Compared with the transfemoral route, the transradial approach is gaining acceptance as a first-line approach for coronary angiography and percutaneous coronary intervention (PCI) because the superficial course of the radial artery allows easier vessel hemostasis and earlier patient ambulation. In turn, this anatomic advantage of the radial artery has been associated with less local hemorrhagic complications and possibly more favorable long-term outcome.1–3

The ulnar artery is rarely selected for coronary procedures in the context of a primary angiographic strategy, 4–11 despite the following potential advantages of the transulnar access: to circumvent a possible vascular trauma and to ensure an intact radial artery for subsequent coronary artery bypass grafting (CABG); to serve as an alternative access artery for repeated angiographies, thereby minimizing the transfemoral approach; to avoid both the femoral route and the risk of potential hand ischemia in the event of radial artery occlusion in those patients with abnormal Allen test; and to provide under certain circumstances ipsilateral cross-over access after failed radial cannulation.13,14

Background—The ulnar artery is rarely selected for coronary angiography or percutaneous coronary intervention despite the expanding use of the transradial approach. We aimed to establish noninferiority of a default transulnar relative to transradial approach in terms of feasibility and safety.

Methods and Results—This was a prospective, randomized, multicenter, parallel-group study involving 902 patients at 5 sites eligible to undergo diagnostic coronary angiography and percutaneous coronary intervention. Patients were randomized in a 1:1 ratio to either diagnostic coronary angiography or percutaneous coronary intervention regardless of the Allen test results. The primary end point was a composite of crossover to another arterial access, major adverse cardiovascular events, and major vascular events of the arm at 60 days. The study was prematurely terminated after the first interim analysis because of inferiority of the transulnar approach. Although the difference in the primary end point became inconclusive after adjustment for operator clustering (24.30%; 99.99% confidence interval [CI], −7.98% to 56.58%; P=0.03 at α=0.0001), need for cross-over in the transulnar group remained inferior to transradial access site with a difference of 26.34% (95% CI, 11.96%–40.69%; P=0.004).

Conclusions—As a result of higher cross-over rates, a first-line transulnar strategy was proven inferior to the transradial approach for coronary procedures. At present, the transulnar route should not be regarded as an acceptable alternative to the transradial access site.


Key Words: catheterization ◼ percutaneous coronary intervention ◼ transradial approach ◼ transulnar approach
WHAT IS KNOWN

• Use of the ulnar artery access site may lessen the rates of the transradial approach and ensure an intact radial artery for repeat coronary procedures and subsequent coronary artery bypass grafting.

• The ulnar artery as a workhorse access site seems to be a feasible alternative in small randomized trials.

• Nonrandomized studies are in accord with the common belief of the interventional community that transular over transradial access is a second-line option only.

WHAT THE STUDY ADDS

• The transulnar or transradial instead of coronary tranfemoral angiographies noninferiority trial involving 902 patients demonstrated that a first-line transular strategy was in fact inferior to the transradial approach for coronary procedures as a result of higher cross-over rates of the ulnar access site.

• No ulnar nerve damage was noticed.

• At present, the transulnar route should not be regarded as an acceptable alternative to the transradial access site.

Cannulation rates in nonrandomized studies or similar feasibility as that of the transradial approach in 2 randomized trials. The controversies surrounding these studies have provided uncertainty regarding the feasibility and the safety of the transulnar approach, including cross-over rates and the risk of ulnar nerve damage and hand ischemia.

Therefore, we aimed to compare the feasibility and safety of the transulnar with the transradial artery access as a default strategy for coronary angiography and PCI in consecutive patients with broad inclusion criteria.

Methods

This was a prospective, randomized, multicenter, noninferiority study of parallel design. Procedures were performed by 6 operators at 5 centers in Greece. All operators had an adequate transradial experience (≥150 transradial coronary procedures per year) but no specific training in the transulnar procedure. To determine potential learning effects, no specific minimum number of transulnar procedures was required for operators to participate in the study. Therefore, the transulnar experience of all trial interventionalists was as low as 20 to 50 to 50 coronary procedures per year. We enrolled consecutive patients aged >18 years who were scheduled for either coronary angiography with ad hoc PCI if necessary or elective PCI, and we enrolled those with ST-segment elevation myocardial infarction undergoing primary or rescue PCI. Patients planned for left/right catheterization or with history of CABG and bilateral use of either the internal mammary or radial artery; history of CABG and ipsilateral use of both the internal mammary artery and radial artery. Eligible patients were randomized in a 1:1 ratio to either the transradial or the transulnar approach on arrival to the catheterization laboratory using open randomization list, derived from computer-generated random numbers. Allocation was not stratified by operator or by any other variable. The clinical Allen and the reverse Allen tests at the initially attempted forearm was performed in all patients with a cutoff time of ≤10 seconds for normal postischemic palmar perfusion to estimate the adequacy of the ulnar-dependent and transradial-dependent collateral circulation, respectively. An abnormal result was not an exclusion criterion. We selected the right forearm arteries in most patients. Operators were advised to attempt obtaining an arterial access even if the pulse was near absent on palpation. The allowed arterial puncture time was ≤15 minutes for most interventions and ≤5 minutes for primary PCI.

Pulse quality was graded on a scale from 0 to 10 (ie, absent pulsation to excellent pulse). Arterial cannulation was obtained in most cases with a nonhydrophilic 5- or 6-French (F), 11-cm-long introducer sheath (Cordis Corporation, Miami Lakes, Florida). In ≥10% of the patients, other sheathes were used. Thereafter, 200-μg nitroglycerin and unfractionated heparin were injected intra-arterially. The antiocoagulation dose of either 2500 or 5000 U heparin was administered in all coronary angiography patients and was increased to 70 to 100 U/kg body weight if PCI had to be performed. Patients with development of arterial spasm received additional nitroglycerin, verapamil, and xylocaine intra-arterially, and, if necessary, intravenous mild sedation. We used conventional 5-F Judkins or Tiger catheters for diagnostic purposes and 6- or 7-F Extra back-up, Judkin, or Amplatz guide catheters for PCI. Ad hoc PCI was performed with use of guiding catheters after upgrading the radial sheaths with larger conventional sheaths. Cross-over was allowed at the discretion of the operators to either the ipsilateral other forearm artery, whether the initial artery was considered undamaged by the failed attempt, or the contralateral forearm before ultimately opting for the femoral artery. A forearm artery was thought to be undamaged after a failed attempt when the artery was not punctured or, if it was palpable, no sheath was inserted and neither proximal spasm nor prolonged local pain was evident after the preceded puncture. Under these premises, a failed wire insertion was not considered a contraindication for ipsilateral cross-over. The numbers of attempted punctiones were calculated by adding the total number of visible skin entry sites of the puncture needle until successful arterial access. Possible trauma of the ulnar nerve during ulnar interventions was recognized as a lightening pain and paresthesias extending across the ulnar side of the wrist. The amount of contrast medium as well as procedural and fluoroscopy times were collected in all patients. The total duration of each intervention included the time elapsed during sheath insertion, coronary angiography, and PCI (definitions of procedural times are provided in the online-only Data Supplement and Supplementary Figure 1). We assessed vagal reactions, spasm, and pain using a subjective 3-point scale (low, moderate, and severe). Postprocedural hemostasis was applied to all patients by ensuring minimal pressure hemostasis (ie, just before entry site bleeding had occurred) with appropriate devices (Radistop; Radi Medical Systems AB, Sweden; D-Start Radial; Vascular Solutions; or TR Band; Terumo International). Patients were discharged within 4 to 6 hours after coronary angiography or one of the next days after PCI.

Follow-up

We ascertained incident death, myocardial infarction, stroke, and urgent target vessel revascularization (major adverse cardiac events [MACEs]) both in-hospital and within the first 60 days after the procedure. Major vascular events of the arm included one or more of the following: (1) arterial occlusion or severe narrowing (including asymptomatic occlusion); (2) arterial perforation/dissection; (3) pseudoaneurysm formation; (4) arterio-venous fistula; (5) large hematomas of the forearm extending beyond the forearm; (6) compartment syndrome; (7) major bleeding; and (8) any arterial complication necessitating intervention or prolonged hospitalization of the patient (detailed definitions are provided in the online-only Data Supplement). Major bleeding was defined as ≥2 g/dL decrease in hemoglobin or ≥15% absolute decrease in hematocrit or any life-threatening bleeding (confirmed by MRI or computer tomography). Both forearm arteries in each patient were evaluated either in-hospital or during a subsequent visit by 1 physician who was blinded to the eventually cannulated artery and included both clinical examination and Doppler echocardiography. All patients were asked about any
symptoms suspicious for hand ischemia and to perform a hand-grip exercise test. Appearance of premature palmar discolorization in the presence of an occluded forearm artery was interpreted as an ischemic exertional response. The integrity of the ulnar nerve was assessed by examining motor and sensory neural properties for possible persistent injury. Forearm arteries were considered occluded whether they exhibited no or retrograde collateral flow signal, confirmed by Doppler flow measurements.

Primary and Secondary End Points

The primary end point of the study was a composite of MACEs, rates of cross-over to another artery, and major vascular events (including asymptomatic arterial occlusion) of the arm at 60 days. The secondary end points included components of the primary end point, as well as procedural and fluoroscopy time, the amount of contrast medium used, and measures of patient discomfort (vagal reactions, pain, and spasm). The primary end point was prespecified to be analyzed in the intention-to-treat (ITT) population (including patients according to initial access route assignment, regardless of whether they actually adhered to it). All end points were also analyzed in the per-protocol (PP) population by including only patients who adhered to the initial assigned access route.

The primary end point was analyzed by a 2-sided, 2-group Farrington–Manning exact test with $\alpha = 0.0001$ (corresponding 2-sided 99.99% CIs are presented). For the cross-over rate (ITT analysis), a 2-sided, 2-group Farrington–Manning exact test was used with $\alpha = 0.05$ (corresponding 2-sided 95% CIs are presented). All the other end points (ITT and PP analyses) were analyzed by a 1-sided, 2-group Farrington–Manning exact test with $\alpha = 0.05$ (corresponding 1-sided 95% CIs are presented). The margin ($\Delta$) of 4.87% was used for all tests.

In a post hoc analysis, CIs for cross-over rate were adjusted for design effect ($D_{\text{eff}} = 1 + (n-1)(\text{intracluster correlation coefficient})$) to account for clustering on operator. Intracluster correlation coefficient for cross-over was calculated by 1-way ANOVA. Because cluster size varied, we used the harmonic mean of the number of participants per cluster ($n$). To obtain the standard error when clustering was considered, we multiplied the standard error by the square root of $D_{\text{eff}}$.

Nonprespecified exploratory stratified analyses were performed and estimates of the odds ratios (95% CIs) were obtained using the Mantel–Haenszel fixed effects model. The subgroups examined were age (<75 and ≥75 years), sex, PCI, Allen test at the attempted upper arm (normal vs abnormal), body mass index (<25, ≥25 to <35, and ≥35 kg/m²), reason of catheterization (ST-segment–elevation myocardial infarction, non-ST-segment–elevation myocardial infarction, acute coronary syndrome, and nonacute coronary syndrome), sheath size (5-F vs 6-F), center’s median operator’s radial PCI volume (<100 vs >100), and each operator’s annual radial PCI volume (<60, ≥60 to <100, and ≥100). The significance level for interaction was set at 0.05. No corrections to $P$ values were made for multiple comparisons.

To assess potential risk factors for the composite primary outcome, we used log-binomial regression models because the odds ratio produced by logistic regression may overestimate the relative risk when the outcome is not rare.17 We first assessed the unadjusted relative risks of the composite primary outcome for various patient characteristics and then a final multivariate model was fitted, including all the factors found to be related to the occurrence of the primary outcome at the level of $P \leq 0.1$ in the univariate analyses.

Statistical analyses were performed using Statistical Package for the Social Sciences for Windows (version 16.0; SPSS, Chicago, IL), MedCalc for Windows (version 11.2.1.0; MedCalc Software, Mariakerke, Belgium), Number Cruncher Statistical System 8 (NCSS, Kaysville, Utah), and MetaAnalyst Beta version 3.1 (Tufts University, Boston, MA).18

The study was approved by the ethical committee in each center. All patients gave informed consent for study participation. Dr Hahalis had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. The authors have nothing to disclose.

Results

Between July 2010 and March 2012, 976 patients were screened for participation, 51 (5.2%) met ≥1 exclusion criterion and 925 were randomized. Because this figure represented 40.5% of the anticipated total number of patients to be enrolled, we conducted the first interim analysis.

Among the 925 patients, 23 were lost to follow-up, leaving 902 patients, with 440 assigned to radial access and 462 assigned to ulnar access with evaluable data (Figure 1). The demographic and baseline characteristics were balanced between the 2 patient groups (Table 1). The Allen or the reverse Allen test results were abnormal in 67 patients (7.4%), whereas the reason for coronary angiography was acute coronary syndrome in more than half of them. Angiographic and procedural data were similar between the 2 groups and are...
Approximately one-third of the patients underwent PCI. Patients in the ulnar arm compared with those in the radial arm required more punctures, more time to obtain arterial access, more total procedural and fluoroscopy time, and received a higher amount of contrast medium. However, both the coronary angiography time and the PCI time did not differ significantly between the 2 groups.

In the ITT analysis, the composite primary end point at first interim analysis was significantly higher in the ulnar arm (42.2%) compared with the radial arm (18.0%), with a difference of 24.30% (99.99% CIs, 12.26%–35.44%) between arms \( (P < 0.0001) \). Therefore, the study was terminated early because of inferiority of the transulnar over the transradial approach. Cross-over was higher in the ulnar compared with the radial group, with a difference of 26.34% (95% CIs, 21.53%–31.27%; \( P < 0.0001 \)). When adjusting for clustering on operator, cross-over was higher in the ulnar compared with the radial group, with a difference of 26.34% (95% CIs, 11.96%–40.7%; \( P = 0.004 \); intraclass correlation coefficient, 0.16; \( D_{\text{null}} \), 8.48). However, the composite primary end point became inconclusive after adjustment for clustering effect, yielding a difference between arms of 24.30% (99.99% CIs, −7.98% to 56.58%; \( P = 0.03 \) at an \( \alpha = 0.0001 \)) (Figure 2). Using the noninferiority margin of 4.87%, use of transulnar approach was noninferior to transradial approach in MACEs, major in-hospital access-site complications, large hematomas, vagal reactions, and arterial occlusions (Figure 2).

Cross-over rates according to initial allocation route are presented in Table 3. Of note, there was a low cross-over rate of the transradial route among the study operators. The ultimate frequency of transfemoral use was 3.5%.

**Multivariate Analysis for the Predictors of the Primary Outcome**

We found an independent association of both male sex and randomization to radial route with a lower risk, as well as of need for \( \geq 3 \) cannulation punctures with an increased risk for the primary outcome (Figure 3; Supplementary Table I).

**Exploratory Analyses**

In a separate analysis of the primary and secondary outcome measures according to Allen test (Supplementary Table II), no significant differences were observed \( (P > 0.19) \) for each. No significant interactions were detected between the studied subgroups and the effect of access site on the composite primary outcome \( (P > 0.40) \) for each. With respect to incident arterial occlusion at Doppler follow-up, a statistically significant trend in favor of the radial over ulnar artery approach was evident for patients with moderate or severe arterial spasm, for men, and for those with need for cross-over \( (P = 0.10–0.12; \text{Figure 4}) \). This indicates...
a trend for greater relative risk reduction of the transradial access for subsequent artery occlusion among these subgroup patients. Regarding the need for cross-over, we found a significant benefit for the radial in comparison with the ulnar artery approach among patients who either did not
have development of moderate or severe spasm (interaction $P=0.0005$) or required $\geq 3$ attempts for arterial cannulation (interaction $P=0.02$), as shown in Figure 5. This finding indicates a significant risk reduction for cross-over favoring the radial artery in patients who either did not develop spasm or required multiple artery access attempts. With respect to major in-hospital access-site complications, we detected no significant interactions between the studied subgroups ($P>0.28$ for each).

**Discussion**

In this trial we enrolled all-comers for forearm coronary procedures and compared a strategy of first-line transulnar with that of primary transradial access. The main findings of this study are summarized as follows. In the ITT analysis for the composite primary end point, the transulnar route was significantly inferior compared with the transradial access site before adjustment for operator clustering. After adjustment, the comparison results became inconclusive for the primary end point and showed significant inferiority of the ulnar compared with the radial artery on the cross-over rates. However, the transulnar was noninferior to the transradial approach with respect to MACEs, large hematomas, vagal reactions, and forearm arterial occlusions. In the PP analysis, among patients who remained cross-over-free, the ulnar artery approach was found to be noninferior with the radial artery approach on MACEs, major access site complications in hospital, and components of safety outcomes. No significant interactions were detected between the studied subgroups and the effect of access site on the composite primary outcome. Male sex and radial approach were independent protective factors for the primary outcome.

The rate of forearm arteries occlusion was relatively high but not different between the 2 arteries. Although not the primary objective of the current study, none of the 87 patients with an occluded artery (9.2% of whom had abnormal functional test results) experienced hand ischemia. In addition, ipsilateral forearm artery cross-over in...
several patients safely minimized the use of the femoral artery as previously shown.20

The Ulnar Artery
Cannulation of the ulnar artery seemed time-consuming, with longer procedural and fluoroscopy times, and with more attempts and contrast medium use in comparison with the transradial approach group. Therefore, we do not recommend a routine ulnar primary approach for coronary interventions because it is cumbersome for the patient and for the operator.

We found that cross-over from ulnar to the other access site was the major component of the total cross-over rate, critically contributing to the observed difference in the composite primary outcome between the radial and the ulnar approach. The high cross-over incidence of the transulnar approach corresponds to the prevailing belief of a difficult-to-cannulate artery and to the limited adoption of transulnar coronary procedures by the interventional community. The ulnar artery is, on average, smaller than or as large as the radial artery at the wrist level9,10,21 but is located deeper and has a weaker pulse quality, thereby making a successful puncture much more laborious. Even minimal additional depth may substantially affect the chance of ulnar puncture in the 3-dimensional space, with supervening tissue edema, hematoma, and vessel spasm from multiple attempts further contributing to access failure. In this study, incident spasm seemed to make a crossover-free procedure equally difficult between the 2 forearm arteries. Expectedly, absence of spasm and requirement for multiple punctures rendered the transradial over the transulnar route more accessible (Figure 5). Once successfully cannulated, however, the ulnar artery almost invariably allowed ease of sheath insertion and completion of the angiographic procedure. It is reassuring that in rigorous clinical follow-up visits, no major nerve damage was documented. The theoretical concern for permanent nerve trauma arises from the ulnar artery-to-nerve anatomic proximity and the difficult arterial access in many patients. This study substantially extended the limited information on this topic4–11 and suggests that ulnar nerve palsy is unlikely after transulnar cannulation.5

Previous Studies
In nonrandomized studies of a small number of patients and a nonsystematic event capture, the success rate for coronary procedures of transulnar was inferior to that of the transradial approach (ie, 74%–90%).5–8 In contrast, 2 randomized trials did not demonstrate any cannulation differences between the 2 forearm arteries. In the more recent investigation of 240 patients,9,10 98.3% and 100% of coronary angiographies or PCIs were successful among the patients in the ulnar and radial artery group, respectively. However, patients with artery diameter <1.5 mm were excluded from that study and study analysis was confined to patients with successful artery access only.9,10 Aptecar et al9 randomized 441 patients and excluded 2.3% of them after randomization because of ischemic Allen or reversed Allen tests. Many attempts (1.6 vs 1.4; P=0.02), but not the procedural time (14.0 vs 12.7 minutes; P=0.06), slightly favored the transradial route. The authors demonstrated a 7% cross-over rate in the ulnar group of patients (P=0.84 vs the radial group).9 On a calculated ITT basis, the frequency of crossovers in this study would amount to only 10%.9 These results are at variance with the current study. Both studies included patients with similar baseline characteristics. The long radial experience, the stable high radial success rates over time, and the immediate plateau of the ulnar learning curve emphasize the inability of our study operators to ensure further improvement of their transulnar skills. Aptecar et al9 state enrollment of their patients before the quality of the ulnar pulse was known. Notwithstanding that, information is elusive regarding the percentage of excluded patients after screening for possible study participation.9 We enrolled ≈95% of screened patients on the basis of broad criteria and regardless of the ulnar pulse quality. In fact, we might have encountered a lower frequency of transulnar crossovers if those patients with absent ulnar pulse had been excluded from the current study.

Allen Test, Vascular Occlusions, and Ipsilateral Cross-over
The current study allowed the inclusion of patients with abnormal Allen test results because its value in predicting hand ischemia after forearm artery occlusion remains debatable.11,22,23 Despite long-standing radial hemodynamic monitoring, surgical harvesting for CABG, and coronary procedures, there has been no link of Allen test results with the rare instances of critical hand ischemia.11,22 This was evident in our study as well. The Allen test likely delivers approximate information on the
adequacy of the dense palmar vascular network, suffers from interobserver variability, and does not account for microembolic digital obstructions. Therefore, the relevance of this test outside the context of a clinical trial is being increasingly questioned. In post hoc analysis, any abnormal functional test result was marginally associated with cross-over to the radial artery. This more likely indicates enhanced difficulties in accessing the ulnar artery, which seems smaller in these patients as compared with those exhibiting normal Allen test results. This study is the largest one with respect to ultrasonographic vascular follow-up after forearm coronary procedures. The rate of arterial occlusion in this study is toward the upper end of that reported in the literature, despite application of minimal pressure hemostasis. Furthermore, we demonstrated a 2-fold higher occlusion rate of the ulnar artery as compared with those previously reported. Recently, a much higher incidence of radial artery occlusions than in our patients has been reported. Whether higher anticoagulation levels, less procedural stress, or other more sophisticated strategies reduce incident forearm artery occlusions have not been conclusively demonstrated as yet and more research is needed on this topic. In the present trial, the strong statistical trend in the interaction analysis suggests greater risk reduction for artery occlusion in patients with cannulation difficulties (spasm or cross-over) if the radial instead of the ulnar artery is initially selected (Figure 4). Notably, we and other investigators recently have shown that forearm artery spasm tends to develop more frequently at lower levels of endothelium-derived vasorelaxation and can be prevented by appropriate premedication.
Thus, less functional vigilance of the endothelium probably renders the artery vulnerable to superimposed stress, such as multiple attempts to access the artery, thereby promoting spasm and subsequent vascular occlusion.

The ipsilateral approach after an unsuccessful attempt of the other forearm artery was safe under the aforementioned premises that intended to limit a possible arterial trauma. We observed 19 asymptomatic arterial occlusions among the 134 initially assigned arteries with failed attempts and subsequent ipsilateral cross-over. Sporadic reports refer to uneventful ulnar cannulation in the presence of radial occlusion and hand ischemia after ulnar artery use and antecedent unsuccessful radial artery catheterization.29,30

Study Limitations
The study was not sufficiently powered for PP analysis or to detect subgroup access site effect interactions. Initial sample size calculation and interim analysis did not account for clustering or operator. Operators had no specific training in the transulnar procedure and this could have potentially affected the observed cross-over rate. In addition, post hoc analyses provide hypothesis-generating nonconclusive data. A less favorable outcome for the ulnar artery might have been encountered if patients with absent ulnar pulse had been excluded from participation in this study. A lower frequency of forearm artery occlusions would have been likely if hydrophilic sheaths had been used, if truly patent (instead of minimal pressure) hemostasis had been performed,19 and if our study patients had not been subjected to the superimposed stress of a default ulnar artery selection with its associated high cross-over rates. Our findings have suggested that a more liberal use of forearm arteries for coronary procedures is possible. However, this practice aiming at minimizing femoral artery cross-over might nevertheless, when cross-over has not been required, the transulnar procedure and this could have potentially affected the prevalence ratio.

Conclusions
A default strategy of transulnar approach for coronary angiography and PCI was found inferior to transradial approach in terms of the need for cross-over. The radial artery therefore should remain the first option for coronary interventions. Nevertheless, when cross-over has not been required, the transulnar route seems noninferior to transradial in terms of major access site complications and large hematomas, indicating that in selected cases the transulnar route may serve as a second-line arterial approach, especially when surgical harvesting of the radial artery for CABG is anticipated. Strategies are needed to reduce the incidence of vascular occlusions20 and to properly select the forearm arteries on the basis of robustly validated physiological tests to minimize the transfemoral use.11,20

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Transulnar Compared With Transradial Artery Approach as a Default Strategy for Coronary Procedures: A Randomized Trial The Transulnar or Transradial Instead of Coronary Transfemoral Angiographies Study (The AURA of ARTEMIS Study)