MáLEI (Minimal Arterial Access Lower Extremity Intervention) In Severe Peripheral Arterial Disease

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INTRODUCTION

- A common manifestation of atherosclerotic cardiovascular disease (ASCVD) is peripheral arterial disease (PAD) in the infrarenal abdominal aorta, iliac, and/or infra-inguinal arteries.
- Severe PAD can lead to worsening of the disease including critical limb ischemia (CLI) and potentially amputation if not treated.
- Traditionally, transfemoral access has been favored due to their high success rate and the length of time this approach has been used, however, with an increased patient complexity, risk for cardiovascular complications and extended length of stay post-revascularization, it can be undesirable and costly to patients and the health system.
- In patients with severe peripheral arterial disease (PAD) Rutherford Classification Grade 4-6, the transradial approach is even more underutilized due to the newness of the approach, number of lesions and lesion complexity including the amount of calcium and the length.
- Longer-length sheaths specifically designed for peripheral procedures (i.e. Above-the-Knee (ATK) and PAD/CLI vascular interventions) have been developed.
- This post hoc analysis aimed to evaluate the efficacy and safety of transradial access (MáLEI- Minimal Arterial Access Lower Extremity Intervention) compared to transfemoral access in patients with severe PAD.

METHODS

Main Study Design Overview

- This was a retrospective, unmatched, cohort study with data collection (via chart review) on a convenience sample.
- The research site performed chart review and completed a data collection form for eligible patients (according to the Inclusion Criteria and Exclusion Criteria).
- Data collected was analyzed according to the protocol statistical analysis plan.

Inclusion Criteria

Patients must meet all the following inclusion criteria to be eligible to participate in this study:

- 18 years of age or older
- Lower extremity PAD secondary to atherosclerosis (Rutherford Classification Category 2-6)
- Have received one or more transradial, transfemoral, or transulnar peripheral revascularizations procedure using the Terumo sheath from July 1, 2018 through June 30, 2019

Exclusion Criteria

- There are no exclusion criteria.

OBJECTIVES

Objective

- This post hoc analysis aimed to evaluate the efficacy and safety of transradial access (MáLEI- Minimal Arterial Access Lower Extremity Intervention) compared to transfemoral access in patients with severe PAD (i.e. Rutherford Classification Grade 4 through Grade 6.

RESULTS

Patients

- A total of 90 patients were included in study.
- The Rutherford classification breakdown for the total population is displayed in **Table 1.**
- Baseline characteristics per Rutherford Classification are shown in **Table 2.**

Table 1: Rutherford Classification for Total Population

	All (n=90)	Transfemoral (n=27)	Transradial (n=63)
Rutherford Classification			
• Grade 3	36 (40.0%)	10 (37.0%)	26 (41.3%)
• Grade 4	14 (15.6%)	4 (14.8%)	10 (15.9%)
• Grade 5	17 (18.9%)	10 (37.0%)	7 (11.1%)
• Grade 6	23 (25.6%)	3 (11.1%)	20 (31.7%)

Table 2: Baseline Characteristics Per Rutherford Classification

Rutherford Grade *Transfemoral* *Transradial*	Grade 3-6 *(n=27)* *(n=63)*	Grade 3 *(n=10)* *(n=26)*	Grade 4 *(n=4)* *(n=10)*	Grade 5 *(n=10)* *(n=7)*	Grade 6 *(n=3)* *(n=20)*
Age					
• Transfemoral	69.9 (10.3)	68.7 (10.9)	73.3 (9.0)	71.7 (11.2)	63.2 (5.5)
• Transradial	72.2 (10.0)	69.5 (8.7)	75.9 (10.9)	67.8 (15.4)	75.5 (7.5)
Weight (kg)					
• Transfemoral	90.4 (47.2)	79.3 (15.6)	70.2 (22.0)	110.7 (70.6)	86.7 (34.8)
• Transradial	81.2 (17.4)	79.5 (14.6)	72.5 (21.7)	79.8 (17.4)	88.3 (16.9)
Height (cm)					
• Transfemoral	169.7 (11.4)	171.1 (8.1)	171.8 (17.0)	164.4 (10.6)	180.0 (11.8)
• Transradial	170.4 (10.4)	168.7 (9.8)	166.7 (11.2)	168.4 (11.4)	175.1 (9.4)
Male					
• Transfemoral	13 (48.1%)	5 (50.0%)	3 (75.0%)	2 (20.0%)	3 (100.0%)
• Transradial	36 (57.1%)	15 (57.7%)	6 (60.0%)	3 (42.9%)	12 (60.0%)
T2DM					
• Transfemoral	15 (55.6%)	5 (50.0%)	0	7 (70.0%)	3 (100.0%)
• Transradial	25 (39.7%)	7 (26.9%)	4 (40.0%)	3 (42.9%)	11 (55.0%)
Hx of HTN					
• Transfemoral	26 (96.3%)	10 (100.0%)	3 (75.0%)	10 (100.0%)	3 (100.0%)
• Transradial	62 (98.4%)	25 (96.2%)	10 (100.0%)	7 (100.0%)	20 (100.0%)
Hx of CAD					
• Transfemoral	20 (74.1%)	8 (80.0%)	4 (100.0%)	5 (50.0%)	3 (100.0%)
• Transradial	49 (77.8%)	17 (65.4%)	10 (100.0%)	6 (85.7%)	16 (80.0%)
Hx of CAD Procedure					
• Transfemoral	10 (37.0%)	5 (50.0%)	1 (25.0%)	2 (20.0%)	2 (66.7%)
• Transradial	32 (50.8%)	9 (34.6%)	8 (80.0%)	4 (57.1%)	11 (55.0%)

Data are mean (std) or count (%). CAD, coronary artery disease; HTN, hypertension; T2DM, type 2 diabetes mellitus.

RESULTS

Objectives

- All procedures (n=90) resulted in clinical success as displayed in **Table 3**.
- The arteries successfully revascularized according to Rutherford Classification are presented in **Table 4.**
- The procedure time, fluoroscopy time, and time to discharge for all Rutherford Classification groups are listed in **Table 5.**
- **Table 6** demonstrates only one complication was noted in the transfemoral group, which was an access site bleed that was classified as BARC Type 1 and did not require transfusion.

Table 3: Primary Objective- Success Rate

Rutherford Grade	Grade 3-6	*Grade 3*	Grade 4	Grade 5	Grade 6
Success Rate					
• Transfemoral	27 (100%)	10 (100%)	4 (100%)	10 (100%)	3 (100%)
• Transradial	63 (100%)	26 (100%)	10 (100%)	7 (100%)	20 (100%)

Table 4: Revascularized Arteries According to Rutherford Classification

	Grade 3		Grade 4		Grade 5		Grade 6	
	Trans-femoral (n=10)	Trans-radial (n=26)	Trans-femoral (n=4)	Trans-radial (n=10)	Trans-femoral (n=10)	Trans-radial (n=7)	Trans-femoral (n=3)	Trans-radial (n=20)
Common Femoral Artery	2	5	0	0	0	1	0	2
Anterior Tibial Artery	1	1	0	1	6	4	1	6
Superficial Femoral Artery	7	16	4	4	4	3	1	13
Peroneal Artery	0	0	0	2	4	0	1	10
Common Iliac Artery	2	5	1	5	0	1	0	0
Popliteal Artery	2	4	1	2	6	3	1	6
Posterior Tibial Artery	0	0	0	0	0	2	3	3
Dorsalis Pedis Artery	0	1	0	0	2	0	1	1

RESULTS

Table 5: Secondary Objectives- Procedure Time, Fluoroscopy Time, and Time to Discharge

Rutherford Grade	Grade 3-6		Grade 3		Grade 4		Grade 5		Grade 6	
	Trans-femoral (n=27)	*Trans-radial (n=63)*	*Trans-femoral (n=10)*	*Trans-radial (n=26)*	*Trans-femoral (n=4)*	*Trans-radial (n=10)*	*Trans-femoral (n=10)*	*Trans-radial (n=7)*	*Trans-femoral (n=3)*	*Trans-radial (n=20)*
Procedure Time (min)										
Mean (std)	85.2	84.5	59.5	64.2	67.5	83.5	107.0	85.7	121.7	110.9
Median (IQR)	75.0	75.0	60.0	62.5	70.0	87.5	115.0	90.0	110.0	90.0
Range (min, max)	(15.0, 180.0)	(10.0, 240.0)	(15.0, 90.0)	(10.0, 140.0)	(55.0,7 5.0)	(40.0, 120.0)	(50.0, 180.0)	(25.0, 160.0)	(100.0, 155.0)	(55.0, 240.0)
Fluoroscopy Time (min)										
Mean (std)	29.4	30.3	15.6	20.9	24.0	36.3	43.1	29.6	37.3	40.0
Median (IQR)	21.9	25.7	14.7	18.6	16.6	37.0	46.1	24.1	39.5	36.4
Range (min, max)	(6.7, 78.3)	(9.5, 87.8)	(6.7, 23.3)	(9.5, 46.9)	(15.0, 47.7)	(18.1, 50.5)	(15.0, 78.3)	(14.8, 67.9)	(29.2, 43.1)	(17.2, 87.8)
Time to Discharge (hr.)										
Mean (std)	42.4	56.5	9.1	5.2	13.0	47.8	79.1	96.5	70.2	113.4
Median (IQR)	11.6	6.6	7.4	5.4	11.6	17.4	27.1	11.3	51.7	88.8
Range (min, max)	(3.8, 253.2)	(2.8, 402.0)	(3.8, 22.4)	(2.8, 7.1)	(4.3, 24.7)	(4.4, 316.0)	(5.0, 253.2)	(4.9, 402.0)	(7.7, 151.3)	(5.9, 342.2)

Table 5: Secondary Objectives- Complications

	All (n=90)	Transfemoral (n=27)	Transradial (n=63)
Complications	1	1*	0

*BARC Type 1 access site bleed; Rutherford Classification3

CONCLUSIONS

- Despite the severity PAD (Rutherford Grade 4-6), a transradial approach for peripheral revascularizations is a comparative alternative to transfemoral.
- Findings from this analysis demonstrate that utilizing transradial access has similar efficacy and safety for successful peripheral revascularizations compared to transfemoral access, even in patients with minor tissue loss, ulceration, or gangrene.

DISCLOSURES

- This study was funded by Terumo Medical Corporation.
- I.A. has consulted with Terumo Medical Corporation and Cardiovascular Systems, Inc.
- No other disclosures are noted.

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