Journal of the American College of Cardiology
© 2014 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 63, No. 18, 2014
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2013.12.043

CLINICAL RESEARCH | Interventional Cardiology

Transradial Coronary Catheterization and Intervention Across the Whole Spectrum of Allen Test Results

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Objectives The aim of this study was to investigate the safety and feasibility of transradial coronary catheterization across the whole spectrum of Allen test (AT) results.

Background Whether the AT can predict ischemic complications after transradial access (TRA) is controversial. No prospective assessment exists on the safety and feasibility of TRA across the whole spectrum of AT results.

Methods From October 2007 to June 2009, a total of 942 patients undergoing TRA were screened, and 203 were recruited, of whom 83, 60, and 60 had normal, intermediate, and abnormal AT results, respectively. Patients underwent serial assessments of thumb capillary lactate (the primary endpoint), thumb plethysmography, and ulnar frame count to investigate the patency of the ulnopalmar arches, as well as handgrip strength tests to examine the isometric strength of the hand and forearm muscles and discomfort ratings.

Results Lactate did not differ among the 3 study groups after the procedure (1.85 $\pm$ 0.93 mmol/l in patients with normal AT results, 1.85 $\pm$ 0.66 mmol/l in those with intermediate results, and 1.97 $\pm$ 0.71 mmol/l in those with abnormal results; $p = 0.59$) or at other time points during the study. Plethysmographic readings showed improvements of ulnopalmar collateralization in patients with non-normal AT results, whereas the ulnar frame count was decreased, suggesting enhanced ulnar flow, in patients with abnormal AT results after TRA. Handgrip strength test results and discomfort ratings did not differ across AT groups. No hand ischemic complications occurred.

Conclusions This study provides proof of concept for a paradigm shift in cardiovascular intervention, suggesting the safety and feasibility of TRA across the whole spectrum of AT results. Given the multiple implications of our findings, a broader clinical validation is needed. (Predictive Value of Allen's Test Result in Elective Patients Undergoing Coronary Catheterization Through Radial Approach [RADAR]; NCT00597324) (J Am Coll Cardiol 2014;63:1833–41)

Compared with the femoral artery, the radial artery (RA) is more superficial and has a smaller caliber, which makes access-site homeostasis highly predictable (1,2). In addition, the forearm has a dual blood supply, the ulnar artery and the RA, anastomosing across the hand in the superficial and deep palmar arches, which limits the potential for limb-threatening ischemia (3). Yet cannulation of the RA carries a risk for vessel occlusion, ranging from 0.8% to 30.0% (4). It is therefore recommended that the integrity of the palmar arches of the hand be confirmed before transradial access (TRA) is established for arterial pressure monitoring (5) or to perform coronary catheterization (6,7) or vessel harvesting for coronary artery bypass grafting (8).

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The modified Allen test (AT), despite its known limitations (9,10), has been used to evaluate the patency of the ulnopalmar arches, with an arbitrary threshold of 6 to 10 seconds to achieve full blushing of the hand after the release of RA compression (11). This has resulted in the exclusion of as many as 27% of patients who have been referred

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Manuscript received September 8, 2013; revised manuscript received December 5, 2013, accepted December 17, 2013.

Abbreviations and Acronyms

AT = Allen test

IQR = interquartile range

RA = radial artery

TRA = transradial access

for TRA (12). Whether the AT can predict ischemic complications after TRA is controversial, and several centers, including ours, no longer perform the AT before TRA (13–17). However, 30-min RA occlusion, achieved in an experimental setting with the use of an external clamping device, led to increased thumb capillary lactate, suggestive of hand ischemia, in patients with abnormal AT results compared with those with normal AT results (18). This finding cautioned the interventional community about the possible risks of not properly selecting patients for TRA.

We sought to investigate in a clinical (i.e., not experimental) setting the safety and feasibility of transradial catheterization across the full spectrum of AT results by serially assessing thumb capillary lactate as well as other markers of hand ischemia and ulnar flow.

Methods

Study design and population. The RADAR (Should Intervention Through Radial Approach be Denied to Patients With Negative Allen's Test Results) study is a single-center prospective study designed to evaluate the safety and feasibility of transradial catheterization and intervention in patients with abnormal or intermediate AT results compared with those with normal AT results.

Patients undergoing elective or urgent coronary angiography were stratified on the basis of the results of the AT into 3 groups: normal, intermediate, and abnormal. Patients were enrolled consecutively until the pre-specified number of at least 60 patients was reached in each AT result group. Exclusion criteria were hemodynamic instability, including ongoing chest pain or recent ST-segment elevation myocardial infarction; planned intra-aortic balloon pump insertion; previous trauma or surgical intervention in the instrumented arm; and absence of a valid radial pulse in at least one arm. The institutional ethics committee approved this protocol, and all participants gave written informed consent.

Modified AT. The modified AT was performed as follows. After vigorous compression of both the radial and ulnar arteries, the patient was asked to forcefully clench one hand several times to expel blood from the hand. The hand was then opened, avoiding wrist and finger hyperextension, before release of ulnar artery compression. The amount of time to achieve maximal palmar blush was measured after compression release of the ulnar artery with continuing occlusive pressure of the RA. AT results were defined as normal, intermediate, or abnormal if maximal palmar blush after compression released was achieved within 5 s, between 6 and 10 s, or after 10 s, respectively.

Plethysmography and pulse oximetry. Plethysmography was recorded with a pulse oximeter with the clamp sensor applied to the thumb before and immediately after RA compression, as previously described (Barbeau test) (11), and results were divided into 4 types: pattern A, no damping of pulse tracing immediately after RA compression; pattern B, damping of pulse tracing; pattern C, loss of pulse tracing followed by recovery of pulse tracing within 2 min; and pattern D, loss of pulse tracing without recovery within 2 min. A single investigator (C.P.) who was blinded to AT results and thumb capillary lactate measurements performed all plethysmographic assessments. A reverse Barbeau test (i.e., after ulnar artery compression) was systematically implemented after the procedure to screen for the patency of the previously instrumented RA. In cases of pattern D readings, RA occlusion was confirmed on duplex echocardiographic examination.

Thumb capillary lactate assessment. A single drop of blood from the distal thumb was collected to assess thumb capillary lactate concentration (Accutrend Lactate analyzer; Boehringer Mannheim, Mannheim, Germany), as previously described (18), before catheterization, immediately before radial sheath removal at the end of the procedure, immediately before removal of the RA compressing system (TR Band, Terumo Corporation, Tokyo, Japan), the day after the procedure, at 30 days, and at 1 year.

Ulnar frame count. To objectively evaluate an index of ulnar flow, the number of cine frames required for contrast to first reach the standardized distal ulnar landmark (the ulnar frame count) was measured at radial sheath insertion (baseline measurement before cardiac catheterization) and removal (final measurement after cardiac catheterization) with a frame counter (Dicom Viewer 2.0, Rubo Medical Imaging BV, Aerdenhout, the Netherlands) after setting image acquisition at 30 frames/s.

The first frame used for ulnar frame counting is the first frame in which dye fully enters the arterial sheath after automated 6-ml contrast injection through the side port using the Avanta Fluid Management Injection System (Medrad, Inc., Pittsburgh, Pennsylvania) (Fig. 1). In analogy to the previously developed Thrombolysis In Myocardial Infarction frame count (19), this occurs when 3 criteria are met: 1) a column of nearly full or fully concentrated dye must extend across the entire width of the origin of the arterial sheath; 2) dye must touch both borders of the head of the sheath; and 3) there must be anterograde motion to the dye.

The last frame is defined as the frame when dye first reaches the distal ulnar landmark, defined as the tract of the ulnar artery, which lies on the virtual orthogonal axis connecting it to the entry site of the side port into the radial arterial sheath (Fig. 1). To standardize the recognition of the ulnar landmark, the side port of the radial sheath was strained before filming internally to the wrist to orthogonally cross the ulnar artery (Fig. 1). Full opacification of the ulnar artery was not required. Online Videos 1 and 2 showing how the ulnar frame count was generated, are provided in the online version of this article.

Handgrip strength test. Patients were asked to hold the dynamometer in the hand, which was selected for

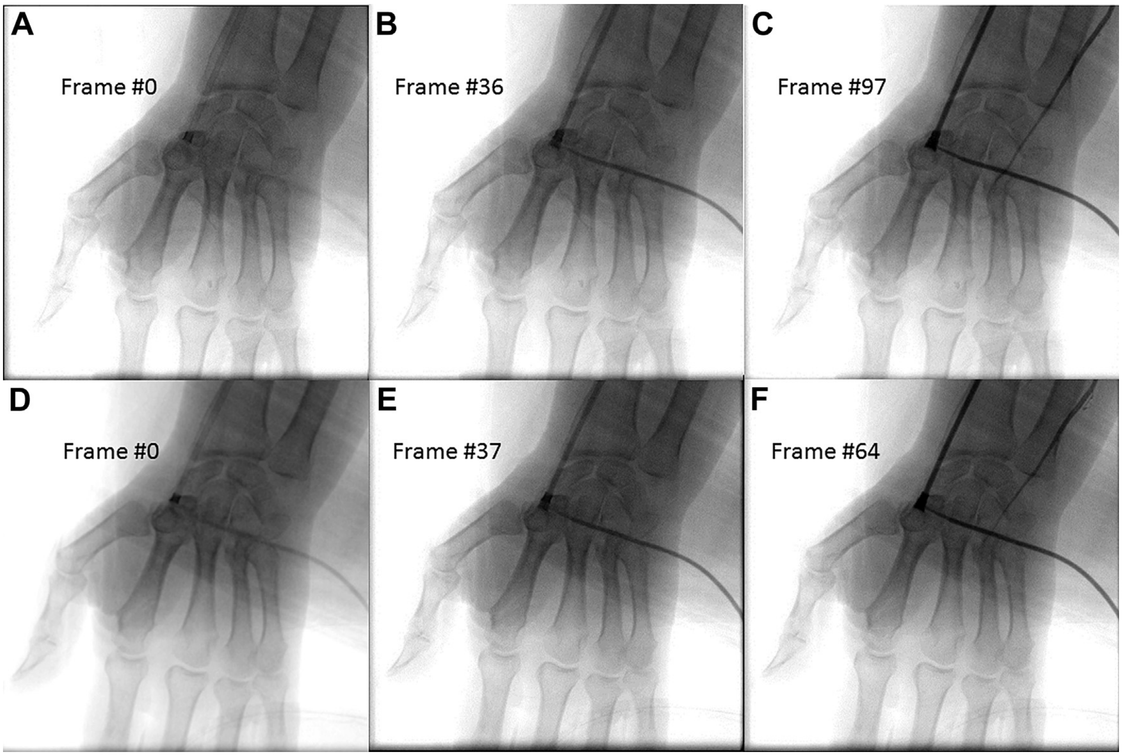

Figure 1 **Ulnar Frame Count**

An example of how the ulnar frame count is quantified before **(A to C)** and after **(D to F)** catheterization. **(A,D)** First still frame obtained immediately after radial sheath insertion before **(A)** or immediately after **(D)** catheterization. The side port of the radial sheath is strained internally to the wrist before filming to orthogonally cross the passage of the ulnar artery. **(B,E)** The first frame used for ulnar frame counting is the one in which the dye fully enters the arterial sheath via the side port, corresponding to frame #36 before **(B)** or frame #37 after **(E)** catheterization. **(C,F)** The last counted frame is defined as the frame when dye first reaches the distal ulnar landmark, defined as the tract of the ulnar artery, which lies on the virtual orthogonal axis connecting it to the entry site of the side port, corresponding to frame #97 before **(C)** or to frame #64 after **(F)** catheterization. The ulnar frame count was thus quantified as 61 before and 27 after catheterization. See accompanying Online Videos 1 and 2.

catheterization and AT screening, with the arm at right angles and the elbow by the side of the body. Patients were asked to squeeze the dynamometer with maximal isometric effort, and the best result from 3 trials with at least 15 s of recovery between each effort was recorded at each time point. Results are expressed in kilograms, and mean range values are 48 to 52 kg for men and 26 to 30 kg for women.

Discomfort rating. Each patient quantified the pain or discomfort as well as the amount of dysesthesia or soreness of the instrumented arm and/or hand serially after intervention. A visual analogue scale with 100-mm bars was used to standardize symptom collection for both pain or discomfort and dysesthesia. A mark at 0 mm indicated no discomfort, whereas a mark at 100 mm indicated the most severe discomfort. The results of the 2 questionnaires were then summed and divided by 10, resulting in a uniform scale ranging from 0 to 20.

Follow-up. Patients returned for study visits at 30 days and 1 year, at which the AT, thumb capillary lactate, plethysmography, and handgrip strength test were performed.

Statistical analysis. The primary objective of this study was to show that the thumb capillary lactate concentration after the procedure, assessed immediately before radial sheath removal, was influenced by the AT result, as previously reported (18). Using a conservative assumption of previous findings (18), we expected post-procedural thumb capillary lactate concentration to be in the range of 1.5, 1.65, and 1.8 mmol/l in patients with normal, intermediate, and abnormal AT results, respectively. This corresponds to an increase of respectively 10% or 20% thumb capillary lactate concentration in patients with intermediate or abnormal results compared with normal AT results. Sixty patients per group were required to reach a study power >95%, with a sigma of 0.4 mmol/l and a type I error of 5%, which was confirmed in a Monte Carlo simulation using the simpower Stata library (StataCorp LP, College Station, Texas).

Categorical variables are expressed as frequencies, whereas continuous variables are expressed as median (interquartile range [IQR]) or mean ± SD when the normality assumptions were met. Baseline or procedural continuous variables were compared between groups using the Wilcoxon rank sum test, whereas for binary variables, the chi-square or Fisher exact test was used as appropriate.

One-way analysis of variance was used to compare the primary endpoint across groups, stratified by AT result, after normal distribution of the variable was demonstrated using the Kolmogorov-Smirnov goodness-of-fit test. The general linear mixed model for repeated measures was used to assess the changes in the primary and secondary study endpoints over time and their possible interaction with AT results by setting the time of the assessment as the within-subjects covariate and AT result group as the between-subjects factor. Post-hoc comparisons were performed using the Tukey honestly significantly different test. To assess the change in plethysmographic readings over time in each AT stratum, the Friedman test was applied. Two-sided p values <0.05 were considered significant. All analyses were performed using Stata version 11.1 or SPSS version 20 (IBM Statistics, Armonk, New York).

Results

From October 2007 to June 2009, a total of 942 patients were screened, and 203 were finally recruited into the study, of whom 83, 60, and 60 had normal, intermediate, and abnormal AT results, respectively (Fig. 2).

Patients with abnormal AT had a higher prevalence of insulin-dependent diabetes and less frequently underwent previous homolateral transradial catheterization compared with patients with normal or intermediate test results (Table 1). The pattern of plethysmographic readings differed across the 3 AT result groups ($p < 0.0001$) (Fig. 3). Pattern A decreased from 83% in the normal to 2% in the abnormal AT result groups, whereas pattern D was not observed in the normal or intermediate groups but was recorded in as many as 40% of patients in the abnormal AT result category.

No ischemic vascular or bleeding access-site complications occurred during or after the transradial procedures, and no patient underwent vascular surgery.

Kinetics of capillary thumb lactate. Capillary thumb lactate is shown in Figure 4. The primary endpoint (post-procedural lactate) did not differ among the 3 study groups immediately after catheterization (1.85 ± 0.93 mmol/l in the normal group, 1.85 ± 0.66 mmol/l in the intermediate group, and 1.97 ± 0.71 mmol/l in the abnormal group; $p = 0.59$ on 1-way analysis of variance). Similarly, capillary thumb lactate did not differ across the 3 study groups at baseline or at other time points. Mean capillary thumb lactate increased by almost 20%, irrespective of AT results, immediately before transradial occlusion removal (2.21 ± 0.93 mmol/l in the normal group, 2.16 ± 1.21 mmol/l in the intermediate group, and 2.10 ± 0.98 mmol/l in the abnormal group; $p < 0.002$ vs. baseline on post-hoc analysis). Similar results were obtained in a sensitivity analysis when patients were stratified on the basis of baseline plethysmographic readings.

Discomfort rating and handgrip strength test. Self-reported discomfort rating consistently peaked at the time of radial occlusion, whereas AT results failed to identify patients with a greater likelihood of developing symptoms during or after transradial catheterization (Fig. 4). Similarly, maximal isometric strength on the handgrip strength test was not affected by AT results, and it did not change over time.

Ulnar frame count. The ulnar frame count was significantly affected by both AT results (median 34 [IQR: 19 to 64], 55 [IQR: 43 to 88], and 70 [IQR: 51 to 125] in the normal, intermediate, and abnormal AT result groups, respectively, $p < 0.001$), as well as the timing of assessment with respect to the transradial procedure (median 56 [IQR: 32 to 85] before vs. 28 [IQR: 14 to 60] after catheterization, $p < 0.001$), with no interaction between the timing of assessment (i.e., before or after catheterization) and the AT result ($p = 0.30$) (Fig. 4). Patients with normal AT results had significantly lower ulnar frame counts both before and after transradial catheterization compared with those with abnormal test results ($p < 0.01$ on post-hoc analysis). Yet after catheterization, the ulnar frame count decreased relatively more in patients with intermediate (median 31 [IQR: 27 to 35]) or abnormal (median 28 [IQR: 20 to 32]) AT results compared with those with normal AT results (median 11 [IQR: 8 to 15]).

RA patency and plethysmographic readings at follow-up. At day 1 after catheterization, the absence of the previously instrumented radial pulse was observed in 5 completely asymptomatic patients, 1 of which occurred in a patient in the abnormal AT result group. The presence of collateral flow through a patent ulnar circulation was confirmed on Doppler echocardiographic examination in all 5 patients. At 30 days, 1 patient in the intermediate AT result group, who had pattern C on plethysmography before TRA, showed spontaneous RA recanalization. Pattern A on plethysmography was recorded in this individual at both 30-day and 1-year follow-up. Spontaneous RA recanalization also occurred at 30 days in a patient in the normal AT result group. The RA remained occluded in the other 3 patients, who remained asymptomatic with no discomfort and unchanged thumb capillary lactate and handgrip strength at follow-up. The plethysmography readings remained consistent over time in patients with normal Allen's test at baseline ($p = 0.56$). In contrast, plethysmographic readings showed an increase of patterns A and B over time at the expenses of pattern C in the intermediate AT result group and patterns C and D in the abnormal AT result group ($p < 0.001$ for both).

Discussion

This is the first study investigating the safety and feasibility of TRA across the full spectrum of AT results in a clinical (i.e., not experimental) setting. The results of our investigation can be summarized as follows.

First, post-procedural thumb capillary lactate was not affected by AT results, and it did not increase after TRA compared with pre-procedural levels.

Second, self-reported hand discomfort or perceived hand disability as well as maximal isometric strength of the hand and forearm muscles did not differ among the 3 AT result groups after the procedure and at follow-up.

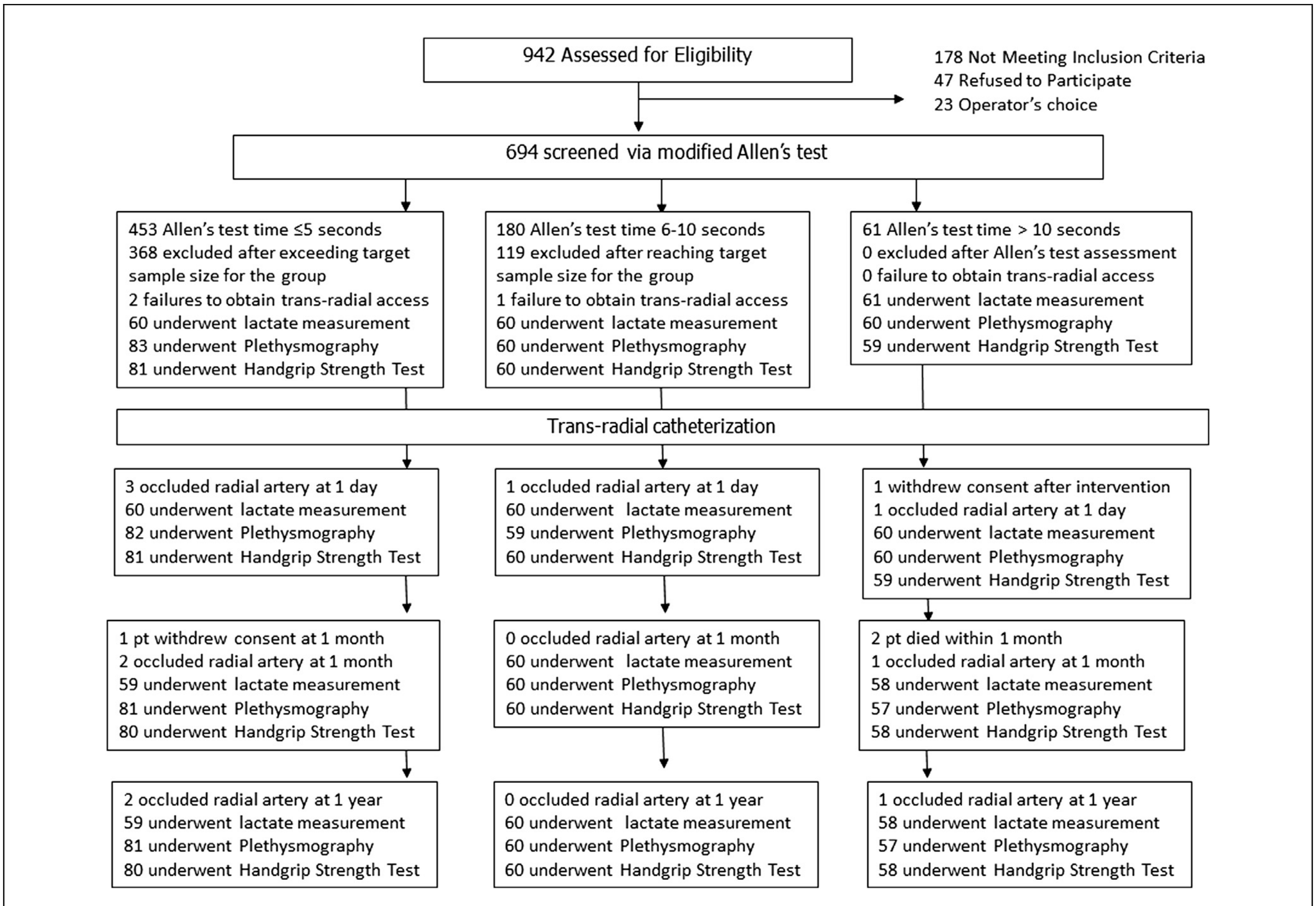

Figure 2 **Study Profile**

Third, thumb capillary lactate levels were consistently increased across the whole spectrum of AT results before RA bandage removal. Hand ischemic symptoms and patient reports also peaked at this time point in all patients, with no detectable influence of pre-procedural AT results.

Fourth, the ulnar frame count was significantly affected by pre-procedural AT result. Patients with normal compared with those with abnormal pre-procedural AT results displayed significantly lower ulnar frame counts, suggestive of greater ulnar blood flow, immediately after arterial sheath insertion. Although the difference in ulnar frame counts persisted after catheterization across the 3 AT groups, there was a distinct and significant post-procedural improvement (i.e., a count reduction) only in patients with baseline abnormal AT results.

Finally, the patency of the ulnopalmar arches of the hand varied over time in patients who underwent TRA, with those showing less prominent ulnar and ulnopalmar collateralization (i.e., patients with intermediate or abnormal AT results) displaying improvements after TRA. This was confirmed by both the changes in the plethysmographic readings observed in patients with intermediate and abnormal AT results at follow-up (pattern D, which was observed in 40% of patients in the AT-negative group, dropped to 10% at 24 h and to a single-digit finding thereafter) and the identification of distinct ulnar flow on Doppler examination and the absence of ischemic symptoms despite RA occlusion in the 2 patients with non-normal AT results and plethysmographic pattern C or D before TRA.

Thus, altogether these findings suggest that the patency of the ulnopalmar arches of the hand is highly dynamic, and vascular reserve inherent in the hand circulation can be recruited during and after TRA, especially in patients with poor collateral circulation at baseline, thus preventing detectable objective and subjective signs of hand ischemia during and after transradial catheterization.

Our observations do not lend support to the concept that normal AT results are a prerequisite for selecting patients who can safely undergo TRA. This may explain the paradox that has been repeatedly observed in recent years (13,16) that although TRA is becoming increasingly more popular worldwide (1), and several thousands of patients have undergone transradial procedure either with false-positive AT results or with no assessment of palmar arch circulation, only very few cases of hand ischemia after TRA have been recently reported (20–22). Importantly, none of them demonstrated a clear association with the presence of inadequate ulnar and ulnopalmar vessel patency before the procedure (20–22).

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Table 1 Baseline Characteristics of the Patients Stratified by AT Time

	Allen's Test Time (s)			
	0–5 (n = 83)	6–10 (n = 60)	>10 (n = 60)	p Value
Age, yrs	70 (64–76)	71 (60–76)	71.5 (64–77)	0.56
Men	58 (70%)	49 (82%)	42 (70%)	0.22
Weight, kg	76 (67–83)	76 (69–87)	77 (68–89)	0.67
Body mass index, kg/m^2	26 (24–28)	26 (24–30)	27 (25–31)	0.12
Diabetes	20 (24%)	14 (23%)	18 (30%)	0.66
Insulin-dependent diabetes	3 (4%)	1 (2%)	7 (12%)	0.03
Hypertension	64 (78%)	41 (68%)	48 (80%)	0.27
Hyperlipidemia	38 (46%)	28 (47%)	29 (48%)	0.97
Current cigarette use	22 (27%)	14 (23%)	11 (18%)	0.48
Creatinine clearance, ml/min	80.7 (64–103)	81.1 (62–102)	79.2 (66–100)	0.49
Prior percutaneous coronary intervention	14 (17%)	10 (16.6%)	10 (16.6%)	0.99
Prior coronary artery bypass grafting	2 (2.4%)	10 (6.0%)	2 (3.3%)	0.12
Prior instrumentation of homolateral RA for coronary angiography/intervention	7 (8.4%)	10 (16.7%)	2 (3.3%)	0.04
Systolic pressure, mm Hg		140 ± 12	139 ± 14	
At sheath insertion	139 (129–141)	139 (132–144)	136 (122–149)	0.44
At sheath removal	142 (131–147)	140 (130–147)	139 (120–163)	0.26
Heart rate, beats/min				
At sheath insertion	64 (52–73)	63 (50–71)	64 (53–74)	0.84
At sheath removal	142 (131–147)	140 (130–147)	139 (120–163)	0.26
Left ventricular ejection fraction, %	51 ± 12	49 ± 13	49 ± 12	0.87
	142 (131–147)	140 (130–147)	139 (120–163)	0.26
Indication for coronary catheterization				
Stable angina	27 (32.5%)	22 (36.7%)	15 (25%)	0.33
Unstable angina	23 (27.7%)	22 (36.7%)	18 (30%)	0.48
Non–ST-segment elevation myocardial infarction	24 (28.9%)	13 (21.7%)	17 (28.3%)	0.49
Dilated cardiomyopathy or valvular heart disease	9 (10.8%)	3 (5%)	10 (16.7%)	0.10
Patients who underwent isolate coronary angiography	33 (39.7%)	25 (41.7%)	29 (48.3%)	0.58
Patients who underwent coronary angiography followed by ad hoc intervention	50 (60.3%)	35 (58.3%)	31 (51.7%)	
Duration of the transradial procedure, min	51 ± 26	47 ± 27	49 ± 26	0.54
Medical therapy				
Aspirin	53 (88%)	69 (84%)	54 (90%)	0.56
Clopidogrel	48 (80%)	58 (71%)	44 (73%)	0.45
Beta-blockers	48 (81%)	66 (81%)	47 (78%)	0.88
Statins	48 (81%)	60 (74%)	46 (77%)	0.60
ACE inhibitors	51 (86%)	73 (90%)	52 (87%)	0.74
Calcium-channel blockers	8 (14%)	13 (16%)	8 (13%)	0.88
Nitrates	21 (36%)	22 (27%)	11 (18%)	0.11
Warfarin	4 (7%)	2 (2%)	3 (5%)	0.47

Values are median (interquartile range), n (%), or mean ± SD.
ACE = angiotensin-converting enzyme; AT = Allen test; RA = radial artery.

The feasibility and preliminary safety of transulnar catheterization and intervention have also been reported in unselected patients or even those with previously documented homolateral RA occlusion, with no evidence of hand ischemia during or after the procedure (23,24).

The presence of compensatory recruitable collateral vessels in the hand is well established (18,25–27), and contrary to previous beliefs that the palmar arches may be incomplete in a sizable proportion of patients, autopsy studies have recently shown that either the deep or superficial palmar arch is always complete in cadaver dissections (28).

Consistent with our findings, Greenwood et al. (18) observed a progressive increase of blood flow in the principal artery of the thumb after external RA occlusion, especially in patients with abnormal AT results. Moreover, the majority of these patients with apparently no patency of the ulnopalmar arches of the hand developed good functioning of the palmar arches during a relatively short (i.e., 30 min) period of external RA compression. This observation supports the concept that anatomically pre-existing collateral vessels can be functionally recruited during a relatively brief episode of hand ischemia (18).

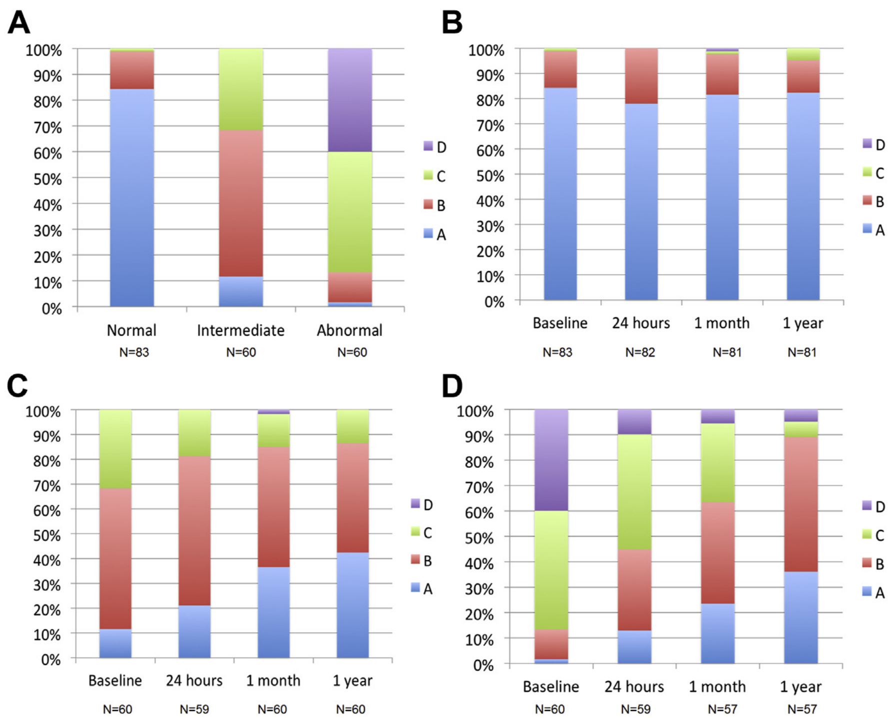

Figure 3 **Plethysmographic Readings at Baseline and Follow-Up**

(A) Plethysmographic readings at baseline stratified on the basis of Allen test AT result. **(B)** The pattern of plethysmographic readings in patients with normal AT results remained consistent at follow-up ($p = 0.56$). **(C)** Plethysmographic readings showed an increase of the prevalence of patterns A and B over time at the expenses of pattern C in patients with intermediate AT results ($p < 0.001$). **(D)** Plethysmographic readings showed an increase of the prevalence of patterns A and B over time at the expenses of patterns C and D in patients with abnormal AT results ($p < 0.001$).

At variance with our findings, Greenwood et al. (18) observed significant increases in thumb capillary lactate in patients with abnormal AT results, which has been interpreted as a demonstration that TRA should not be pursued in this patient population. Our study, which was designed to reproduce in a much larger sample and in a clinical (i.e., not experimental) context the previous findings on capillary lactate elevation, failed to do so. It is conceivable to speculate that the difference in the study designs (i.e., experimental with external RA compression vs. real-world consecutive patients undergoing TRA) might account for such a discrepancy in study results. External compression of the RA not only occludes the artery but also invariably increases tissue pressure within the wrist compartments, which may preclude or hamper functional recruitment of pre-formed collateral vessels. Interestingly, in our study, thumb capillary lactate did not peak after TRA, but it did so immediately before RA bandage release, irrespective of AT results. Vascular hemostasis was obtained in our study with the use of the TR Band system, which has been designed to selectively compress from outside the RA. Although we cannot exclude the possibility that the use of the TR Band in our clinical practice may at least partially affect ulnar flow in a more prominent way compared with the previously used external compressor device (18), it remains intriguing to speculate that also in our study, the external compression of the RA determined the increase in thumb capillary lactate. Whether the implementation of the patent hemostasis technique prevents the increase of thumb capillary lactate requires further investigation (29).

Study limitations. We have developed the ulnar frame count to obtain an angiographic proxy of intraprocedural collateral circulation of the hand. Our study shows a clear association between this new angiographic index and AT results. Yet hand collateralization largely depends on the superficial and deep palmar arches, which were not directly assessed or quantified in the present analysis. The present observation that TRA is both feasible and apparently safe in patients with abnormal AT results, who constituted roughly 10% of the screened population in our study, should be regarded as preliminary. Only 60 patients with abnormal AT results were evaluated with respect to the clinical safety of TRA in our study. Thus, the risk for hand ischemia if TRA is performed routinely in these patients may range from 0% to 6%, on the basis of the 95% confidence intervals. The MATRIX (Minimizing Adverse Haemmhorragic Events by TRansradial Access Site and Systemic Implementation of angioX; NCT01433627) study is currently investigating whether AT results and plethysmographic readings before transradial intervention predict the

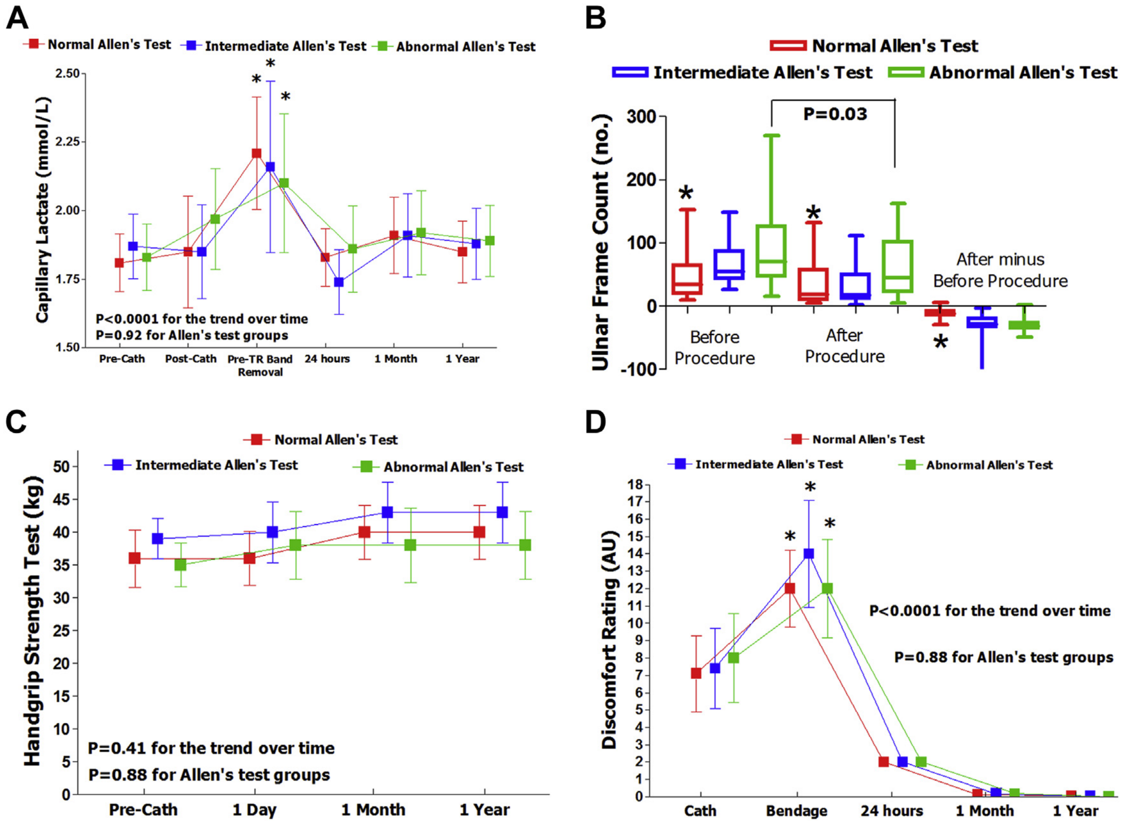

Figure 4 **Thumb Capillary Lactate, Ulnar Frame Counts, Handgrip Stress Test, and Self-Reported Discomfort Rates Over Time Across AT Results**

(A) The levels of thumb capillary lactate did not differ after compared with before catheterization (cath) irrespective of Allen test (AT) results obtained at baseline. Thumb capillary lactate peaked immediately before arterial bandage removal in all AT result groups. *p $<$ 0.002 versus baseline values in post-hoc analysis. **(B)** Patients with normal AT results showed lower ulnar frame counts both before and after catheterization compared with patients with abnormal AT results. Ulnar frame count was significantly lower after compared with the value before catheterization in patients with abnormal AT results. *p $<$ 0.05 versus patients with abnormal AT results in post-hoc analysis for the difference of ulnar frame counts after minus before catheterization. **(C)** Handgrip test at baseline and follow-up. **(D)** Self-reported hand discomfort rating after transradial catheterization.

occurrence of local ischemic complications in a large and unselected patient population with acute coronary syndromes.

Conclusions

Our study provides proof of concept for a paradigm shift in cardiovascular intervention, as the widespread, but unproved, belief that normal AT results are a prerequisite for selecting patients before TRA could not be confirmed. No clinical or subclinical sign of hand ischemia was detected in patients with abnormal AT results undergoing TRA. A confirmatory study focusing on clinical endpoints and involving a larger patient population is ongoing.

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Key Words: Allen test ■ capillary lactate ■ transradial intervention ■ ulnopalmar arches.

APPENDIX

For accompanying videos and their legends, please see the online version of this article.