anesthesia with 2% xylocaine was performed at the site where the pulse was strongest, usually 1–3 cm proximal to the pisiform bone (ulnar artery), and 1 cm proximal from the styloid process (radial artery). The artery was punctured with a 20-gauge × 2″ entry needle, into which a straight 0.025″ plastic mini-guidewire was inserted (RADIFOCUS INTRODUCER II, Terumo Corporation, Tokyo, Japan). A 4-French tapering introducer (Terumo) was placed on the 0.025″ wire through a skin incision made by cutting gently with a surgical knife. Sodium heparin (3,000 IU) and verapamil (2.5 mg) were injected through the introducer. When required, a 5- or 6-French introducer over a 0.035″ wire was substituted for the 4-French introducer.

Analgesia and sedation with synthetic opioids and benzodiazepines was used as needed.

Cardiac Catheterization

For diagnostic procedures, we used 4-French diagnostic catheters (Terumo, Tokyo, Japan) or 5-French catheters (Cordis Corporation, Miami Lakes, FL) with appropriate shapes. PTCA was done with 6-French guiding catheters having an inner diameter of 0.07 in. (Medtronic, Danvers, MA; or Cordis Corporation, Miami Lakes, FL) or 5-French guiding catheters having an inner diameter of 0.058 in. (Medtronic, Danvers, MA) or 0.056 in. (Cordis Corporation, Miami Lakes, FL). The catheters were advanced over a standard 0.035″ spring guidewire.

Coronary 0.014″ guidewires and rapid-exchange balloons were used according to standard procedures. Commercially available balloon-premounted stents were used, and direct stenting was performed when possible.

Anticoagulation

All patients received 500 mg aspirin IV prior to an angioplasty procedure. When necessary, additional hep-

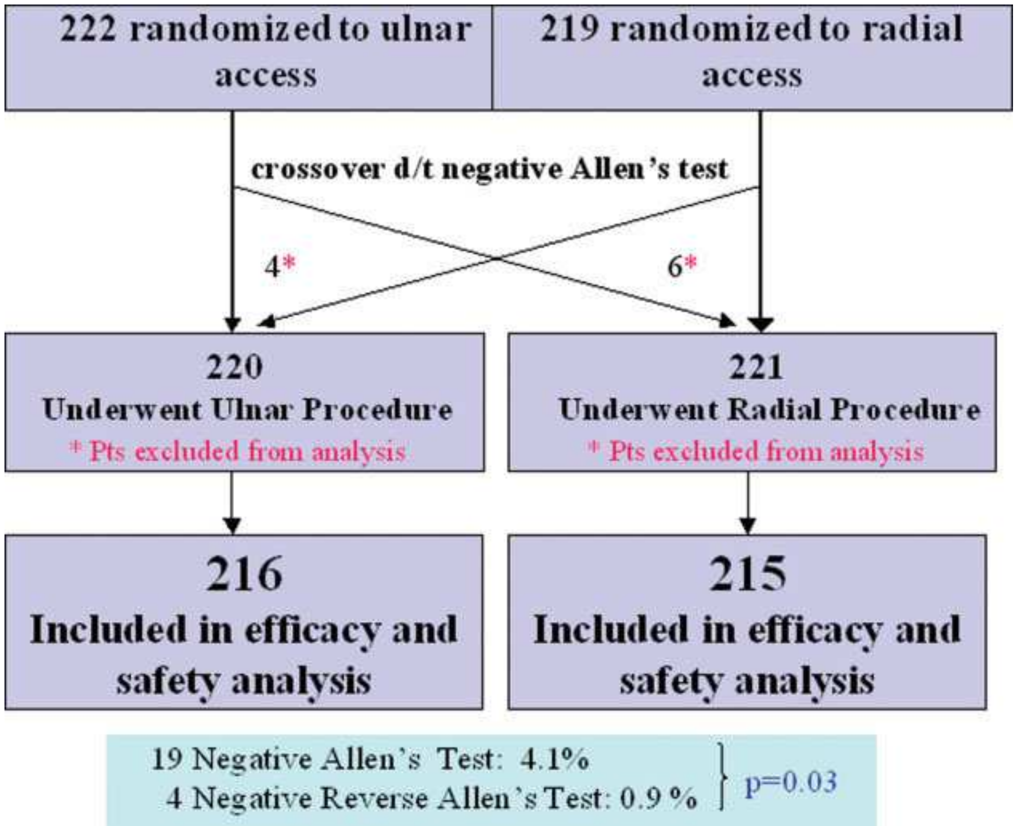

Fig. 1. Outcome of patients randomized before coronarography. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

arin was given on a weight-adjusted basis before the interventional procedure. Activated clotting times were not measured during or after intervention. Platelet glycoprotein IIb/IIIa receptor inhibitors were administered as clinically indicated before or during the procedure, followed by a 12-h intravenous infusion.

After sheath removal and local hemostasis, heparin infusion was continued at the discretion of the operators in those patients with acute coronary syndromes.

After PTCA, all patients received clopidogrel (75 mg/day for 1 month at least, after a loading dose of 300 mg given at least 3 hr before the procedure, or at procedure completion) and long-term aspirin (80–160 mg per day).

Sheath Removal and Postprocedure Management

Vascular sheaths were removed immediately after the procedure and a haemostasis strap over a gauze wad applied to the puncture site for 4 hr, followed by a non-occlusive pressure dressing. No compression devices were used. The patients were advised to restrict wrist movements and were allowed to ambulate after 4 hr, unless their clinical status dictated otherwise.

Patients were allowed to leave the hospital 4 hr after diagnostic procedures, and as dictated by the clinical situation after therapeutic procedures.

Ultrasound Assessment and Follow-up

A week to 15 days after PTCA, all patients were scheduled for Doppler ultrasound assessment of the forearm vessels. For patients who underwent two separate procedures (elective or repeat angioplasty), Doppler ultrasonography was done 7–10 days after the second procedure. When vascular access failed, Doppler ultrasonography was not performed. Doppler ultrasonography was carried out by the referring cardiologists or by angiologists. Patency of the ulnar and radial arteries, presence of procedure-related complications at the access site, and when possible, size of the ulnar and radial arteries at the wrist were recorded.

For all angioplastied patients, including those who did not undergo follow-up Doppler ultrasonography, a phone interview was conducted 30 days after the procedure, so as to screen for the occurrence of procedure-related and access site-related end points, as well as symptoms and functional impairment at the puncture site, forearm, or hand.

TABLE I. Baseline Clinical Characteristics, Procedural and Angiographic Results of the 431 Patients Undergoing Coronary Angiography

	Ulnar group	Radial group	*P* value
Patients, *n*	216	215	
Age (yr)	63 ± 12	63 ± 13	1
(minimal–maximal)	(22–95)	(33–90)	
Men (%)	74	73	0.89
Height (cm)	169 ± 8	169 ± 9	1
Weight (kg)	78 ± 14	78 ± 15	1
(minimal–maximal)	(46–145)	(45–132)	
Diabetes (%)	20.7	22.6	0.77
Smoking (%)	46.8	47.8	1
Previous CABG (%)	3.1	2.8	0.89
Clinical presentation			
Stable angina (%)	26.0	28.4	0.74
NSTEACS (%)	22.5	27.6	0.45
STEACS (%)	17.5	16.7	0.87
Silent ischemia (%)	12.0	10.7	0.78
Other indications (%)	21.9	16.6	0.36
Procedural results			
Successful vascular access (%)	93.1	95.5	0.84
Number of punctures	1.57 ± 0.6	1.40 ± 0.9	0.02
(range)	(1–6)	(1–7)	
Procedural time (min)	14 ± 8.2	12.7 ± 6.7	0.06
Fluoroscopy time (min)	5.6 ± 5.1	5.2 ± 4.2	0.35
DAP (mGy/cm^2)	7 559 ± 4 865	7 195 ± 4 850	0.43
Angiographic results			
No or insignificant lesion (%)	34	36	0.8
Single-vessel disease (%)	36	33.3	0.7
Double-vessel disease (%)	15.6	18.6	0.6
Triple-vessel disease (%)	12.5	9	0.43
Left main stenosis (%)	1.4	2.7	0.52
SVBG lesion (%)	0.5	0.4	0.98

Data presented are mean value ± SD or % of patients. CABG, coronary artery bypass graft; NSTEACS, non ST-elevation acute coronary syndrome; STEACS, ST-elevation acute coronary syndrome; DAP dose-area product; SVBG, saphenous vein bypass graft.

Statistical Analysis

Continuous variables are expressed as mean value ± SD and categorical variables as percentages. An unpaired *t* test was used for comparison of mean values and chi-square test for comparison of percentages. A *P* value < 0.05 was considered statistically significant.

RESULTS

Study Population

Between December 2003 and May 2004, 441 consecutive patients referred for diagnostic coronary angiography and PTCA were randomized to ulnar or radial access. Outcomes in these patients are shown in Fig. 1. Direct and reverse Allen's tests were negative (abnormal) in 19 (4.1%) and 4 (0.9%) of the patients, respectively ($P = 0.03$). Because of negative Allen's test, six patients randomized to radial access underwent ulnar procedure, and four patients randomized to ulnar access underwent radial procedure. These 10 patients were excluded from analysis.

Baseline demographic and clinical characteristics of the study population are shown in Table I. Males contributed three-fourths of the population in both groups and 20 and 22% of patients in ulnar and radial group had diabetes. Fourteen patients (3%) weighed 50 kg or less, and 30 patients (7%) weighed 100 kg or more.

Acute coronary syndrome was the reason for coronary angiography in 40 and 44% of patients in ulnar and radial group, respectively.

Angiographic data for the whole population are shown in Table I. The vessel distribution between the two groups was the same. Based on the angiographic findings, no treatment, medical treatment, PTCA, or surgical revascularization were proposed to 12.7%, 36.3%, 45%, and 6% of patients in the ulnar group, and to 10.8%, 39.2%, 43%, and 7% of patients in the radial group (P = NS).

Clinical and angiographic data of patients undergoing angioplasty are shown in Table II. More than 50% of patients in each group had acute coronary syndrome. There was no significant difference in the two groups in the incidence of patients receiving fibrinolytics or anti GPIIb/IIIa drugs. A loading dose of clopidogrel (300 mg) has been given to 37% of patients in the ulnar group and 26% of patients in the radial group at least 3 hr before the angioplasty (P = NS). The vessel distribution between the two groups was the same. Lesion morphology was also the same in both groups.

Procedural Outcome

Vascular access. All patients had a right-sided arterial puncture. Successful arterial cannulation was obtained in 93.1% of patients in the ulnar group, and in 95.5% of patients in the radial group (P = NS). Because of access failure, 15 patients randomized to ulnar access underwent successful radial ($n = 14$) or femoral ($n = 1$) procedure, and 9 patients randomized to radial access underwent successful ulnar ($n = 5$) or femoral ($n = 4$) procedure.

The number of punctures in the patients undergoing diagnostic procedures is shown in Table I. More punctures were required for ulnar cannulation than for radial cannulation. Cannulation was achieved with the first puncture in 89.2% of patients in the radial group, and in 72.6% of patients in the ulnar group ($P < 0.01$).

Good-quality coronary angiography images were obtained for all diagnostic procedures in both groups. Four-Fr left Judkins, right Judkins, or Amplatz catheters were used in 94.3 and 92.6% of patients in the ul-

TABLE II. Baseline Clinical and Angiographic Data in Patients Undergoing Coronary Angioplasty

	Ulnar group	Radial group	*P* value
Patients, *n*	94	95	
Diabetes (%)	22.2	27.2	0.43
Clinical presentation			
Stable angina (%)	20.0	22.0	0.75
NSTEACS (%)	33.0	36.0	0.69
STEACS (%)	23.0	20.0	0.57
Silent ischemia (%)	13.0	8.0	0.23
Other indications (%)	11.0	14.0	0.53
Adjunctive therapy			
Clopidogrel (%)	37.1	26.3	0.08
Fibrinolytics (%)	11.4	9.3	0.60
Anti GPIIb/IIIa (%)	22.9	22.0	0.84
Angiographic findings			
Lesion location (%)			
LAD	48.9	45.1	0.53
LCX	14.9	13.7	0.78
RCA	29.8	34.2	0.53
Left main	2.1	1.2	0.61
SVBG	0	2.0	0.15
Other	4.3	3.8	0.84
Lesion type (%)			
A	18.4	15.5	0.55
B_1	29.5	31.7	0.77
B_2	32.8	33.7	0.93
C	19.3	20.1	0.91

NSTEACS, non ST-elevation acute coronary syndrome; STEACS, ST-elevation acute coronary syndrome; anti GPIIb/IIIa, platelet glycoprotein IIb/IIIa receptor inhibitors; SBVG, saphenous vein bypass graft.

TABLE III. CoronaryAngioplasty Procedural Characteristics and Outcomes

	Ulnar group	Radial group	*P* value
PTCA number	103	105	
Ad hoc PTCA, *n* (%)	76 (73.7)	79 (75.2)	0.99
Elective PTCA, *n* (%)	27 (26.3)	26 (24.8)	0.78
N° of lesions treated	123	128	0.23
Bifurcation lesions, *n* (%)	5 (4.8)	4 (3.8)	0.70
Stenting rate (%)	97.8	96.5	0.37
Stent/patient	1.33	1.34	0.99
Direct stenting (%)	65.0	61.9	0.53
DES (%)	38.6	37.2	0.75
Outcomes			
Procedural success (%)	95.2	96.2	0.82
Procedural failure (%)	4.8	3.8	0.7
Access failure, *n*	2	0	–
Inability to cross stenosis, *n*	3	3	–
Suboptimal result, *n*	0	1	–
Other procedures			
IVUS	1	2	–
Rotational atherectomy	1	0	–
Ad hoc PTCA			
Procedural time (min)	41 ± 20	39 ± 17	0.5
Fluoroscopy time (min)	17 ± 10	15 ± 8	0.17
DAP (mGy/cm^2)	19 600 ± 10 501	17 200 ± 9 364	0.13
Elective PTCA			
Procedural time (min)	26 ± 17	29 ± 20	0.55
Fluoroscopy time (min)	13 ± 9	14 ± 10	0.70
DAP (mGy/cm^2)	16 430 ± 12 104	16 040 ± 10 900	0.90

Data presented are mean value ± SD or % of patients. PTCA, percutaneous transluminal coronary angioplasty; DES, drug eluting stents; IVUS Intra Vascular Ultrasound; DAP, dose-area product.

nar and radial group ($P = 0.9$). In the remaining 5.7 and 7.4% of patients, respectively in the ulnar and radial group, 5 Fr catheters were required to improve image quality. Left ventriculogram was performed in addition to coronary angiography through a pigtail catheter in 64% of patients. Procedural and fluoroscopy time and DAP were not significantly different in both groups (Table I).

Coronary angioplasty. Following diagnostic coronarography, 103 and 105 angioplasty procedures were performed in 94 and 95 patients in ulnar and radial group, respectively. The PTCA procedural characteristics are shown in Table III. In the ulnar group, 76 (73.7%) were ad hoc procedures (PTCA performed immediately after diagnostic coronarography), and the other 27 (26.3%) were elective procedures (PTCA performed in a separate session), while in the radial group 79 (75.2%) were ad hoc and 26 (24.8%) were elective PTCA. A second elective ($n = 7$) or repeat PTCA (angioplasty involving the same segment after the arterial sheath has been removed) ($n = 2$) was performed in nine patients in the ulnar group, and eight elective, two repeat PTCA in 10 patients in the radial group. Six-French or 5-French guiding catheters were used respectively in 84 and 16% of procedures in the ulnar group, and in 80 and 20% of angioplasty procedures in the radial group ($P = 0.34$ between groups). Adequate guiding position could be obtained in all patients in both groups. The consumption of guiding catheters (1.1/procedure) was similar for the two approaches. Almost all the patients in both groups received at least one stent (Table III), direct stenting (i.e., without predilation) was performed in 65% and 61.9% and drug-eluting stents were used in 38.6 and 37.2% of procedures in ulnar and radial groups, respectively. Additional techniques, such as intra-vascular ultrasound and rotational atherectomy were used in small numbers of patients in each group.

Successful PTCA was achieved in 95.2% and 96.2% of procedures in ulnar and radial group, respectively ($P =$ NS) (Table III). TIMI 3 flow grade was obtained in 96% of patients in both groups (Fig. 2). Reasons for failed angioplasty are shown in Table III.

Procedural time of transulnar ad hoc and elective angioplasty was similar to transradial angioplasty (Table III). Fluoroscopy time and DAP were also similar in the two groups.

Clinical Outcome at 1-Month Follow-up

Cardiac events. Successful PTCA with an uncomplicated clinical course was achieved in 87 (92.6%)

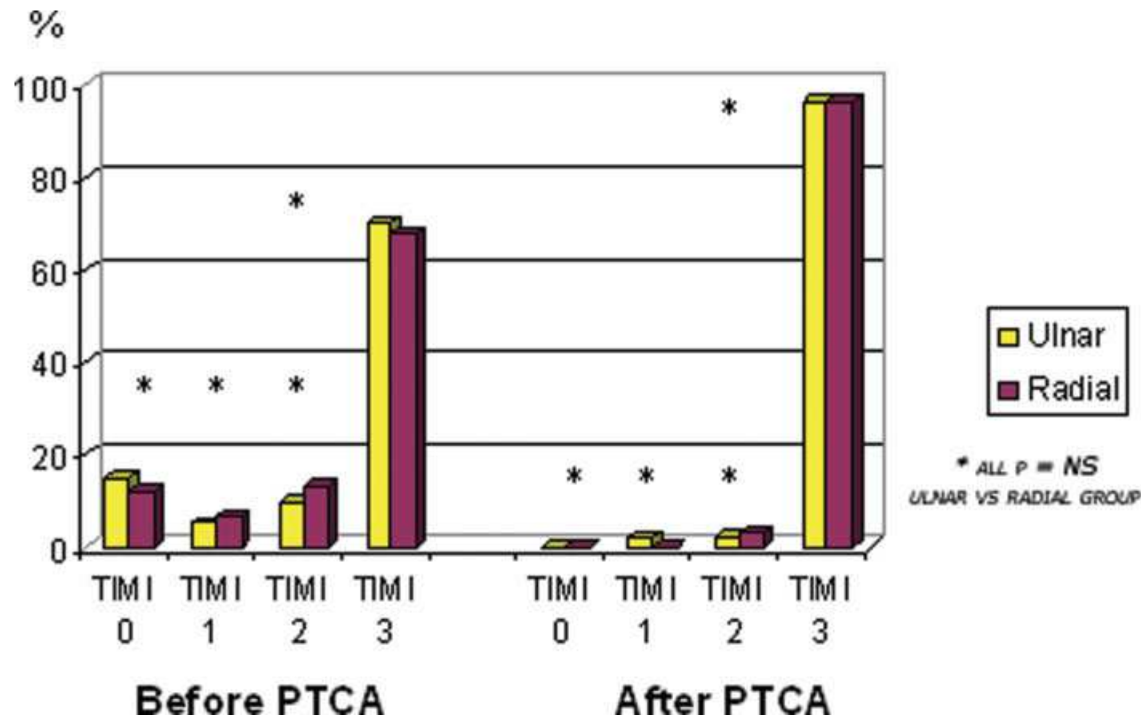

Fig. 2. TIMI flow rates before and after PTCA. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

and 87 (91.6%) patients in the ulnar and radial groups, respectively ($P = 0.36$). Freedom from major events was observed in 92 (97.8%) and 91 (95.8%) patients in the two respective study groups (P = NS) (Table IV). No significant differences in incidence and distribution of major events at 1-month follow-up were noted. The total study mortality rate was 1%. Two patients died, both in the radial group, 6 hr and 24 hr after successful primary PTCA for acute myocardial infarction, after rapid progression to irreversible cardiogenic shock, and without evidence of abrupt target vessel occlusion. Two patients (2.1%) in each group presented non-fatal re-infarction due to abrupt target vessel occlusion in the days following angioplasty, successful repeat angioplasty was performed in the four patients. No patients in this study were referred for emergency bypass surgery. Elective target vessel revascularization was performed in any patient in both groups. Procedure-related cerebrovascular events were not observed in this study.

Entry site complications. Slight or moderate spasm at the wrist, forearm, arm, or subclavian level occurred in eight (7.3%) patients in the ulnar group and in six (5.7%) in the radial group ($P = 0.65$), during coronary angiography or PTCA, not precluding completion of the procedure. In one patient, general anesthesia was required to relieve the spasm. Three patients complained of lightening-flash pain in the ulnar side of the hand caused by needle puncture of the ulnar nerve; the pain resolved before the end of the procedure, leaving no residual sensory or motor abnormalities. In all patients, the ulnar or the radial artery was pulsating to palpation after the procedure. None of the patients had symptoms of signs of hand ischemia. Major bleeding was observed in one patient in the ulnar group, i.e. a big hematoma (>10 cm) treated conservatively, not requiring blood transfusion and not compromising the ulnar artery permeability, but prolonging hospitalization. Neither blood transfusion nor vascular surgery was required in any of the patients. Minor bleeding, i.e. insignificant subcutaneous bleeding or hematoma formation around the puncture site was still observed at the moment of the ultrasound assessment in five (5.7%) and seven (8.1%) patients in the ulnar and radial group, respectively (P = NS).

Doppler ultrasound assessment (Table V). Follow-up Doppler ultrasonography of the forearm vessels was done in 88 (93.6%) of patients in the ulnar group, and in 86 (90.5%) of patients in the radial group, 13 ± 9 and 16 ± 12 days after PTCA, respectively. Asymptomatic ulnar or radial artery occlusion occurred in five (5.7%) and four (4.7%) of patients after transulnar or transradial PTCA, respectively. Three of nine (33.3%) arterial occlusions occurred after a second PTCA procedure, yielding a significant statistical difference between

TABLE IV. Major Adverse Cardiac Events and Their Ranking from PTCA to 1-Month Follow-up

	Ulnar group	Radial group	*P* value
Number of PTCA patients	94	95	
Death	0	2 (2.1)	0.14
Non fatal reinfarction	2 (2.1)	2 (2.1)	1
	Days 4, 5	Days 1, 3	
Revascularization			
Urgent target vessel	2 (2.1)	2 (2.1)	1
Elective target vessel	0	0	
Elective nontarget vessel	7 (7.4)	8 (8.4)	0.81
CABG	0	0	
Total number of patients with event ranked to most serious complication	2 (2.1)	4 (4.2)	0.40
Free of MACE	92 (97.8)	91 (95.8)	0.41

Data are presented as number (%) of patients. PTCA, percutaneous transluminal coronary angioplasty; CABG, coronary artery bypass graft; MACE, major cardiac adverse events.

TABLE V. Entry Site Complications and Ultrasonographic Assessment

	Ulnar group	Radial group	*P* Value
Echo-Doppler done	88 (93.6)	86 (90.5)	0.43
Delay after PTCA, days	13 ± 9 (1–77)	16 ± 12 (1–82)	0.06
Complications			
Occlusion, *n* (%)			
After first PTCA	3 (3.4)	3 (3.5)	0.97
Second PTCA	2 (2.3)	1 (1.2)	0.47
Total	5 (5.7)	4 (4.7)	0.76
Minor bleeding, *n* (%)	5 (5.7)	7 (8.1)	0.47
Major bleeding, *n*	1 (1.1)	0	–
Artery effraction, *n*(%)	0	0	–
Pseudoaneurysm, *n* (%)	0	0	–
A-V fistula, *n* (%)	1 (1.1)	0	–
Ulnar nerve injury,*n*	0	–	–
Arterial diameter			
Ulnar artery (mm) (min–max)	2.83 ± 0.9 (1.3–5.1)		0.73
Radial artery (mm) (min–max)	2.87 ± 0.6 (1.3–5.0)		
Ulnar > Radial (%)	48.9		0.6
Ulnar < Radial (%)	51.1		

Data presented are mean value ± SD or number (%) of patients. PTCA, percutaneous transluminal coronary angioplasty; A-V fistula, arteriovenous fistula.

the incidence of this complication after a first or a second procedure ($P < 0.01$). A little arteriovenous fistula was noted at the site of ulnar puncture in one patient, which disappeared after sustained manual ulnar compression, as confirmed by a second Doppler ultrasound examination performed 1 month later. Pseudoanevrysms did not develop in any of the patients in both groups.

The diameter of the ulnar and radial arteries at the wrist was measured in 149 (85.6%) of 174 ultrasound investigations (Table V). Mean diameter was similar for the ulnar artery (2.83 ± 0.9 mm) and radial artery (2.87 ± 0.6 mm). As compared to the radial artery, the ulnar artery was the same size or larger in 48.9% of patients.

All of the 16 alive patients who did not undergo follow-up Doppler ultrasonography were interviewed over the phone at the end of the 1-month follow-up period. None reported symptoms or functional impairment at the access site.

DISCUSSION

This prospective, randomized study shows that the transulnar approach is a highly effective and safe technique for both transcatheter diagnostic and therapeutic interventions, which compares favorably with the more widespread transradial technique. Similar rates of access success, procedural success, cardiac, and entry-site complications were found with the two techniques.

Efficacy of the Transulnar Approach

The rate of successful ulnar cannulation was high, specially when considering that the entry-site was chosen at random in non-selected patients, before knowing the quality of the ulnar pulse. Access failures (6.9%) were mainly due to inability to puncture the artery, mostly because of operator skill. After successful ulnar cannulation, spasm occurred in 7.3% of patients, but in any case it precluded coronary cannulation. Vessel tortuosities were not found. Coronary ostia could be cannulated in the majority of cases with standard shape catheters (Judkins left and right, Amplatz left and right), allowing optimal or good quality angiograms of both coronary arteries in all cases. Six- or 5-Fr standard guiding catheters (Judkins or Amplatz shapes) were used for the majority of angioplasty procedures, in a few cases Extra Back Up or multipurpose guiding catheters were useful. No procedure performed through the right ulnar artery was associated with inadequate support of the guiding catheter. The high rate of successful balloon PTCA, stenting after predilation, or direct stenting achieved through the ulnar approach was similar to the procedural success rate obtained through the radial approach, the failures were due in two cases to access failure and in three cases to inability to cross the stenosis. More demanding techniques, such as double-balloon (kissing balloon) technique for bifurcation lesions, intravascular ultrasound, and rotational atherectomy could be performed with success in a small number of patients. Procedural and fluoroscopy time (a more reliable marker of procedural complexity), as well as DAP were similar in the ulnar and radial groups, and compare favorably with the results of previous studies addressing transradial ad hoc [8,9] or elective PTCA [3,4,20].

Safety of the Transulnar Approach

Low rates of MACE after coronary angioplasty were found using the transulnar and transradial approaches, not-withstanding more than 50% of patients in both groups presented with acute coronary syndrome.

Entry-Site Complications

Haemostasis after sheath retrieval is easily achieved following ulnar or radial puncture, as both arteries may be easily compressed with a "passive" pressure device or bandage. Major bleeding complications were observed in only one patient in this study, despite the fact that more than 30% of patients in each group received aggressive antithrombotic therapy with thrombolytics and platelet glycoprotein IIb/IIIa receptor inhibitors. Minor bleeding, not requiring any particular treatment other than manual compression, occurred in a small number of patients. These results show that ulnar artery approach, as well as radial approach, virtually abolish entry-site bleeding complications after coronary angioplasty, even in patients fully anticoagulated. This constitutes a major advantage of both approaches over the more classical femoral approach, as systematically shown in previous studies comparing femoral to radial access [3,4]. In fact, although several strategies are used in order to limit groin complications, including post-procedural discontinuation of anticoagulation, weight-adjusted doses of heparin and GP IIb/IIIa inhibitors and early sheath removal, transfemoral procedures are still burdened by a number of local complications, specially minor and major bleeding and haematomas, that even closure devices cannot completely avoid [20,21].

The rate of asymptomatic thrombotic occlusion of the ulnar or radial artery found in this study is in accordance with the previously reported incidence of radial occlusion, that ranges from 3 to 6% in the studies that planned a Doppler ultrasound examination of the radial artery after the procedure [4,22]. It is noteworthy that access-site artery occlusion occurred more frequently after a second angioplasty procedure, as previously reported [23,24].

Injury to the ulnar nerve, which runs parallel to the ulnar artery and along its medial border, was not observed in our study.

Potential Benefits of the Transulnar Approach

Safe alternative to transradial approach. Because the transradial approach is a safe technique that yields clinical results similar to transfemoral access and is virtually free of vascular entry site complications, it is now widely used in catheterization laboratories worldwide [3,25]. However, the radial approach does not seem suitable for 5–15% of patients undergoing cardiac catheterization for reasons including an abnormal Allen's test [5,18]; significant anatomic variations such as loops, tortuous configurations, stenoses, hypoplasia, and aberrant origin [26,27], and vasospasm leading to radial artery access failure or failure to achieve coronary artery cannulation [3,28,29]. Other reasons, such as local scarring, previous hand injury, synovial cysts, local haematomas due to previous intravenous line placement or artery punctures for blood gas measurement can preclude the use of the radial artery approach. In our study, 4.1% of patients were found to have a negative direct Allen's test, and 5% of patients randomized to radial access finally underwent successful ulnar access due to negative Allen's test or failed radial cannulation. Thus, when the transradial access is not possible or fails, the transulnar approach may be considered as a safe alternative before reverting to the transfemoral approach.

Preservation of the Radial Artery as a Potential Bypass Graft for Surgical Revascularization

Previous transradial catheterization reduces the rate of early graft patency and causes intimal hyperplasia when the radial artery is used as a bypass conduit for myocardial revascularization [30]. As radial conduits are being increasingly used for coronary bypass surgery [31–33], the ulnar-artery approach may be valuable as a radial artery-sparing procedure.

Anatomical Considerations

The ulnar artery has been described as the larger terminal branch of the brachial artery [34,35], whereas in a recent study, postmortem angiograms of 24 cadavers showed that the mean diameter of the radial artery was 28% larger than that of the ulnar artery in the right arm ($P < 0.001$) and 26% larger in the left arm ($P < 0.001$) [36]. However, our results show that mean diameter at the right wrist was similar for the ulnar and radial arteries, as measured during ultrasound investigation. Moreover, as compared to the radial artery, the ulnar artery was same size or larger in almost half of patients.

Both the superficial palmar arch, (primarily ulnar) and the deep palmar arch, (primarily radial) protect the hand against ischemia if one of the source arteries is occluded. However, the superficial arch is more often incomplete than the deep arch, as shown by anatomical studies [37,38]. In an angiographic study, the deep palmar arch was complete in 95% of individuals and the superficial palmar arch in only 40–80% of individuals [35]. Accordingly, we found in our study population, a significantly higher prevalence of negative direct

Allen's test than of negative reverse Allen's test. The greater prevalence of radial collateral support than of ulnar collateral support suggests that ulnar cannulation may be preferable over radial cannulation.

Limitations of the Transulnar Approach

As for the transradial approach, a learning curve exist, even for operators who have extensive experience with radial cannulation, as we showed in a previous study [15]. One reason for that is that, although similar in size, the radial artery is more superficial and thus easier to palpate at the wrist than the ulnar artery. However, in many cases hyperextension of the wrist markedly facilitates ulnar pulse perception and ulnar artery cannulation.

A definite contraindication to the transulnar approach is the inadequacy of radial circulation to the hand, as recognized by an abnormal reverse Allen's test. Moreover, as stated by Dashkoff et al., we have refrained from and would caution against attempted access of the ipsilateral ulnar artery at the same sitting should an initial attempt at radial artery access prove unsuccessful, because of the potential for dual-vessel vasospasm and thrombotic occlusion [13]. Finally, as a positive (normal) Allen's test does not completely exclude the inadequacy of palmar arch collateral support by the ipsilateral complementary wrist artery [27], we recommend to avoid the ulnar approach in patients with a history of ipsilateral radial cannulation.

Limitations of the Study

The current study, aimed to compare the transulnar to the transradial approach for coronary angioplasty is clearly underpowered to detect differences in relevant measures of approach-related efficacy, such as access-site failure rates, and safety, such as frequency of local complications and major adverse cardiac events.

We did not use objective techniques to evaluate the adequacy of collateral circulation to the hand, such as pulse oximetry of the thumb, plethysmography [39], and color Doppler ultrasonography [27]. However, when properly performed, the Allen's test is reliable and suffices to evaluate the adequacy of the palmar arch collateral support.

CONCLUSION

The transulnar approach for diagnostic and therapeutic coronary interventions is a safe and effective alternative to the transradial approach, as both techniques share a high success rate and an extremely low incidence of entry site complications.

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