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# The Effect of Transradial Coronary Catheterization on Upper Limb Function

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# ABSTRACT

**OBJECTIVES** The aim of this study was to analyze the change of upper limb function when percutaneous coronary procedures were performed through the radial artery.

BACKGROUND It is currently unknown if upper limb function is affected by transradial (TR) catheterization.

**METHODS** Between January 2013 and February 2014, upper limb function was assessed in a total of 338 patients undergoing coronary catheterization in an ambulatory setting (85% radial approach, 15% femoral approach). Upper limb function was assessed with the self-reported shortened version of the Disabilities of Arm, Shoulder, and Hand questionnaire. The presence and severity of upper extremity cold intolerance was assessed with the self-reported Cold Intolerance Symptom Severity questionnaire. Both questionnaires were completed before the catheterization and at 30-day follow-up. Higher scores represent worse upper limb function and symptoms. The nonparametric Wilcoxon signed-rank test was used to assess the change of upper limb function and symptoms over time.

**RESULTS** Upper limb function did not change significantly over time when catheterization was performed through the radial artery (p = 0.06). The number of procedure-related extremity complaints that persisted during 30-day follow-up were not different between both access groups (TR access 10.5%, transfemoral access 11.5%; p = 0.82). The upper extremity was not affected by cold intolerance after TR access at 30-day follow-up (p = 0.91).

**CONCLUSIONS** Upper limb function was not affected when coronary catheterizations and interventions were performed through the radial artery. (J Am Coll Cardiol Intv 2015;8:515–23) © 2015 by the American College of Cardiology Foundation.

oronary catheterization is regularly performed to diagnose or treat coronary artery disease (1,2). The femoral artery has been the default access site for many years. Currently, the radial artery is the preferred access route for catheterization, mainly driven by the lower number of access (site)-related complications (3). Transradial (TR) access is also considered to be a more patient-friendly approach. Early mobilization with significantly less discomfort may improve quality of life and shorten hospital length of stay (4).

These benefits have led to the progressive adoption of TR access and have brought attention to its potential complications and remaining challenges (5,6). Radial artery occlusion is the most common complication, which occurs in 2% to 10% of all cases and even up to 30% in selected series (7), but it rarely leads to major ischemic events (necrosis) due to the collateral circulation of the hand (8). However, it has been reported that radial artery occlusion may become symptomatic in 50% to 60% of all cases (7,9). This is supported by perfusion changes of the upper extremity after radial artery harvesting under conditions of stress (10,11). It appears that inadequate collateral flow due to an incomplete superficial palmary arch is present in up to 57% of all hands (12). Therefore, ischemic problems and upper limb dysfunction may occur in patients with radial artery

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#### ABBREVIATIONS AND ACRONYMS

IQR = interquartile range

MCID = minimal clinicallyimportant difference

PCI = percutaneous coronary intervention

RAS = radial artery spasm

TF = transfemoral TR = transradial y occlusion, albeit at a relatively low rate. In addition, a significant amount of vascular damage and chronic intimal thickening is induced by TR interventions (13) with lumen narrowing and endothelial dysfunction, which may jeopardize upper limb function as well (14,15). Other factors that may impair upper limb function are nerve injury, granulomas, and pseudoaneurysms. Apart from mere discomfort, this might have considerable implications for those patients for whom optimal upper extremity function is paramount. We,

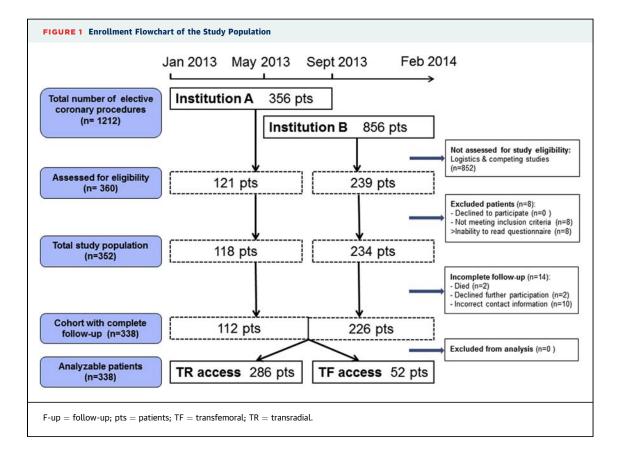
change in upper limb function after TR coronary catheterization.

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# METHODS

**STUDY DESIGN.** ACRA (Assessment of disability after Coronary procedures using Radial Access) is a prospective, 2-center study designed to evaluate the effect of TR coronary catheterization on upper limb function. A total of 1,212 elective percutaneous coronary procedures were performed between January 2013 and February 2014 in 2 academic institutions. Both institutions are high-volume tertiary referral centers that are located in 2 large cities in the Netherlands.

After informed consent was obtained, each patient completed 2 different hand function-related questionnaires during ambulatory day care admission. The results of the questionnaires were unknown to the treating physician and did not influence the choice of vascular access. The study protocol was approved by the local ethics committee and was performed in accordance with the Declaration of Helsinki. Exclusion criteria were: 1) inability to read or not willing to answer the questionnaires; 2) ST-segment elevation myocardial infarction; and 3) hemodynamic instability. The enrollment flowchart of the study is shown in Figure 1. Between January 2013 and February 2014, a total of 338 patients with complete follow-up were included in the present study (TR access: n = 286). Follow-up was incomplete or missing in 14 patients: 2 died before 30-day follow-up; 2 refused further participation; and the remaining patients had incorrect contact information. Before the study was initiated, we performed a power calculation. Based on a type I error of 5% and a power of 80%, assuming a QuickDASH



difference of 2.5 and an SD of 15, we needed 285 analyzable patients with TR access and complete follow-up. We stopped inclusion when this number was reached. The type of vascular access was left to the operator's discretion and was not mandated by the study, resulting in 52 analyzable patients with transfemoral (TF) access.

## CORONARY CATHETERIZATION AND INTERVENTION.

The access site for coronary angiography or percutaneous coronary intervention (PCI) was according to the preference of the treating cardiologist. Institution A performed TR access with a bare-needle technique, and institution B used a venous cannula technique. Both centers cannulated preferably the right radial artery with a 6-F, 10-cm-long sheath (Terumo, Somerset, New Jersey), and a cocktail of 0.2 mg nitroglycerine and 5 mg verapamil was given intra-arterially. In case of coronary angiography a standard dose of 5,000 IU of unfractionated heparin was given intra-arterially, and when a PCI was performed, the amount of unfractionated heparin was adapted to the patient's body weight. At the end of the procedure, the sheath was removed, and a TR band was applied (18-ml TR band, Terumo) for 4 h. In case of TF access, a standard 6-F 10-cm-long sheath (Terumo) was used. A collagen plug device (Angio-seal, St. Jude Medical, St. Paul, Minnesota) was applied at the end of the procedure.

**UPPER LIMB FUNCTION AND SYMPTOMS.** The Quick-DASH questionnaire, a shortened version of the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire (16), was used to assess upper limb function at 2 time points (before and 30 days after catheterization).

Compared with the DASH questionnaire, Quick-DASH enables faster measurement while maintaining its internal consistency and inter-rater reliability (Cronbach's alpha of 0.92 and an intraclass correlation coefficient of 0.94) (17). QuickDASH has been validated in a normative population and a variety of conditions and is completed more often than the DASH questionnaire (18). QuickDASH consists of 11 items to measure physical function, symptoms, and its consequences on daily life, scored from 1 to 5. At least 10 of the 11 items must be completed for a score to be calculated. The assigned values for all completed responses are averaged and then transformed to a score from 0 to 100 by subtracting 1 from the average score and multiplying this by 25. A higher score indicates greater upper extremity disability. The minimal clinically-important difference (MCID) score that would correspond to a change in clinical status appreciated by the patient (19) varies between 8 (20) and 14 (21) points for the QuickDASH questionnaire.

Cold Intolerance Symptom Severity (CISS) is a validated questionnaire to detect the occurrence of cold intolerance (22). Cold intolerance is defined as abnormal pain of the hand and fingers after exposure to mild or moderate cold. It is associated with significant functional impairment and reduced health-related quality-of-life, and it may seriously influence patients' daily life (23). It is a common consequence of a variety of diseases and injuries of the upper extremity, especially when neurovascular structures are involved (24-26). The CISS questionnaire consists of 6 questions that have been validated in a variety of upper extremity injuries (26) and a normative control group (27). Based on the range of normative values, a patient with a score of 30 or higher has pathological cold tolerance (27). In this study, we used the Dutch version of the QuickDASH (28) and CISS (27).

At 30-day follow-up, patients were asked to describe any procedure-related extremity complaints or loss of function.

DATA COLLECTION. Clinical and procedural characteristics were recorded and were prospectively entered into a dedicated electronic database. Before each procedure, capillary refill, pulsations (good, moderate, poor, or no), and vascular communication were assessed by a trained research nurse or physician assistant. Vascular communication was tested with the Allen test (29) in institution A and by plethysmography (Barbeau test) (30) in institution B. The Allen test was defined as abnormal if the maximal palmar blush was achieved 10 s after compression release. Plethysmography was recorded at the thumb before and immediately after radial artery compression and was divided into 4 types (A to D) as previously described (30). The reverse Barbeau test (with compression of the ulnar artery) was performed before discharge to test the vascular patency of the radial artery (31). We considered the (reverse) Barbeau test to be abnormal in case of type C and D, representing suboptimal (collateral) or no blood supply to the thumb. Capillary refill was defined as abnormal when it took >2 s for color to return to the nail bed after pressure removal.

The occurrence of clinical radial artery spasm (RAS) was evaluated during the procedure. RAS was defined as persistent forearm pain, pain response to catheter manipulation, pain response to sheath withdrawal, difficult catheter manipulation after being "trapped" by radial artery, and considerable resistance on withdrawal of the sheath. Patients

who had at least 2 of 5 signs were diagnosed with RAS (32). The amount of self-reported pain was measured by the visual analog scale from 0 to 10 ("no pain at all" was scored as 0 and "unbearable pain" as 10) at the end of the procedure and before discharge. The pain score was considered to be abnormal in case of moderate to severe pain (visual analog scale >5).

**ENDPOINTS.** The primary endpoint was defined as the change in upper extremity function from baseline to 30-day follow-up, as assessed by the QuickDASH score. The change in cold intolerance, as assessed by the CISS score, and the occurrence of other procedure-related symptoms were considered to be secondary endpoints.

**STATISTICAL ANALYSIS.** Continuous variables are presented as mean  $\pm$  SD, and categorical variables are expressed as percentages. Comparisons among clinical and procedural characteristics in patients undergoing TR or TF access were performed using Pearson's chi-square test for categorical variables and independent-samples t test for continuous variables. The Kolmogorov-Smirnov test was used to check for a normal distribution of the variables in our study population. The nonparametric Wilcoxon signed rank test was used to assess the change of upper extremity function and cold intolerance over time. The Mann-Whitney *U* test was used to compare the QuickDASH and CISS scores (nonparametric continuous variables). Logistic regression analyses were applied to test the relation between the applied access route and the development of cold intolerance or loss of upper extremity function. Logistic regression analyses were also used to test the association between vascular communication or patency and clinically-relevant loss of upper extremity function or the development of pathological cold intolerance.

All statistical tests were 2-tailed, and a p value <0.05 was considered statistically significant. All statistical analyses were performed with SPSS for Windows version 22.0 (SPSS, Inc., Chicago, Illinois).

## RESULTS

**STUDY POPULATION.** A total of 352 patients were prospectively enrolled between January 2013 and February 2014. Complete 30-day follow-up was present in 338 patients, and TR access was applied in 85% (n = 286). The mean age of the study population was 64 years, and 72% of the population was male.

Clinical and procedural characteristics are presented in Table 1. Patients undergoing procedures TABLE 1 Clinical and Procedural Characteristics Stratified by Access Site

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Access Site			
	Radial (n = 286)	Femoral (n = 52)	p Value
Demographic characteristics	(11 = 200)	(II – <b>JZ</b> )	p value
Age, yrs	64 ± 9	64 ± 10	0.95
Age, yrs Male	207 (72)	36 (69)	0.64
Cardiovascular history	207 (72)	30 (09)	0.04
Previous MI	(דר) סד	21 (40)	0.06
Previous MI Previous CABG	78 (27) 9 (3)	21 (40)	
		14 (27)	< 0.01
Previous PCI	93 (33)	22 (42)	0.17
Peripheral artery disease	16 (6)	8 (15)	0.01
Previous radial access	120 (42)	23 (44)	0.76
Previous femoral access	95 (33)	27 (52)	0.01
Cardiovascular risk factors	()	- ()	
Current smoking	52 (18)	5 (10)	0.13
Hypertension	155 (54)	28 (54)	0.96
Hypercholesterolemia	117 (41)	30 (58)	0.03
DM	35 (12)	7 (14)	0.81
BMI, kg/m <sup>2</sup>	$28\pm4$	$27\pm4$	0.17
Indication procedure			
Stable CAD	248 (89)	43 (83)	0.44
Medication			
Aspirin	223 (78)	42 (81)	0.65
P2Y <sub>12</sub> inhibitor	135 (47)	32 (62)	0.06
Oral anticoagulant	39 (14)	5 (10)	0.43
ACE inhibitor/AT II antagonist	165 (58)	33 (64)	0.44
Beta-blocker	192 (67)	38 (73)	0.40
Statin	226 (79)	39 (75)	0.52
Nitrate	100 (35)	18 (35)	0.96
Diuretic	64 (22)	9 (17)	0.41
Calcium-channel blocker	85 (30)	15 (29)	0.90
Procedure			
SBP, mm Hg	$139 \pm 22$	$134 \pm 19$	0.09
DBP, mm Hg	77 ± 11	76 ± 11	0.91
PCI	178 (62)	34 (65)	0.67
Procedural time (min)	48 (30)	64 (30)	<0.01
Procedural success	270 (94)	48 (92)	0.56
RAS	31 (11)	,	
Complicated procedure	8 (3)	2 (4)	0.68
Total heparin dose, IE		5,673 (2,806)	0.40
Pain score, VAS	3 (2)	2 (3)	0.40
	J (2)	2 (3)	0.27

Values are mean  $\pm$  SD or n (%). Complicated procedure was defined and reported by the operator. Independent-samples t test. p < 0.05 was considered statistically significant.

 $\label{eq:ACE} ACE = angiotensin-converting enzyme; AT = angiotensin; BMI = body mass index; CABG = coronary artery bypass graft surgery; CAD = coronary artery disease; DBP = diastolic blood pressure; DM = diabetes mellitus; MI = myocardial infarction; PCI = percutaneous coronary intervention; RAS = clinical radial artery spasm; SBP = systolic blood pressure; VAS = visual analogue scale.$ 

with femoral access more often had prior coronary artery bypass graft surgery and longer procedures. All other characteristics were the same for both access routes. RAS occurred in 11% of all TR procedures.

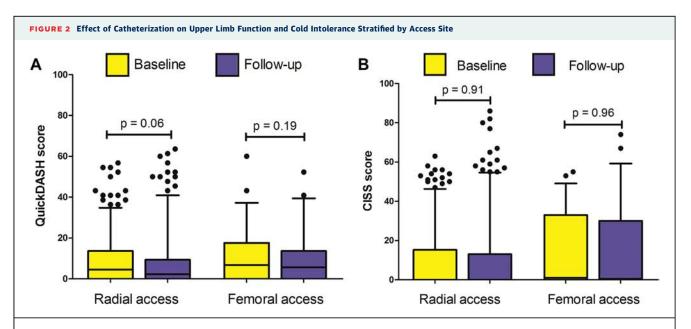
**UPPER LIMB FUNCTION AND SYMPTOMS.** At baseline, QuickDASH scores were significantly higher in female and elderly patients (age  $\geq$ 75 years), representing a worse upper extremity function. The median QuickDASH scores were 2.27 (interquartile range [IQR]: 0.00 to 11.36) for male and 9.09 (IQR: 2.27 to 25.00) for female patients (p < 0.001) and were 9.09 (IQR: 2.27 to 18.18) for elderly patients and 2.39 (IQR: 0.00 to 13.64) for patients age <75 years (p = 0.015). The QuickDASH score was not different for both access groups (p = 0.28).

Figure 2A shows QuickDASH scores at baseline and follow-up. No significant change in upper limb function could be observed when coronary procedures were performed through the radial artery (baseline 4.55 [IQR: 0.00 to 13.64]; follow-up 2.27 [IQR: 0.00 to 9.32]). Similarly, no change in upper limb function was reported when patients were treated via the femoral artery (baseline 6.82 [IQR: 0.00 to 17.61]; follow-up 5.68 [IQR: 0.00 to 13.64). The change in QuickDASH score was distributed the same across both access groups (p = 0.95). These findings underscore the fact that access strategy did not affect postprocedural upper limb function. The applied TR access technique was not associated with an increased QuickDASH score (hazard ratio: 1.32, 95% confidence interval: 0.71 to 2.45; p = 0.38).

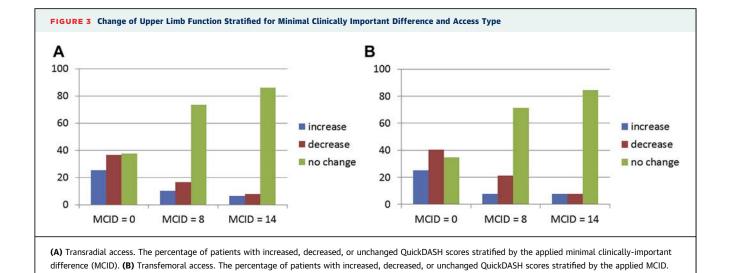
**Figure 3A** stratifies the percentage of TR patients with increased, decreased, or unchanged QuickDASH scores. When treated through the radial artery, 73 patients (25.5%) had increased QuickDASH scores,

with a median score of 6.82 (IQR: 4.55 to 14.77). A decrease was present in 105 patients (36.7%), with a median score of 6.82 (IQR: 2.39 to 12.50). The Quick-DASH score remained unchanged in 108 patients (37.8%). If we applied an MCID of 14, 6.3% of the patients would have a clinically-relevant decrease of upper extremity function, 7.7% would have an increase, and 86.0% would have no clinical relevant change at all. Figure 3B stratifies the percentage of TF patients with increased, decreased, or unchanged QuickDASH scores. An increased QuickDASH score was not associated with the applied access route, irrespective of the implementation of MCID cut-off values (for an MCID of 8: p = 0.58; for an MCID of 14: p = 0.71; and if MCID is not applied: p = 0.94). A decrease of the QuickDASH score was also not associated with the applied access route (p = 0.62, MCID not applied).

Cold intolerance was assessed with the CISS questionnaire. At baseline, significantly higher CISS scores were present in female patients (p < 0.001). The CISS score was similar in both access groups (p = 0.14) and both age groups (elderly vs. non-elderly patients, p = 0.87). CISS scores did not change over time when the procedure was performed through the radial or femoral artery, as represented in Figure 2B. The development of pathological cold intolerance



(A) Upper limb function as assessed with the QuickDASH score over time. **Box plots** show the change of the QuickDASH score between baseline and 30-day follow-up for transradial (TR)- and transfemoral (TF)-treated patients. **Whiskers** represent 5th to 95th percentiles, and p values were calculated with Wilcoxon signed rank test (p < 0.05 was considered statistically significant). A higher QuickDASH score indicates worse upper limb function or symptoms. (**B**) Cold intolerance of the upper extremity as assessed with the CISS (Cold Intolerance Symptom Severity) score over time. **Box plots** show the change of the CISS score between baseline and 30-day follow-up for TR- and TF-treated patients. **Whiskers** represent 5th to 95th percentiles, and p values were calculated with Wilcoxon signed rank test (p < 0.05 was considered statistically significant).

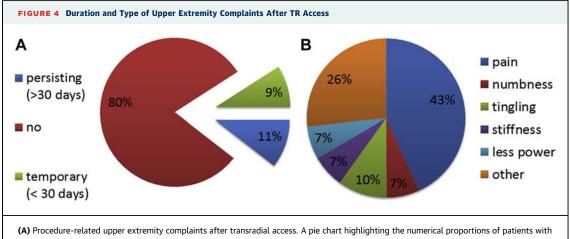


(defined as a CISS  $\geq$ 30 [27]) was not associated with the applied access route (p = 0.71) and was present in 18 patients after TR access (6.3%) and 4 patients after TF access (7.7%).

A lack of patent dual palmar arch circulation was present in 8.0% of patients when assessed with the Allen test and 6.2% when assessed with the Barbeau test. Inadequate post-procedural patency of the radial artery was present in 6.4% of the patients, as assessed with the reverse Barbeau test. No association could be observed between abnormal vascular communication or patency and the loss of upper extremity function (Allen test, p = 0.99; Barbeau test, p = 0.88; reverse Barbeau test, p = 0.99). The same holds true for cold intolerance (Allen test, p = 0.41; Barbeau test, p = 0.99; reverse Barbeau, p = 0.35). Procedure-related extremity problems were equally reported by patients with TR and TF access (19.6% vs. 17.3%, respectively; p = 0.70). Extremity problems that persisted during 30-day follow-up were also not different between both access groups (TR 10.5%, TF 11.5%; p = 0.82). **Figure 4** shows that pain of the upper extremity was the most frequent reported complaint after TR catheterization that persisted during 30-day follow-up (4.5%).

## DISCUSSION

The present study shows that TR access for percutaneous coronary procedures does not affect self-reported upper limb function. The mean preprocedural QuickDASH score was not different from



temporary and persisting upper extremity complaints after transradial access. A pie chart symptotic of procedure-related upper extremity complaints that persisted during 30-day follow-up after transradial access. A **pie chart** summarizing the numerical proportions of different types of persisting extremity complaints after transradial access.

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the score at 30-day follow-up. Although a proportion of patients reported deterioration of upper limb function after TR access, this was not numerically or statistically different from patients with a transfemoral access. Moreover, deterioration of upper limb function will not be of clinical relevance in most instances.

Several outcome measures have been proposed to assess upper limb disability (33). The Short Form Health Survey is a generic questionnaire that is used for evaluating health-related quality-of-life after PCI and a variety of cardiovascular disorders (34). However, this questionnaire is less sensitive to clinical change in patients with problems in a specific anatomic region (35). The QuickDASH score has proven to be a validated outcome measure to monitor upper extremity disability for both clinical and research purposes. This score, with good test-retest reliability, is a reliable tool to assess difference over time in a normative population (18) and a variable number of upper extremity conditions (17). In the case of TR catheterization, upper limb function was not jeopardized. However, a trend toward a lower Quick-DASH score was observed at follow-up, which might be caused by response bias (36). Patients might report less upper extremity symptoms at follow-up when significant coronary artery disease has been successfully treated by PCI. This may be supported by the higher PCI rate (69.5%) in patients with decreased QuickDASH scores, although statistical significance was not reached (p = 0.054). The QuickDASH scores in our study population were comparable to that of the general population (37), with significantly higher scores in female and elderly patients (18,38).

The occurrence of cold intolerance was considered to be a secondary outcome, because it is associated with significant functional impairment, and as many as 85% of patients with all types of upper extremity injuries complain of some degree of cold sensitivity (25). Cold intolerance is mainly present when neurovascular structures are involved, including those injuries caused by injection or puncture (25). However, the estimated prevalence of cold intolerance greatly depends on the method of measuring and defining cold intolerance, ranging from patient-mentioned symptoms to validated questionnaires (24,27,39). The current study used the validated CISS questionnaire (27) and detected no significant change over time when catheterization was performed through the radial artery. As a reference group, we studied the change of cold intolerance in patients with TF access, which was unchanged as well. The baseline score for cold intolerance was comparable with subjects in a normative population. Further follow-up might be needed, because the degree of cold sensitivity increases until 3 months post-procedure and remains constant thereafter (25).

The assessment of a patent dual palmar arch circulation is recommended before every TR procedure (40). The most-applied method of this assessment used to be the Allen test; however, plethysmography assessment (Barbeau test) appeared to be more sensitive to evaluate the collateral supply (30). In clinical practice, both tests are not routinely used (41), because the predictive value for ischemic complications after TR access is not clear. It has been demonstrated that patients with an abnormal Allen test showed a significant increase in thumb capillary lactate (42). However, a recent publication of the RADAR (Should Intervention Through Radial Approach be Denied to Patients With Negative Allen's Test Results?) study group demonstrated that no clinical or subclinical sign of hand ischemia was detected in patients with an abnormal Allen test undergoing TR catheterization (43). We observed 1 patient with a type D plethysmography test who underwent vascular surgery because of radial artery occlusion with ischemic symptoms. In our analysis, we could not find a relationship between abnormal vascular communication and the occurrence of upper extremity disability (p = 0.99). It was previously demonstrated that 50% to 60% of all cases with RA occlusion become symptomatic (7), although we could not find a relation between abnormal vascular patency of the RA and the occurrence of upper extremity disability (p = 0.88). However, we did not confirm every potential radial artery occlusion with echo-duplex.

This is the first study that investigated the effect of TR access on upper extremity function. Although previous studies have solely reported about upper extremity problems, complications, and quality of life, the primary focus in our study was to evaluate upper extremity function. Despite the anatomic and physiologic changes that are induced by radial access, our study demonstrated that patients do not report a significant reduction of upper extremity function after TR catheterization.

**STUDY LIMITATIONS.** Cohort studies are vulnerable to bias; however, the prospective paired design made it less prone to bias with respect to the similarity of external variables. Importantly, we were not able to include all consecutive patients due to competing studies and logistics. Questionnaire bias may affect the outcome by the design of the questions and how the questionnaires are administered or completed (36). However, QuickDASH and CISS are both short questionnaires that have been validated for several injuries and in a normative population. We observed

a good response rate and completion of the questionnaires, which supports the proper design of both questionnaires.

Our study results may have been influenced by response bias and additional treatment (PCI), as previously mentioned. Bias induced by the interviewer with respect to the study hypothesis ("binding") was not applicable to our study results due to the selfreported design. Unfortunately, we were not able to relate upper extremity problems or functionality to the incidence of RA occlusion at follow-up, because a clinical follow-up visit was not mandatory in the present study.

## CONCLUSIONS

Our study demonstrated that self-reported upper limb function was not jeopardized when coronary catheterizations and interventions were performed through the radial artery. The results of our study are of importance to all patients undergoing TR access, especially when optimal upper extremity function is essential.

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## PERSPECTIVES

WHAT'S KNOWN? Anatomic and physiological changes that are induced by radial access might jeopardize upper limb function. Although previous studies have solely reported about upper extremity problems, complications, and quality of life, the primary focus in our study was to evaluate the change of upper extremity function after TR access as reported by the patient.

WHAT'S NEW? This is the first study that investigated the effects of TR access on upper extremity function as reported by the patient. The results of this study are important to inform patients adequately about the functional consequences of TR access, especially when optimal upper extremity function is essential.

WHAT'S NEXT? The assessment of patent dual palmar arch circulation is recommended before TR procedures. However, the clinical value of patency tests is currently unclear, with controversial results of thumb capillary lactate levels in patients with abnormal Allen tests. Future research will be needed to define the safety of TR access in patients with abnormal dual arterial supply.

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