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ORIGINAL CONTRIBUTION

Coronary Procedures via Distal Transradial Access in Older as Compared With Non-Older Patients: Insights From the DISTRACTION Registry

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ABSTRACT

BACKGROUND. Older patients are at a higher risk of access site complications and bleeding. Systematic reviews and meta-analysis have highlighted the benefits of distal over proximal transradial access (mainly, lower rates of radial artery occlusion and faster hemostasis). We aimed to evaluate the feasibility and safety of distal transradial access (dTRA) for routine coronary procedures in older patients compared with non-older patients. **METHODS.** Retrospective analysis of a large and real-world sample of 5524 consecutive all-comers patients who underwent coronary procedures via dTRA were included in the DISTRACTION registry. **RESULTS.** In the older patients (≥65 years) group (n = 2594, 47%), there were higher rates of hypertension (83% vs 71.1%; *P*<.0001), diabetes (45.1% vs 34.7%; *P*<.0001), previous stroke (2.9% vs 2%; *P*=.0425), chronic heart failure (9.2% vs 7.1%; *P*=.0040), severe aortic valvar disease (4.2% vs 2.9%; *P*=.0070), chronic kidney disease stages 3 and 4 (8.1% vs 3.1%; *P*<.0001), previous percutaneous coronary intervention (27.2% vs 24.5%; *P*=.0253), previous coronary artery bypass grafting (5.1% vs 2.2%; *P*<.0001), cardiogenic shock at presentation (1.3% vs 0.4%; *P*=.0003), rotational atherectomy (0.7% vs 0.2%; *P*=.0050), and left main percutaneous coronary intervention (2.7% vs 1.5%; *P*=.0033). No significant differences were observed in the rates of access site crossovers. No major adverse cerebrovascular and cardiac events directly related to dTRA, no hand/thumb dysfunction or ischemia after any procedure, and no access site-related hematomas (early discharge after transradial stenting of coronary arteries ≥2) were recorded. **CONCLUSIONS.** Despite more comorbidities, more complex coronary disease, and more challenging presentation, the adoption of dTRA as the default approach for routine coronary procedures in older patients, by proficient operators, appears to be safe and feasible.

INTRODUCTION

Compared with non-older, the older population is at a higher risk of vascular access site complications and bleeding.[1] For this special subset of patients, the conventional (proximal) transradial approach (pTRA) has shown equal efficacy to the transfemoral approach, with significant reduction of vascular complications and stroke, in general, and, in the setting of ST-segment elevation myocardial infarction (STEMI), lower rates of death.[2]

Distal transradial access (dTRA) has become familiar to interventional cardiologists around the world, and several systematic reviews and meta-analysis have highlighted its benefits over pTRA—mainly, lower rates of proximal radial artery occlusion and faster hemostasis.[3-7]

Since February of 2019, our group adopted dTRA as standard for coronary angiography and interventions. Our overall results, with high success, very low crossovers rates, and no major complications, have been continuously published.[8-11]

To date, despite the growing evidence associated with this novel approach, there are no published data specifically addressing the use of dTRA for coronary procedures in the older population.

We aimed to evaluate the feasibility and safety of dTRA as a default approach for routine coronary angiography and interventions in older patients compared with non-older patients from a large real-world sample of consecutive and all-comers patients with all spectrums of coronary artery disease.

Material and methods. From February 2019 to May 2023, 5524 consecutive patients underwent coronary angiography and/or interventions via dTRA at Hospital Regional do Vale do Paraíba and Hospital Universitário I, Escola Paulista de Medicina, Universidade Federal de São Paulo. These patients have been continuously enrolled in the DIStal TRAnsradial access as default approach for Coronary angiography and intervenTIONs (DISTRACTION) prospective cohort registry (ensaiosclinicos.gov.br Identifier: RBR-7nzxkm). The presence of any (even weak) palpable pulses at both anatomical snuffbox and wrist was the unique eligibility criterion for enrollment. Of note, patients with unstable hemodynamic conditions were not excluded. Patients aged 65 or older were included in the older group, and those under age 65 were placed into the non-older group. The study was approved by the Research Ethics Committee of the Hospital Universitário I of the Universidade Federal de São Paulo (protocol 4.071.731), CAAE 30384020.5.0000.5505, and informed consent was given as a prerequisite before enrolling each subject in this prospective registry. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Our standardized protocol for dTRA procedures has been recently described elsewhere in detail.[8-11]

Statistical analysis. Study data were collected and managed using REDCap (Research Electronic Data Capture) electronic data capture tools hosted at Escola Paulista de Medicina. REDCap is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources.[12,13] Continuous variables were described as mean ± standard deviation and categorical data as numbers and percentages. Chi-square and Mann-Whitney tests were used for comparing the groups; *P* values <.05 were considered statistically significant. All analyses were performed with the BioStat Biology Statistical Software for Windows, version 5.3.

RESULTS

Table 1 depicts demographic features and **Table 2**, procedure characteristics of all 5524 patients according to each group (total, older, and non-older). Overall, there was a predominance of non-older patients (2930, 53%). Mean patient ages were 63.40 ± 10.97, 72.64 ± 5.86, and 55.23 ± 7.37 years for the total, older, and non-older groups, respectively.

Compared with the non-older group, statistically significant predominance of hypertension (83% vs 71.1%; *P*<.0001), diabetes (45.1% vs 34.7%; *P*<.0001), previous stroke (2.9% vs 2%; *P*=.0425), chronic heart failure (9.2% vs 7.1%; *P*=.0040), severe aortic valvar disease (4.2% vs 2.9%; *P*=.0070), former smoking (30.4% vs 25.9%; *P*=.0002), chronic kidney disease stages 3 and 4 (8.1% vs 3.1%; *P*<.0001), known coronary artery disease (40.1% vs 32.3%; *P*<.0001), previous percutaneous coronary intervention (PCI) (27.2% vs 24.5%; *P*=.0253), previous coronary artery bypass grafting (5.1% vs 2.2%; *P*<.0001), chronic coronary syndromes (38% vs 32.7%; *P*<.0001), previous ipsilateral pTRA sheath insertion (10.5% vs 8.4%; *P*=.0078), and cardiogenic shock status at the presentation to the cath lab (1.3% vs 0.4%; *P*=.0003) were seen in the older group **(Table 1)**.

Table 1: Demographic characteristics.

	Total n=5,524 (100%)	Older n=2,594 (47%)	Non-older n=2,930 (53%)	P
Age	63.40±10.97	72.64±5.86	55.23±7.37	<0.0001*
BMI (Kg/m^2)	27.48±4.70	26.78±4.32	28.09±4.92	<0.0001*
Men	3,594 (65%)	1,632 (62.9%)	1,960 (66.9%)	0.0022**
Hypertension	4235 (76.7%)	2,152 (83%)	2,083 (71.1%)	<0.0001**
Diabetes Mellitus	2,189 (39.6%)	1,171(45.1%)	1,018 (34.7%)	<0.0001**
Current smoking	1,254 (22.7%)	384 (14.8%)	870 (29.7%)	<0.0001**
Former smoking	1,547 (28%)	788 (30.4%)	759 (25.9%)	0.0002 **
Obesity (BMI ≥ 30 Kg/m^2)	1,340 (25,1%)	490 (19.7%)	850 (29.7%)	<0.0001**
Previous stroke	134 (2.4%)	75 (2.9%)	59 (2%)	0.0425 **
Chronic heart failure	446 (8.1%)	239 (9.2%)	207 (7.1%)	0.0040 **
Severe aortic valvar disease	196 (3.5%)	110 (4.2%)	84 (2.9%)	0.0070 **
Severe mitral valvar disease	95 (1.7%)	37 (1.4%)	57 (2%)	0.1663 **
Known CAD	1,985 (35.9%)	1039 (40.1%)	946 (32.3%)	<0.0001**
Previous PCI	1423 (25.8%)	705 (27.2%)	718 (24.5%)	0.0253 **
Previous CABG	198 (3,6%)	133 (5.1%)	65 (2.2%)	<0.0001**
Previous ipsilateral pTRA sheath insertion	519 (9.4%)	273 (10.5%)	246 (8.4%)	0.0078 **
Previous ipsilateral dTRA sheath insertion	693 (12.5%)	309 (11.9%)	384 (13.1%)	0.1950 **
CKD stages 3 and 4 (eGFR <60mL/min/1.73m^2)	301 (5.4%)	210 (8.1%)	91 (3.1%)	<0.0001**
CKD stage 5 (under dialysis)	95 (1.7%)	30 (1.2%)	65 (2.2%)	0.0034 **
Indication for Coronary Angiography and/or PCI				
Chronic coronary syndromes	1,945 (35.2%)	986 (38%)	959 (32.7%)	<0.0001**
Unstable Angina	493 (8.9%)	230 (8.9%)	263 (9%)	0.9242 **
NSTEMI	1,196 (21.7%)	582 (22.4%)	614 (21%)	0.1933 **
STEMI	1,296 (23.5%)	506 (19.5%)	790 (27%)	<0.0001**
Anterior STEMI	639 (11.6%)	236(9.1%)	403 (13.8%)	<0.0001**
Inferior STEMI	503 (9.1%)	207(8%)	296 (10.1%)	0.0072 **
Infero-lateral STEMI	112 (2%)	47(1.8%)	65 (2.2%)	0.3299 **
Lateral STEMI	42 (0.8%)	16(0.6%)	26 (0.9%)	0.3172 **
Other reasons	550 (10%)	257(9.9%)	293 (10%)	0.9495 **
Cardiogenic shock at cath lab presentation	44 (0.8%)	33(1.3%)	11 (0.4%)	0.0003 **

Data presented as mean ± standard deviation or number (percentage).
Kg, kilogram; m, meter; BMI, body mass index; CAD, coronary artery disease; PCI, percutaneous coronary intervention; CABG, coronary artery bypass grafting; pTRA, proximal transradial access; dTRA, distal transradial access; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; NSTEMI, non-ST-segment elevation myocardial infarction; STEMI, ST-segment elevation myocardial infarction.

In turn, in the non-older group, as compared with the older one, there were statistically significant higher rates of men (66.9% vs 62.9%; *P*=.0022), current smoking (29.7% vs 14.8%; *P*<.0001), obesity (29.7% vs 19.7%; *P*<.0001), end-stage chronic kidney disease requiring dialysis (2.2% vs 1.2%; *P*=.0034), and presentation as STEMI (27% vs 19.5%; *P*<.0001) **(Table 1)**.

Regarding the procedural characteristics, the rates of elective coronary angiography (36.5% vs 31.5%; *P*<.0001), ad hoc PCI (33.3% vs 27.1%; *P*<.0001), rotational atherectomy (0.7% vs 0.2%; *P*=.0050), left dTRA (7.9% vs 5.5%; *P*=.0003), and left main PCI (2.7% vs 1.5%; *P*=.0033) were statistically significantly higher in the older group, as compared with the non-older one. In this last group, there was statistically significant predominance of primary PCI (24.4% vs 18.2%; *P*<.0001) and redo left dTRA (12.5% vs 0.2%; *P*<.0001) **(Table 2)**.

Table 2: Procedure characteristics.	Total n=5,524 (100%)	Older n=2,594 (47%)	Non-older n=2,930 (53%)	P
Coronary angiography				
Elective coronary angiography	1,869 (33.8%)	946 (36.5%)	923 (31.5%)	<0.0001**
Urgency coronary angiography	3,126 (56.6%)	1,379 (53.2%)	1,747 (59.6%)	0.4350 **
PCI				
Elective PCI	475 (8.6%)	237 (9.1%)	238 (8.1%)	0.1960 **
Primary PCI	1,186 (21.5%)	471 (18.2%)	715 (24.4%)	<0.0001**
Rescue PCI	43 (0.8%)	18 (0.7%)	25 (0.9%)	0.6037 **
Ad hoc PCI	1,658 (30%)	865 (33.3%)	793 (27.1%)	<0.0001**
Wire-based intracoronary physiological assessment	29 (0.5%)	12 (0.5%)	17 (0.6%)	0.6766 **
Intravascular imaging (IVUS or OCT)	129 (2.3%)	61 (2.4%)	68 (2.3%)	0.9891 **
Rotational atherectomy	23 (0.4%)	18 (0.7%)	5 (0.2%)	0.0050 **
Chronic total occlusion PCI	143(2,6%)	72 (2.8%)	71 (2.4%)	0.4603 **
Target coronary territory				
Left Main	113 (2%)	69 (2.7%)	44 (1.5%)	0.0033 **
Left Anterior Descending	1,627 (29.5%)	775 (29.1%)	872 (29.8%)	0.9488 **
Left Circumflex	742 (13.4%)	357 (13.8%)	385 (13.1%)	0.5237 **
Ramus Intermedius	29 (0.5%)	12 (0.5%)	17 (0.6%)	0.6766 **
Right Coronary Artery	1,085(19.6%)	535 (20.6%)	550 (18.8%)	0.0898 **
Surgical grafts	36 (0.6%)	23 (0.9%)	13 (0.5%)	0.0609 **
Type of distal transradial access				
ldTRA	366 (6.6%)	206 (7.9%)	160 (5.5%)	0.0003 **
redo ldTRA	15 (0.3%)	6 (0.2%)	365 (12.5%)	<0.0001 **
rdTRA	4,452(80.6%)	2,073 (79.9%)	2,377 (81.1%)	0.2709 **
redo rdTRA	662(12%)	297 (11.4%)	365 (12.5%)	0.2672 **
Simultaneous bilateral dTRA	31(0.6%)	12 (0.5%)	19 (0.6%)	0.4578 **
Sheath size				
5 Fr	19 (0.3%)	12 (0.5%)	7 (0.2%)	0.2352 **
6 Fr	5,436 (98.4%)	2,547 (98.2%)	2,889 (98.6%)	0.2650 **
7 Fr	60 (1.1%)	31 (1.2%)	29 (1%)	0.5454 **
Hemostasis of dTRA				
TR band™	5,429 (98.3%)	2,563 (98.8%)	2,866 (97.8%)	0.0066 **
Access site crossover	115 (2.1%)	64 (2.5%)	53 (1.8%)	0.1091 **
Successful dTRA sheath insertion	5,424 (98.2%)	2,538 (97.8%)	2,884 (98.4%)	0.1279 **

PCI, percutaneous coronary intervention; IVUS, intravascular ultrasound; OCT, optical coherence tomography; ldTRA, left distal transradial access; rdTRA, right distal transradial access; dTRA, distal transradial access; Fr, French.
* Mann-Whitney
** Chi-square

Standard 6F radial sheaths and regular radial compression devices were used for most patients. Right dTRA was the most frequent primary access site. There were no significant differences between the groups in the rates of access site crossovers, some of them successfully performed via contralateral dTRA. **(Table 2)**.

No major adverse cerebrovascular and cardiac events directly related to dTRA, no hand/thumb dysfunction or ischemia after any procedure, and no access site-related hematomas (early discharge after transradial stenting of coronary arteries [EASY] ≥2) were recorded.

DISCUSSION

The present study assessed the particularities of older and non-older patients from a real-world experience with dTRA as a default approach for routine coronary procedures, in a broad and unselected sample of all-comers patients, encompassing all presentations of coronary artery disease. Data were obtained from the DISTRACTION registry, the first Brazilian observational registry to assess dTRA as standard for routine coronary angiography and/or interventions.

To the best of our knowledge, this is the first assessment of dTRA as the default for coronary procedures in the older population, compared with non-older. For such a peculiar subset of patients, there was no specific comparison found between pTRA and dTRA.

A meta-analysis of 16 studies (13 observational and 3 randomized and controlled), assessed 777,841 older patients submitted to PCI via pTRA (99,201 patients) or transfemoral approach (678,640 patients). Observational studies associated pTRA to lower rates of vascular complications (0.4% vs 0.8%, odds ratio [OR] 0.36, 95% confidence interval [CI] 0.30–0.44), stroke (0.3% vs 0.4%, OR 0.81, 95% CI 0.66–1.0), and death (2% vs 2.2%, OR 0.51, 95% CI 0.41–0.63). Randomized and controlled trials endorsed significant reduction for vascular complications (2.7% vs 7%, OR 0.37, 95% CI 0.23–0.60) and stroke (0.4% vs 1.4%, OR 0.31, 95% CI 0.10–0.97), but not for mortality (3.3% vs 2.8%, OR 1.20, 95% CI 0.69–2.09). Notwithstanding, for older patients with STEMI, pTRA was associated with a mortality benefit (5% vs 7%, OR 0.48, 95% CI 0.25–0.90, *P*=.02).[2]

In the most recent meta-analysis of 6208 participants from 14 randomized trials, dTRA, as compared with pTRA, was associated with a significantly lower risk of radial artery occlusion, either at latest follow-up (risk ratio [RR] 0.36; 95% CI 0.23-0.56; *P* < .001; number needed to treat [NNT] = 30) or in-hospital (RR 0.32; 95% CI 0.19-0.53; *P*<.001; NNT = 28), as well as EASY ≥2 hematoma (RR 0.51; 95% CI 0.27-0.96; *P*=.04; NNT = 107). On the other hand, dTRA was related to more access site crossover (RR 3.08; 95% CI 1.88-5.06; *P*<.001; NNT = 12), longer time for radial artery puncture (standardized mean difference [SMD] 3.56; 95% CI 0.96-6.16; *P*<.001), longer time for sheath insertion (SMD 0.37; 95% CI 0.16-0.58; *P*<.001), and higher number of arterial puncture attempts (SMD 0.59, 95% CI 0.48-0.69; *P*<.001).[7]

In the DISTRACTION registry, our total rates of access site crossover have decreased from 3% in the early experience[8] to only 2.5% with 8½ -fold the initial number of patients.[11]In this updated analysis, this temporal trend was maintained: 2.1% for the total group, 1.8% for the non-older, and 2.5% for the older, without statistical significance. Of note, all crossovers resulted from failed wire advancement despite successful distal radial artery puncture, and the most frequent was from dTRA to ipsilateral pTRA, thus avoiding the transfemoral approach.

Contrary to most data published so far,[3-7] which essentially included patients in stable conditions, we have included patients with any (even weak) distal radial artery palpable pulses, regardless the clinical scenario. Of note, the majority of our patients (in all groups) had acute coronary syndromes. Older patients exhibited statistically significant higher rates of comorbidities, previous PCI and coronary bypass grafting surgery, left main PCI, rotational atherectomy need, and cardiogenic shock at presentation.

One case of 0.035" J-tip wire-induced forearm radial artery perforation (not directly related to dTRA) spontaneously sealed by the guiding catheter[14] and another of local pseudoaneurysm successfully managed by prolonged and ultrasound-guided pneumatic neck compression[15] were recorded.

Randomized and controlled trials are mandatory to corroborate our observational and preliminary findings.

Study limitations. This is a 2-center observational registry, and all procedures were performed by 2 experienced interventional cardiologists with dTRA (more than 2750 consecutive patients each operator). Thus, the results of the present study cannot be extrapolated and generalized to other centers and to interventional cardiologists unfamiliar with the technique. Distal radial artery puncture attempt numbers, time to sheath insertion, and fluoroscopy and procedure times were not systematically recorded. The lack of routine post-procedure Doppler ultrasound evaluation might have underestimated the vascular complication rates. Performing dTRA without ultrasound guidance, in turn, might help to disseminate the technique.

CONCLUSIONS

Despite more comorbidities, more complex coronary disease, and more challenging presentation, the adoption of dTRA as default approach for routine coronary procedures in older patients, by proficient operators, appears to be safe and feasible. Larger and randomized trials are warranted to corroborate our observational findings.

Affiliations and Disclosures

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