A Retrospective Cohort Study to Evaluate the Efficacy, Safety, and Cost of MáLEI via Transradial vs Transfemoral Peripheral Revascularizations

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Abstract: Purpose. This study aimed to evaluate the efficacy and safety of transradial (TR) access (MáLEI: Minimal Arterial Access Lower Extremity Intervention) compared with transfemoral (TF) access in patients with peripheral arterial disease (PAD). **Methods.** A retrospective, unmatched cohort study was conducted on patients with lower extremity PAD, Rutherford classification category 2 through 6, who had at least 1 peripheral revascularization. The primary objective was to compare clinical success with radial access to femoral access. **Results.** Ninety patients with Rutherford category 3 through 6 PAD underwent a peripheral revascularization. All procedures (n = 90) resulted in clinical success. For TR vs TF access, average procedure time was 85.2 vs 84.5 minutes; average fluoroscopy time was 30.3 vs 29.4 minutes; and median time to discharge was 6.6 vs 11.6 hours. One TF patient (3.7%) experienced an access site bleed (BARC Type 1). TR access resulted in a procedure resource cost expenditure of $242.43 and a duration-of-stay savings of $1,116.14, for a total cost-savings of $873.71 per procedure. **Conclusion.** In patients with severe PAD, a TR approach for peripheral revascularizations is a comparative alternative to a TF approach.

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Key words: peripheral arterial disease, transfemoral access, transradial access

Background

Peripheral arterial disease (PAD) is a common progressive condition affecting 8.5 million Americans over age 40, and over 200 million people worldwide.[1,2] PAD results from atherosclerosis and calcified plaque occlusions in the infrarenal abdominal aorta and iliac and/or intra-inguinal arteries.[3] Health implications of PAD stem from both its limb and cardiovascular (CV) manifestations and is associated with a 5-year mortality of 25%.[1] The limb manifestations of PAD induce considerable suffering, and 10% to 20% of patients experience intermittent claudication (an exertional leg pain that limits walking ability) and often, disability.[4] Due to the nature of the disease, persistently decreased blood flow and tissue perfusion of the lower extremities can lead to severe complications, such as critical limb ischemia (CLI) and potentially amputation if left untreated. In addition, polyvascular disease is prevalent in PAD, and patients with PAD are at an elevated risk for CV events.[2,4] A meta analysis of over 48,000 participants showed an association between PAD severity (determined by ankle-brachial index [ABI]) and risk for myocardial infarction and ischemic stroke. Patients with the lowest ABI values exhibited the most severe limb complications and were at a 2-fold higher risk of death and CV death at all ranges of the Framingham Risk Score.[5] Furthermore, this risk is maintained in both symptomatic and asymptomatic patients, making it crucial to optimize therapeutic strategies to improve long-term outcomes.[4,5] Patients with severe PAD benefit from treatments that utilize risk factor-modifying approaches with pharmacologic interventions, as well as revascularization, to prevent amputation.[1,3] Various peripheral revascularization methods, such as percutaneous transluminal angioplasty, stenting, and atherectomy, are the cornerstone procedures for treating PAD.[7]

Transfemoral access (TFA) has been the traditional mode for peripheral interventions. When feasible, femoral access provides relatively easy access and adequate platform length for successful peripheral vascular interventions using currently available sheaths, balloons, and catheters. However, due to an increased risk for complications and extended length of stay post revascularization, its use can be undesirable and costly to patients. Therefore, considerations such as quality of life and cost have become increasingly relevant in choosing between TFA and alternative revascularization access points, such as transradial access (TRA) or transulnar with or without transpedal access, defined as MáLEI (minimal arterial access lower extremity intervention).

Historically, TRA has been reserved for select patients with narrowly defined characteristics, such as weight, height, and presence of factors that limit TFA (eg, heavily calcified femoral arteries or absence of femoral pulse) due to the concern for serious complications.[8] Over the last decade, however, TRA has emerged as a preferred route for coronary interventions, with multiple studies showing its use to be safer and cost-effective, with better patient satisfaction, when compared with TFA.[7] Specifically, one meta-analysis that evaluated the efficacy of TRA in patients showed a 57% reduction in major bleeds with TRA compared with TFA (P<.0001) for coronary interventions.[9,10] A decrease in hospital stay by 0.4 days was also observed with TRA in this study, demonstrating early ambulation post coronary revascularization, which may shorten hospital length of stay.[10] Another study by Brueck et al in 512 patients demonstrated a decrease in access site vascular complications (pseudoaneurysms, hematomas, decreased hemoglobin levels, and arteriovenous fistulas) with TRA compared with TFA for coronary procedures (0.58% vs 3.71%, P<.0008).[11,12] Furthermore, the TRA platform provides an alternative approach for vascular interventions that exhibits positive data in both hospital stay duration and the minimization of access complications.[9,11]

Despite the robust literature available supporting TRA feasibility and safety compared with TFA for coronary procedures, scant data are available regarding its use in peripheral percutaneous interventions. The major reason for the continued paucity of such data was the lack of availability of longer length sheaths. When considering the radial artery's anatomic location, distance and catheter accessibility to the periphery are important factors that have limited TRA utilization. This limiting factor is seen in practice where TR procedures have been restricted to patients who are 185 cm or less in height. To address this issue, Terumo Interventional Systems developed 2 sheaths for peripheral procedures: Glidesheath Slender and Radial to Peripheral (R2P) Destination Slender.[13] Glidesheath Slender is a hydrophilic-coated introducer sheath that utilizes a thin-wall technology, allowing the user to easily insert and remove the sheath during peripheral procedures. The R2P Destination Slender is a guiding sheath with a reduced outer diameter and larger inner diameter. The R2P Destination Slender has a hydrophilic coat that provides a smooth transition within the radial and, with a length of 119 cm and 149 cm, is the ideal sheath for R2P procedures.[13]

Overall, even though numerous studies have examined the efficacy and safety of TRA vs TFA for cardiovascular revascularization, the clinical success of peripheral vascular interventions remains ill-defined. Therefore, the aim of this study is to directly evaluate the safety and efficacy of TRA with or without transpedal access compared with TFA in MáLEI among patients with mild-to-severe PAD.

Methods

Study Design and Patient Population

This retrospective, unmatched, cohort, single-center chart review study included a convenience sample of 90 distinct patients who underwent one or more TR, TF, or transulnar peripheral revascularization from 2017 to 2019. The study cohort consists of patients who were age 18 or older with a diagnosis of lower extremity PAD secondary to atherosclerosis, meeting Rutherford classification category 2 through 6. Patients who did not meet all eligibility criteria were identified as ineligible for this study and were not included. The study protocol was approved by the IntegReview institutional review board, and a waiver of informed consent was granted as patient data were reviewed and analyzed in a retrospective manner. The study was conducted in accordance with Good Clinical Practice; the United States Code of Federal Regulations, Title 21, Part 50 (21CFR50); and the study protocol.

Procedure Description

Once the access site was identified for the peripheral vascular procedure, the artery was visualized under ultrasound guidance to confirm it was clear of any proximal or distal stenosis and to determine whether the size of the vessel was within acceptable parameters. This was done by catheterization with a 4 Fr catheter into the left brachial artery and angiography to confirm the artery was not hypoplastic, anomalous takeoff, and the other corresponding artery was widely patent. If radial arteries were less than 0.26 cm, an intervention was not performed. Once confirmed, the local site was infiltrated with 2% lidocaine solution using ultrasound guidance. A 21-gauge needle was then used to access the vessel using a modified Seldinger technique to create an anterior wall puncture.

For radial/ulnar access, a 0.021" guidewire was introduced into the radial/ulnar artery. Then either a 5 Fr or 4 Fr 10 cm radial sheath was introduced into the radial artery, activating its glide coating. A radial/ulnar cocktail was then administered, which included 5000 units of heparin, 2.5 mg of verapamil, and 200 µg of nitroglycerin diluted with 20 mL of blood.

For femoral access, a 0.018" micro-guidewire was introduced into the femoral artery, then either a 4 Fr, 5 Fr, or 6 Fr 10 cm micropuncture sheath was introduced into the femoral artery. An access site angiogram was then performed using contrast injected in the hand; if the access site was acceptable, using a 0.035" J-tip guidewire, the micropuncture sheath was removed and a 4 Fr or 5 Fr sheath was placed in the femoral artery.

The interventional cardiologist determined the method to accomplish hemostasis post procedure by standard procedure utilized at the hospital. Removal of 2 mL of air started 2 hours after the sheath removal, continuing the removal of 2 mL of air every 15 minutes until the band came off. This compression is based off a new protocol now considered standard for deflation of the TR band following coronary procedures via the radial route via protocol 1, which removes 2 mL of air 1 hour after sheath removal and continuing to remove 2 mL of air every 30 minutes; or protocol 2, which involves removing 4 mL of air 2 hours after sheath removal, then 4 mL every 15 minutes. The technique utilized is considered standard uniform method for closure. The radial artery was not evaluated post procedure except via pulse oximeter that was connected to the patient's index finger. No patient had ischemic complication of the hand.

Objectives and Outcomes

The primary objective of this study was to compare the clinical success of peripheral revascularization with radial access with or without pedal access to femoral access. The primaryoutcome was clinical success defined by residual stenosis of less than

Table 1. Demographic and Baseline Clinical Characteristics.

Characteristic	All Procedures (n = 90)	Transfemoral (n = 27)	Transradial (n = 63)	P-value
Age (years)	71.5 ± 10.1 (44.9, 91.3)	69.9 ± 10.3 (51.5, 90.0)	72.2 ± 10.0 (44.9, 91.3)	0.32
Weight (kg)	84.0 ± 29.6 (37.0, 238.0)	90.4 ± 47.2 (37.0, 238.0)	81.2 ± 17.4 (42.0, 108.0)	0.33
Height (cm)	170.2 ± 10.6 (147.0, 193.0)	169.7 ± 11.4 (147.0 193.0	170.4 ± 10.4 (152.0, 187.0)	0.79
Male	49 (54.4%)	13 (48.1%)	36 (57.1%)	0.49
Smoking status				0.10
Current smoker	18 (20.0%)	9 (33.3%)	9 (14.3%)	
Former smoker	36 (40.0%)	8 (29.6%)	28 (44.4%)	
Never smoker	36 (40.0%)	10 (37.0%)	26 (41.3%)	
Glycemic status				0.24
Non-DM	46 (51.1%)	12 (44.4%)	34 (54.0%)	
T1DM	4 (4.4%)	0	4 (6.3%)	
T2DM	40 (44.4%)	15 (55.6%)	25 (39.7%)	
History of HTN				0.51
No	2 (2.6%)	1 (3.7%)	1 (1.6%)	
Yes	88 (97.8%)	26 (96.3%)	62 (98.4%)	
History of CAD				0.78
No	21 (23.3%)	7 (25.9%)	14 (22.2%)	
Yes	69 (76.7%)	20 (74.1%)	49 (77.8%)	
History of CAD procedure				0.25
No	48 (53.3%)	17 (63.0%)	31 (49.2%)	
Yes	46 (46.7%)	10 (37.0%)	32 (50.8%)	
Number of prior CAD procedures				0.35
1	27 (30.0%)	7 (25.9%)	20 (31.7%)	
2	7 (7.8%)	2 (7.4%)	5 (7.9%)	
3	3 (3.3%)	1 (3.7%)	2 (3.2%)	
4	5 (5.6%)	0	5 (7.9%)	
Rutherford classification				0.02
Category 3	36 (40.0%)	10 (37.0%)	26 (41.3%)	
Category 4	14 (15.6%)	4 (14.8%)	10 (15.9%)	
Category 5	17 (18.9%)	10 (37.0%)	7 (11.1%)	
Category 6	23 (25.6%)	3 (11.1%)	20 (31.7%)	

Data are mean (SD), range (min, max) and count (%). Plus-minus values are means ± SD. Percentages (%) may not total 100 because of rounding. Abbreviations: CAD, coronary artery disease; cm, centimeters; DM, diabetes mellitus; HTN, hypertension; kg, kilograms; max, maximum; min, minimum; SD, standard deviation; T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus.

30% post peripheral revascularization in patients where radial access with or without pedal access was utilized compared with traditional femoral access. The secondary objective of this study was to assess peripheral revascularizations through radial access with or without pedal access compared with femoral access with regards to procedure time, fluoroscopy time (FT), time to discharge, complications (hematoma, pseudoaneurysm, radial aneurysm, femoral aneurysm, asymptomatic radial artery thrombosis, asymptomatic femoral artery thrombosis, retroperitoneal [RP] bleed, embolization, access site bleed, inability to withdraw sheath, and perforation), and cost. The exploratory objective of this study was to describe peripheral revascularizations through the ulnar access with or without pedal access with regards to clinical success, procedure time, FT, time to discharge, complications (hematomas, pseudoaneurysm, ulnar aneurysm, asymptomatic ulnar artery thrombosis, RP bleed,

Table 2. Revascularized Arteries.

	All Procedures (n = 90)	Transfemoral (n = 27)	Transradial (n = 63)	P-value
Common femoral artery	10 (11.1%)	2 (7.4%)	8 (12.7%)	0.71
Anterior tibial artery	20 (22.2%)	8 (29.6%)	12 (19.0%)	0.28
Superficial femoral artery	52 (57.8%)	16 (59.3%)	36 (57.1%)	1.0
Peroneal artery	17 (18.9%)	5 (18.5%)	12 (19.0%)	1.0
Common iliac artery	14 (15.6%)	3 (11.1%)	11 (17.5%)	0.54
Popliteal artery	25 (27.8%)	10 (37.0%)	15 (23.8%)	0.21
Posterior tibial artery	10 (17.8%)	3 (11.1%)	13 (20.6%	0.37

Table 3. Time Outcomes per Procedure.

	All Procedures (n = 90)	Transfemoral (n = 27)	Transradial (n = 63)	P-value
Total procedure time (minutes)				
Mean	84.7 ± 42.4	85.2 ± 40.2	84.5 ± 43.7	0.94
Median (IQR)	75.0 (60.0, 100.0)	75.0 (55.0, 110.0)	75.0 (60.0, 95.0)	
Range (min, max)	(10.0, 240.0)	(15.0, 180.0)	(10.0, 240.0)	
Total fluoroscopy time (minutes)				
Mean	30.1 ± 17.3	29.4 ± 19.7	30.3 ± 16.4	0.81
Median (IQR)	24.9 (16.6, 39.5)	21.9 (15.0, 45.1)	25.7 (17.9, 37.3)	
Range (min, max)	(6.7, 87.8)	(6.7, 78.3)	(9.5, 87.8)	
Time to discharge (hr)				
Mean	52.2 ± 84.7	42.4 ± 66.7	56.5 ± 91.4	0.43
Median (IQR)	9.6 (5.4, 54.3)	11.6 (6.9, 28.3)	6.6 (5.3, 72.8)	
Range (min, max)	(2.8, 402.0)	(3.8, 253.2)	(2.8, 402.0)	

Plus-minus values are means ± SD. Abbreviations: hr, hours; IQR, interquartile range; max, maximum; min, minimum; SD, standard deviation.

embolization, access site bleed, inability to withdraw sheath, and perforation). Bleeding was defined according to the Bleeding Academic Research Consortium (BARC) classification.

Statistical Analysis

Patient characteristics were summarized through descriptive statistics and compared by independent t-test and chi-square test. For the primary analysis, success rates for each group were calculated as the proportions meeting the clinical success criteria. If the success rate in the TR group was greater than the TF group, a formal non-inferiority test of the difference between the proportions with a margin of -0.05 was conducted to test whether the TR access had a success rate no worse than 5% below the TF access. Secondary outcomes were compared through statistical tests that were appropriate to the variable form. Specifically, procedure time and FT were compared through independent t-test for normally distributed data, or otherwise, non-parametric tests were used (eg, rank-sum test). Time to discharge was compared through the Cox proportional hazards regression model with verification of the

Table 4. Time Outcomes per Procedure According to PAD Severity Classification.

Rutherford Category	Category 3		Category 4		Category 5		Category 6	
	TFA (n = 10)	TRA (n = 26)	TFA (n = 4)	TRA (n = 10)	TFA (n = 10)	TRA (n = 7)	TFA (n = 3)	TRA (n = 20)
Total procedure time (minutes)								
Mean Median (IQR) Range (min, max)	59.5 60.0 (15.0, 90.0)	64.2 62.5 (10.0, 140.0)	67.5 70.0 (55.0, 75.0)	83.5 87.5 (40.0, 120.0)	107.0 115.0 (50.0, 180.0)	85.7 90.0 (25.0, 160.0)	121.7 110.0 (100.0, 155.0)	110.9 90.0 (55.0, 240.0)
Total fluoroscopy time (minutes)								
Mean Median (IQR) Range (min, max)	15.6 14.7 (6.7, 23.3)	20.9 18.6 (9.5, 46.9)	24.0 16.6 (15.0, 47.7)	36.3 37.0 (18.1, 50.5)	43.1 46.1 (15.0, 78.3)	29.6 24.1 (14.8, 67.9)	37.3 39.5 (29.2, 43.1)	40.0 36.4 (17.2, 87.8)
Time to discharge (hr)								
Mean Median (IQR) Range (min, max)	9.1 7.4 (3.8, 22.4)	5.2 5.4 (2.8, 7.1)	13.0 11.6 (4.3, 24.7)	47.8 17.4 (4.4, 316.0)	79.1 27.1 (5.0, 253.2)	96.5 11.3 (4.9, 402.0)	70.2 51.7 (7.7, 151.3)	113.4 88.8 (5.9,342.2)

Abbreviations: hr, hour; IQR, interquartile range; max, maximum; min, minimum; PAD, peripheral arterial disease; TFA, transfemoral access; TRA, transradial access.

proportional hazard assumption. Incident complications were compared through chi-square test, and costs were adjusted for inflation to 2019 dollars and compared between groups.

This study included a convenience sample of all patients meeting the study criteria. Therefore, no formal sample size determination was undertaken. If the data appeared to support a test for non-inferiority, success rates for non-inferiority were tested. Otherwise, only event rates were reported without formal statistical comparison. Using a margin of -0.05 (ie, TRA success rate no lower than 5% below TFA), a test for non-inferiority of the difference between the 2 proportions would have more than 80% power to reject a false null hypothesis, if the success rate was 95% with TF procedures and the success rate was 100% in the TR access procedure, assuming a one-sided alpha of 0.025. Under similar assumptions, in the case where the success rate was 90% with TF procedures, a test for non-inferiority would have approximately 80% power to reject a false null hypothesis if the success rate with TR procedures was 98%.

Results

This study included 90 procedures that had well-balanced baseline patient characteristics between groups (female 49.6%, male 54.4%) with a mean age of 71.5 ±10.1 years and a mean height of 170 cm (**Table 1**). Glycemic status was not significantly different between the groups, with 51.1% (n = 46) of patients non-diabetic; 4.4% (n = 4) type 1 diabetics; and 44.4% (n = 40) type 2 diabetics. At the time of the procedure, 97.8% (n = 88) had a history of hypertension and 76.7% (n = 69) had a history of coronary artery disease. TRA composed 70% (n = 63) of the cases, with a baseline Rutherford classification distribution of 41.3% category 3, 15.9% category 4, 11.1% category 5, and 31.7% category 6. TFA composed 30% (n = 27) of the cases with a baseline Rutherford classification distribution of 37% category 2, 14.8% category 4, 37% category 5, and 11.1% category 6. All femoral and radial procedures were performed by the same operator.

For our studies' primary and secondary objectives, all procedures (n = 90; 100%) resulted in clinical success; only 1 complication was noted in the TFA group, which was a BARC type 1 access site bleed that did not require blood transfusion. The vessels treated across all procedures (TRA and TFA) were common femoral artery (n = 10), anterior tibial artery (n = 20), superficial femoral artery (n = 52), peroneal artery (n = 17), common iliac artery (n = 14), popliteal artery (n = 25), and posterior tibial artery (n = 16) (**Table 2**). Time outcomes are detailed in **Table 3**.

Table 5. Time Outcomes for All Vessels and Number of Vessels Revascularized per Procedure.

Time per Number of Vessels Revascularized per Procedure	TFA	TRA
Total procedure time (min)		
All revascularizations 1 vessel revascularized 2 vessels revascularized 3 vessels revascularized 4 vessels revascularized 5 vessels revascularized	85.2 ± 40.2 (15.0, 110.0) 64.5 ± 33.4 (15.0, 140.0); 78.2 ± 24.6 (50.0, 125.0) 132.5 ± 39.1 (75.0, 180.0) 0 0	84.5 ± 43.7 (10.0, 240.0) 62.1 ± 27.6 (10.0, 110.0) 91.6 ± 48.5 (40.0, 225.0) 86.7 ± 25.2 (60.0, 140.0) 115.8 ± 41.0 (73.0, 160.0) 240
Total fluoroscopy time (min)		
All revascularizations 1 vessel revascularized 2 vessels revascularized 3 vessels revascularized 4 vessels revascularized 5 vessels revascularized	29.4 ± 19.7 (6.7, 78.3) 17.8 ± 11.2 (6.7, 47.3) 27.0 ± 13.5 (13.4, 47.7) 51.3 ± 21.5 (23.4, 78.3) 0 0	30.3 ± 16.4 (9.5, 87.8) 21.9 ± 11.7 (9.5, 49.6) 30.9 ± 15.4 (16.2, 87.8) 30.7 ± 11.1 (14.5, 50.5) 64.5 ± 11.2 (48.2, 73.5) 55.2
Time to discharge (hr)		
All revascularizations 1 vessel revascularized 2 vessels revascularized 3 vessels revascularized 4 vessels revascularized 5 vessels revascularized	42.4 ± 66.7 (3.8, 253.2) 32.9 ± 65.2 (3.8, 217.2) 55.9 ± 83.8 (4.3, 253.2) 33.5 ± 28.2 (6.9, 80.3) 0 0	56.6 ± 91.4 (2.8, 402.0) 12.7 ± 20.7 (2.8, 74.7) 49.0 ± 80.8 (3.6, 316.0) 98.6 ± 136.5 (4.6, 402.0) 141.6 ± 28.7 (103.0, 172.3) 167.5

Data are mean and range values (minimum, maximum). Plus-minus values are means ± SD. All vessel revascularizations: TFA n = 27, TRA n = 63; 1 vessel revascularized TFA n = 10, TRA n = 21; 2 vessels revascularized TFA n = 11, TRA n = 22; 3 vessels revascularized TFA n = 6, TRA n = 15; 4 vessels revascularized TRA n = 4; 5 vessels revascularized TRA n = 1. Abbreviations: hr, hours; min, minutes; SD, standard deviation; TFA, transfemoral access; TRA, transradial access.

Procedural time outcomes were comparable between both the TRA and TFA groups, with a mean total procedure time of 84.5 minutes vs 85.2 minutes, P=.94; mean total FT of 30.3 minutes vs 29.4 minutes, P=.81; and median time to discharge of 6.6 hours vs 11.6 hours, P=.43, respectively. There was some heterogeneity for disease severity relative to time outcomes (**Table 4**), and a notable numerical difference was seen between TRA and TFA in category 5, with a mean total procedure time of 85.7 minutes vs 107 minutes; a mean total FT of 29.6 minutes vs 43.1 minutes; and a median time to discharge of 11.3 hours vs 27.1 hours, respectively. In addition, the TRA group included patients who underwent revascularization of 4 and 5 vessels per procedure compared with none in the TFA group (**Table 5**). Stent placement occurred in a total of 24 patients (TRA n = 17, TFA n = 7). Exploratory outcomes are detailed in **Table 6**. When compared with TFA, TRA resulted in a procedure resource cost expenditure of $242.43 and a duration-of-stay savings of $1,116.14, for a total cost savings of $873.71 per procedure.

Table 6. Exploratory Outcomes.

	Transulnar (n = 3)
Procedure success	3 (100%)
Total procedure time (minutes)	
Mean Median (IQR) Range (min, max)	98.3 ± 63.3 75.0 (50.0, 170.0) (50.0, 170.0)
Total fluoroscopy time (minutes)	
Mean Median (IQR) Range (min, max)	32.7 ± 21.7 33.3 (10.7, 54.0) (10.7, 54.0)
Time to discharge (hr)	
Mean Median (IQR) Range (min, max)	114.9 ± 138.0 74.9 (1.4, 268.5) (1.4, 268.5)

Plus-minus values are means ± SD. Abbreviations: hr, hour; IQR, interquartile range; max, maximum; min, minimum; SD, standard deviation.

Discussion

Radial artery access has often been avoided because of concerns of severe complications, such as hand ischemia or hand amputation.[8] These feared complications are due to radial artery occlusion, which has been shown to be strongly correlated to sheath size.[9] Also, radial access has been traditionally reserved for a narrowly defined patient population based on estimated radial artery size and patient demographics. In our set of cases patients taller than 185 cm were included, and our data suggest that these concerns may be overstated. This is due to the use of Terumo's advanced peripheral sheath platforms, which eliminate these potential problems and broaden the applicability of TRA from its typical patient population. Other studies exist within the cardiology literature that provide further supporting evidence. One study of 90 patients evaluated the safety and feasibility of TRA in peripheral endovascular procedures.[9] A clinical success rate of 100% was achieved, and radial artery site-related complications occurred only in 3 cases (3.2%) that were deemed minor hematomas requiring no treatment.[8] It should be recognized that the TRA approach has some limitations and contraindications. In cardiac catheterization, 10% to 23% of patients do not qualify for TRA due to an abnormal Allen's test and a risk for hand ischemia.[6] In addition, patients who require larger catheters for coronary interventions or a balloon pump cannot undergo the TRA approach.[6]

Despite the known benefits of TRA for coronary procedures, interventional cardiologists' preference of access site selection may be influenced by perceived increased FT related to personnel training requirements and an extended learning curve. One small study that evaluated FT in 358 patients noted that TRA was associated with longer FT. After an average of 50 percutaneous coronary intervention (PCI) cases, however, there was a discernible improvement in total FT efficiency comparable with TFA FT.[14] Our study demonstrated similar time outcomes between both approaches (TRA and TFA) with no statistically significant difference in total FT. There also was a statistically significant difference in disease severity between groups, with more patients with severe disease undergoing TRA vessel revascularization than TFA. This is reflective in our data, where TRA time outcomes included patients with 4 and 5 vessels revascularized per procedure, likely due to a worse PAD disease category. Because procedure time duration increases with respect to the number of vessels revascularized, the lack of a comparable number of vessels revascularized between groups may underestimate TFA time outcomes and suggest a difference in overall time outcomes between groups in favor of TRA.[14]

It should be noted that in this study, the interventional cardiologist's institution considered TRA as the first-line approach and reserved TFA as a last resort, resulting in the rationale of selecting TRA over TFA to perform a peripheral orbital atherectomy (POA). This algorithm was reflective in our results, with a notable procedure number difference between TRA and TFA, and a wide variety of patient demographics (weight, height, body mass index, and age) observed. In addition, the institution had the R2P Destination Sheath and the Diamondback 360 POA system (Cardiovascular Systems, Inc.) readily available, allowing the interventional cardiologist to perform orbital atherectomies on a range of patients and not be restricted due to equipment.

Due to the retrospective nature of the study, one limitation of the study is that the patient-specific factors used for determining access site selection are unknown. In addition, many assumptions were made regarding direct costs. Monetary amounts for procedure resources were calculated from the center's February 2020 Charge Description Master, and the ultrasound and angiogram test duration were assumed to be equivalent regardless of the access site and disease severity. In addition, the Diamondback 360 device utilized in atherectomies was assumed to be the same regardless of access site and had a cost of $14,213.25. Also, cath lab costs were tabulated for procedure time and the cardiovascular unit costs were accounted as the patient's location post procedure. The cost for total hospitalization duration was calculated separately from procedural equipment cost, and the difference was taken to determine cost savings. The cost savings seen in our study is not all-inclusive, and further evaluation is needed. In addition, many patients presented with other complications, which likely influenced their duration of hospitalization and time to discharge post procedure. However, it should be noted that cost savings seen in our study of $873.71 per procedure is comparable to the EASY study, which included 1005 patients who underwent radial coronary PCI and showed a savings of around $1,000 per procedure.[13]

An additional limitation in our study was that not all patients were evaluated post procedure and not all were followed up within 30 days. In addition, for our primary endpoint, sedation time was used as a marker for procedure time and if sedation time was not recorded, total service time was used in its place. This may overestimate the total procedure time, and despite both groups exhibiting similar time results, future studies are needed to evaluate TRA's procedural time and associated direct costs to support its cost-savings potential. Our study provides data to support TRA use in MáLEI among patients with PAD no matter the baseline patient demographic characteristics.

Conclusion

Patients who underwent TRA peripheral revascularization, when compared with TFA, had a similar clinical success rate with no incidence of complications. This is consistent with the low complication rates shown in studies that investigate the efficacy of TRA for coronary procedures. Our results suggest that using a MáLEI approach with TRA is a comparative alternative to TFA in patients with mild-to-severe PAD and demonstrate that its utilization has similar efficacy and safety for successful peripheral revascularizations. ■

Disclosure: The authors have completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. The authors report no conflicts of interest regarding the content herein.

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