Safety and feasibility of transradial coronary angioplasty in elderly patients

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Aging;
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Background. **The aim of this study was to assess the safety, feasibility and efficacy of transradial coronary angioplasty in elderly (≥ 70 years) vs younger patients (< 70 years).**

Methods. **We studied 1125 consecutive patients submitted to transradial coronary angioplasty by a single operator. An angiography of the arteries of the upper limbs was performed before and after the procedure. The presence of the radial pulse was assessed at 1 month of follow-up.**

Results. **At angiography, elderly patients (n = 323) were found to have a higher incidence of radial and brachiocephalic trunk anatomical tortuosity compared to younger subjects (35.3 vs 17.3%, p < 0.05; 10.5 vs 5.3%, p < 0.05, respectively). Radial access was successful in 98.8% of elderly and in 99% of younger patients (p = NS). The procedural success by radial access did not significantly differ between the two groups (97.5 vs 98.7%; p = NS). The cannulation time (from skin anesthesia to arterial cannulation) and the total procedure time (from patient arrival at the catheterization room to the completion of the procedure) were not significantly different between the two groups (1.5 ± 0.8 vs 1.6 ± 0.4 min, p = NS; 57 ± 23 vs 56 ± 12 min, p = NS, respectively). There were no access site bleeding complications in younger and only one (0.4%) such a complication in elderly patients. In all patients, there was no case of forearm ischemia and the incidence of asymptomatic loss of the radial pulse during the 30-day follow-up period was not different between the two groups (1.5 vs 1.4%, p = NS).**

Conclusions. **Performed by experienced operators, transradial access constitutes a safe and feasible approach for coronary angioplasty in elderly patients. The results are similar to those observed in younger patients.**

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Introduction

As life expectancy continues to increase, the number of patients aged > 70 years with coronary artery disease who are candidate to a percutaneous coronary intervention (PCI) keeps increasing too[1]. The rate of access site complications after coronary angiography or PCI has been shown to be higher in elderly patients[2-8].

Recently, the transradial approach has been increasingly employed as an alternative way to perform elective diagnostic and interventional coronary procedures[9,10]. This approach showed a lower incidence of vascular access site complications and allows an earlier mobilization of the patients, with a reduced hospital stay and hospitalization costs[11]. The very low incidence of access site bleeding complications suggests that the transradial approach is an interesting alternative to the femoral technique in all interventional coronary procedures, particularly in elderly patients[12-20].

The transradial approach could represent an attractive alternative for these patients, but data regarding the effect of aging on the success rate, complications and clinical outcome of this procedure are limited.

The aim of this study was to assess the safety, feasibility and efficacy of transradial coronary angioplasty in elderly patients (≥ 70 years) compared to younger patients (< 70 years).

Methods

Population. We studied 1125 consecutive patients submitted to transradial coronary angioplasty by a single experienced operator. The exclusion criteria for a right transradial approach were an abnormal Allen test, the absence of a radial pulse, and cardiogenic shock.

In all patients, an angiography of the arteries of the upper limbs was performed at the beginning and at the end of the procedure.

Arterial cannulation. Radial artery cannulation was performed with the right arm positioned beside the patient's body and the wrist hyperextended. After local anesthesia with 1 ml of 2% xylocaine and 1 ml of $NaHCO_3$, the radial artery was punctured with a 20G 1-piece metal needle through which a 0.025" straight guidewire was inserted. Upon removal of the needle, a 23 cm long 6F sheath (Cordis Corporation, Miami, FL, USA) was placed over the guidewire. To reduce spasm and discomfort, an intra-arterial injection of a drug "cocktail" containing 200 μg of nitroglycerin, 5 mg of verapamil, 2 ml of $NaHCO_3$, and 2 ml of 2% xylocaine were administered through the sheath. Diagnostic angiography was performed using 6F catheters (Cordis Corporation) and PCI using 6F guiding catheters manufactured by either Boston Scientific/Scimed (Maple Grove, MN, USA) or Medtronic (Minneapolis, MN, USA) with an inner lumen diameter of 0.064". Right femoral artery access was achieved in the usual manner, followed by insertion of a 6F sheath. Coronary angiography was performed using 6F diagnostic catheters (usually the Sones type). Coronary interventions were performed using 6, 7 or 8F guiding catheters as appropriate.

Treatment. Before PCI, all patients received aspirin and a 5000 IU bolus of unfractionated heparin. During PCI an adjunctive bolus of heparin was administered at a dosage calculated on the basis of the body weight (70 IU/kg) and of the activated clotting time (therapeutic range 250-350 s). Glycoprotein IIb/IIIa inhibitors were administered as clinically indicated during the procedure. After the procedure no more heparin was prescribed and the activated partial thromboplastin time was monitored for the following 12 hours. Patients who received a coronary stent were treated with aspirin 100 mg/day plus ticlopidine 250 mg twice a day for one month. Angiographic success of PCI was defined as achievement of a residual stenosis < 30% with a TIMI flow grade 2-3.

Sheath management. The arterial sheath was removed following completion of the procedure and hemostasis of the puncture site was achieved by selective application of a pile of gauzes with a compressive bandage supported by one tourniquet. The occlusive pressure was gradually decreased during the following 30 min, and the tourniquet was finally replaced by a selective radial pressure bandage. The patients were then transferred to recovery or the coronary care unit, as appropriate.

Clinical and metabolic data. All patients were screened for ECG changes; creatine kinase (CK) and CK-MB levels were assessed every 6 hours during the first day and then every day until discharge unless clinical events necessitated repeat measurements. Adverse clinical events (death, reinfarction, recurrent angina, target lesion revascularization, and heart failure) were evaluated during a 30-day period of follow-up.

Bleeding was defined according to the criteria of the Thrombolysis in Myocardial Infarction trial (TIMI)[21]; major bleeding was defined as a decrease in the hemoglobin basal level of 5 g/dl, intracranial hemorrhage or cardiac tamponade; minor bleeding was defined as a decrease in the hemoglobin basal level > 3 g/dl from an identified site, spontaneous gross hematuria, hematemesis, hemoptysis or puncture site bleeding.

The presence of the radial pulse was assessed at 1 month of follow-up.

Statistical analysis. Categorical data are presented as absolute values and percentages, whereas continuous data are summarized as the mean value ± SD. The χ^2 and Fisher's exact tests were used for comparison of categorical variables as appropriate. Comparison of continuous variables was performed by means of the Student's t-test or the Wilcoxon rank-sum test, as appropriate; p values < 0.05 were considered as statistically significant.

Results

A total of 1125 consecutive patients (885 males, 240 females, mean age 63 ± 12 years) were included in the study; 323 (28.7%, mean age 76 ± 5 years, range 70-96 years) patients were ≥ 70 years (elderly) and 802 < 70 years (younger). Of all patients, 579 (51.5%) were submitted to an urgent PCI for acute coronary syndromes (264 patients [23.5%] with acute myocardial infarction were submitted to primary PCI).

The baseline demographic and clinical characteristics according to age are summarized in table I. Elderly patients were more frequently female (32.9 vs 16.7%, p < 0.001) and at higher risk (previous acute myocardial infarction 15.8 vs 6.2%, p < 0.05, previous stroke 6.5 vs 2.2%, p < 0.05, multivessel disease 58.5

Table I. Baseline patient characteristics.

Variable	< 70 years (n=802)	≥ 70 years (n=323)	p
Age (years)	57.8 ± 8.6	75.6 ± 4.6	< 0.001
Male	668 (83.3%)	217 (67.1%)	< 0.001
Current smoker	332 (41.4%)	29 (8.9%)	< 0.001
Dyslipidemia	218 (27.2%)	87 (26.9%)	0.1
Hypertension	304 (37.9%)	128 (39.6%)	0.5
Diabetes	104 (12.9%)	49 (15.1%)	0.1
Previous AMI	50 (6.2%)	51 (15.8%)	< 0.05
Previous CABG	31 (3.8%)	17 (5.2%)	0.2
Previous stroke	18 (2.2%)	21 (6.5%)	< 0.05
Unstable angina	204 (25.4%)	111 (34.3%)	< 0.05
AMI	196 (22.4%)	68 (21%)	0.4

AMI = acute myocardial infarction; CABG = coronary artery bypass graft.

vs 46.2%, p < 0.05). Furthermore, elderly patients were less likely to be current smokers (8.9 vs 41.4%, p < 0.001). The incidence of urgent PCI for unstable angina was higher in the elderly group (34.3 vs 25.4%, p < 0.05) whereas no significant difference between the two groups was found for the number of primary PCI during acute myocardial infarction (21 vs 22.4%; p = NS). The two groups did not differ with regard to the prevalence of diabetes mellitus, dyslipidemia and hypertension.

Procedural data. At angiography, elderly patients showed a higher incidence of radial and brachiocephalic trunk anatomical tortuosity (35.3 vs 17.3%, p < 0.05; 10.5 vs 5.3%, p < 0.05, respectively) (Fig. 1). The procedural outcomes in both groups are shown in table II. Radial puncture was successful in 98.8% of elderly patients and in 99% of younger patients (p = NS). In 45 patients with an abnormal right Allen test, the procedure was successfully performed through a left radial approach. The procedural success by a transradial approach was similar in the two groups: 97.5% in elderly and 98.7% in younger patients (p = NS). The overall procedural success was also similar in the two groups: 99.1% in elderly and 99.5% in younger patients (p = NS).

Three of the four failed transradial approaches in the elderly group were due to radial artery puncture failure and one to an occluded ipsilateral subclavian artery; these patients were all successfully converted to a right femoral approach.

Overall, 74 patients (6.6%) had been previously submitted to a transradial approach procedure without any difference between the two groups (7.7 vs 6.1%, p = NS). The cannulation time (from skin anesthesia to arterial cannulation) and the total procedure time (from patient arrival at the catheterization room to the completion of the procedure) were not significantly different between elderly and younger patients (1.5 ± 0.8 vs 1.6 ± 0.4 min, p = NS; 57 ± 23 vs 56 ± 12 min, p = NS, respectively). In 70.9% of elderly and 78.2% of younger patients (p = NS), a single catheter was used for diagnostic angiography (Sones type I-II, Cordis Corporation) and for the right and left coronary arteries and left ventricle. Balloon angioplasty alone was performed in 7.7% of elderly patients vs 10.8% of younger patients (p = NS). Direct stenting was performed in the majority of patients without any difference between the two groups (49.5 vs 51.3%, p = NS). Only a few patients received multiple stents, and the number of stents implanted was the same in both groups (average 1.4 ± 0.8 vs 1.3 ± 0.8 stents per patient, p = NS). The vessel distribution and lesion morphology were similar in both groups. The majority of patients had a complex le-

Table II. Procedural and angiographic characteristics.

Variable	< 70 years (n=802)	≥ 70 years (n=323)	p
Target lesion			
LAD	352 (43.9%)	149 (46.1%)	0.8
LCx	186 (23.2%)	68 (21%)	0.6
RCA	219 (27.3%)	80 (24.8%)	0.2
LM	14 (1.7%)	12 (3.7%)	0.1
Graft	31 (3.8%)	14 (4.3%)	0.8
Multivessel disease	371 (46.2%)	189 (58.5%)	< 0.05
GP IIb/IIIa inhibitors	87 (10.8%)	20 (6.2%)	< 0.05
Cannulation time (min)	1.6 ± 0.4	1.5 ± 0.8	0.8
Procedural time (min)	56 ± 12	57 ± 23	0.7
Radial redo procedure	49 (6.1%)	25 (7.7%)	0.8
Left radial approach	28 (3.5%)	17 (5.2%)	0.1
Radial puncture failure	8 (1%)	4 (1.2 %)	0.4
TRA procedural success	792 (98.7%)	315 (97.5%)	0.1
Femoral approach	8 (1%)	4 (1.2%)	0.4
Stent rate	1.3 ± 0.8	1.4 ± 0.8	0.8
Direct stenting	412 (51.3%)	160 (49.5%)	0.4
LVEF (%)	57.2 ± 5.6	55.4 ± 6.8	0.5

GP = glycoprotein; LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery; LM = left main coronary artery; LVEF = left ventricular ejection fraction; RCA = right coronary artery; TRA = transradial approach.

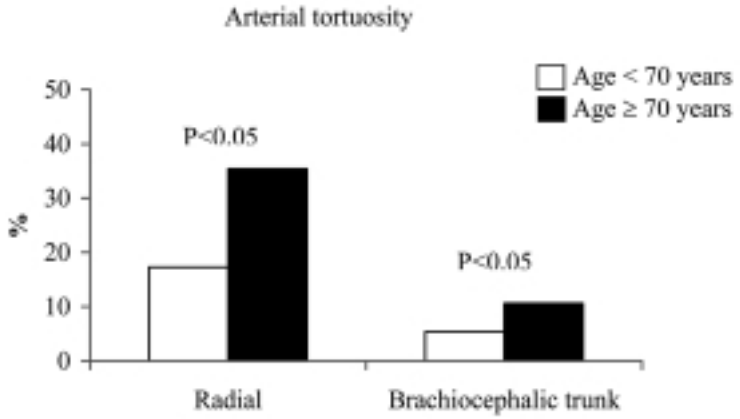

Figure 1. *Elderly patients showed a higher incidence of radial and brachiocephalic trunk anatomical tortuosity as detected at angiography.*

sion morphology on the left anterior descending coronary artery. A slightly higher percentage of younger patients received glycoprotein IIb/IIIa inhibitors (6.2 vs 10.8%, $p < 0.05$). Coronary interventions were performed using 6F guiding catheters in the large majority of patients without any difference between the two groups (95.3 vs 95.6%, p = NS); 7F guiding catheters were used in 2.8% of elderly patients and in 1.4% of young patients whereas an 8F catheter was used in 1 elderly (0.3%) and 2 younger (0.2%) patients only. The types of guiding catheters used were similar in the two groups: Extra backup 4 catheter (59%), Amplatz left 2 (22.5%), Judkins left 3.5 (13%), Amplatz left 1 (2%), Multipurpose (2%), Judkins left 4.0 (0.5%), and others (1%) for the left main coronary artery; Multipurpose (32%), Amplatz left 2 (25.5%), Amplatz left 1 (12.5%), Amplatz right (12%), Judkins right 4.0 (8.5%), mammary (6%), and others (3.5%) for the right coronary artery. Venous bypass grafts were cannulated using Multipurpose and Judkins right catheters.

Bleeding complications and follow-up. No patient developed a major bleeding complication. Minor bleeding complications occurred only in 1 patient of the elderly group and in 2 of the younger group (0.3 vs 0.2%, p = NS). All patients had a palpable radial artery following the procedure and no patient had symptoms or physical signs of hand ischemia. The incidence of an asymptomatic loss of the radial pulse during the 30-day follow-up period did not differ between elderly and younger patients (1.5 vs 1.4%, p = NS).

The clinical course was slightly worse in elderly patients. A cardiac death occurred within 30 days in 3 elderly patients (0.9%; 2 of them had been submitted to primary PCI during acute myocardial infarction) and in 2 younger patients (0.2%, $p < 0.05$); both had been submitted to primary PCI. In both groups, the patients submitted to primary angioplasty were also similar with regard to the development of Q waves and to their peak CK and CK-MB levels.

Discussion

The present study demonstrates that in elderly patients transradial PCI may be performed safely and efficaciously by interventional cardiologists who are familiar with the transradial procedure.

In this prospective study, a single experienced operator achieved radial access in 98.8% of elderly patients. Despite the higher incidence of radial and brachiocephalic trunk anatomical tortuosity as detected at angiography in elderly patients, the procedural success rate for the transradial approach was similar in the two groups (elderly 98.8%, younger 99%). Only in 4 elderly patients was it necessary to convert to a femoral approach, because of failure to puncture the radial artery, an occluded ipsilateral subclavian artery or tortuosity of the brachiocephalic artery. The overall procedural success was also identical in the two groups. Moreover, the mean cannulation time and total procedural time did not differ between elderly and younger patients. In no case was the transradial procedure associated with inadequate support of the guiding catheter despite the fact that most guiding catheters are not designed for the right radial approach. Furthermore, for an experienced operator the learning curve phenomenon does not seem to significantly change the procedural results. In fact, the radial puncture failure rate for the first 20 patients was only 5% (1 patient) with a 95% transradial approach procedural success.

The safety of the transradial approach is mainly due to 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 such structures. Thrombotic or traumatic arterial occlusion does not endanger the viability of the hand if an adequate collateral blood supply from the ulnar artery is present. The superficial location of the radial artery allows easy hemostasis, and the use of a mechanical compression device minimizes utilization of personnel[22,23]. No major vascular complications occurred in either group, whereas minor bleeding complications occurred only in 1 patient of the elderly group and in 2 of the younger group without any significant difference.

Moreover, despite a less favorable baseline profile in the elderly, the incidence of major cardiac events in the short-term evolution was similar to that observed for the younger patients. Previous studies have shown worse short- and long-term outcomes in elderly patients who underwent coronary artery bypass surgery or balloon angioplasty compared with younger patients[2-8,24-29]. These studies showed that the elderly have worse baseline characteristics in terms of a higher incidence of previous myocardial infarction[24,25], heart failure, unstable angina, multivessel disease[2,5,24], and of a lower left ventricular ejection fraction[2,5]. Growing experience in interventional cardiology has led to a remarkable improvement in angioplasty results[2-8], in particular since the introduction of the stent[2]. Despite this undeniable advance, the initial outcome of stent implantation remains worse among elderly patients, with an in-hospital mortality rate ranging between 2.2 and 4.7%[30-32]. However, to the best of our knowledge, there are few date available in the literature regarding a transradial approach in these patients[19,20].

Chun et al.[19] retrospectively reviewed the clinical and angiographic data of 894 consecutive patients who underwent transradial coronary angiography. A comparison was made using the procedure-related results from two groups: patients aged < 70 years and those > 70 years (n = 256). In this study, just as in the present one, no significant difference in the rate of procedural success was found between patients > 70 years and patients < 70 years. Moreover, the procedure-related variables

including the procedure time, fluoroscopy time, radiographic contrast use, and the number of catheters used per case, were similar between the two groups. Finally, concordantly to our results, there were no severe complications such as death, vascular dissection, rupture, and major cerebrovascular accidents in either group.

In a recent study Louvard et al.[20] presented a randomized comparison of the transradial and transfemoral approaches for coronary angiography and PCI in octogenarians (147 patients). They found that in octogenarians the transradial approach was associated with a lower risk of access site complications compared with the transfemoral approach. Analysis of the procedure-related variables in the latter study, including the duration of angiography and of the PCI and the success rate were similar in the two groups and only the X-ray exposure time for angiography was longer in the transradial group.

Finally an important criticism of the radial approach is that it is not suitable for all patients. However, several reports attest to the use of the transradial approach in virtually all clinical situations[10-20,33,34] and in our study a PCI was successfully performed in almost all patients (98.4%). Of course, patient selection before the procedure, on the basis of the clinical status (Killip class < 4) and of the anatomic characteristics of the radial artery (normal Allen test), is very important.

Study limitations. One limitation of the present study is the lack of follow-up Doppler information on the patency of the radial artery. Although no patient in the present study had symptoms suggesting vascular ischemia of the hand, it is likely that asymptomatic radial artery occlusion occurred in a small percentage of patients. Previous series have shown that the incidence of asymptomatic radial occlusion ranges between 3 and 5%, but the benign nature of this problem has been emphasized[35,36]. Finally the large experience of the single operator (OV) with the transradial route makes do that our results do not necessarily apply for less experienced, low-volume centers and operators who may need an adequate learning curve.

In conclusion, provided it is performed by experienced operators, the radial approach may be safe and feasible for coronary angioplasty in elderly patients with outcomes which are similar to those observed in younger patients.

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