

Efficacy And Safety Of MáLEI (Minimal Arterial Access Lower Extremity Intervention) Using Peripheral Orbital Atherectomy

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INTRODUCTION

- Atherosclerotic cardiovascular disease (ASCVD) commonly presents due to plaque formation within the infrarenal abdominal aorta, iliac, and/or intrainguinal arteries, resulting in peripheral arterial disease (PAD)¹.
- Plaque formation can be dangerous when calcified due to the association of calcification with arterial stiffness and increased risk for adverse cardiovascular events.
- Transfemoral access is the most common access used for peripheral procedures due to their high success rate, however, due to an increased risk for complications and extended length of hospital stay post-revascularization, it can be undesirable and costly to patients².
- The introduction of transradial access for revascularization has provided a novel interventional strategy for peripheral revascularization procedures and most notably introduces the possibility of using a single access site to treat bilateral lesions in the same procedure³.
- Traditionally, transradial access has been avoided due to concern for serious complications and preferred for patients with factors that limit transfemoral access, such as obesity, heavily calcified femoral arteries or absence of femoral pulses⁴.
- Clinical studies have shown a decrease in access site related complications with transradial access compared to the transfemoral approach⁵.
- Sheaths longer in length have been developed specifically for peripheral procedures.
- The overall efficacy and safety of transradial with or without transpedal access among patients receiving peripheral revascularization, such as atherectomy is unknown.
- This study will evaluate these factors for transradial with or without transpedal access in patients with mild to severe PAD and who have been treated with at least one peripheral atherectomy.

METHODS

Design Overview

- 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 peripheral orbital atherectomy procedure from July 1, 2018 through June 30, 2019

Exclusion Criteria

- There are no exclusion criteria.

OBJECTIVES

Primary Study Objective

- The primary objective of this study is to evaluate the clinical success of peripheral orbital atherectomy procedures with radial access with or without pedal access.

Secondary Study Objective

- The secondary objectives of this study are to assess the acute complications of peripheral orbital atherectomy procedures via radial access with or without pedal access with regards to:
 - Hematomas, pseudoaneurysm, radial aneurysm, asymptomatic radial artery thrombosis, RP bleed, embolization, access site bleed, and perforation

Primary Study Outcome

- The primary outcome of this study is clinical success defined as the total number of successful transradial with or without transpedal access peripheral orbital atherectomy procedures without conversion to transfemoral access.

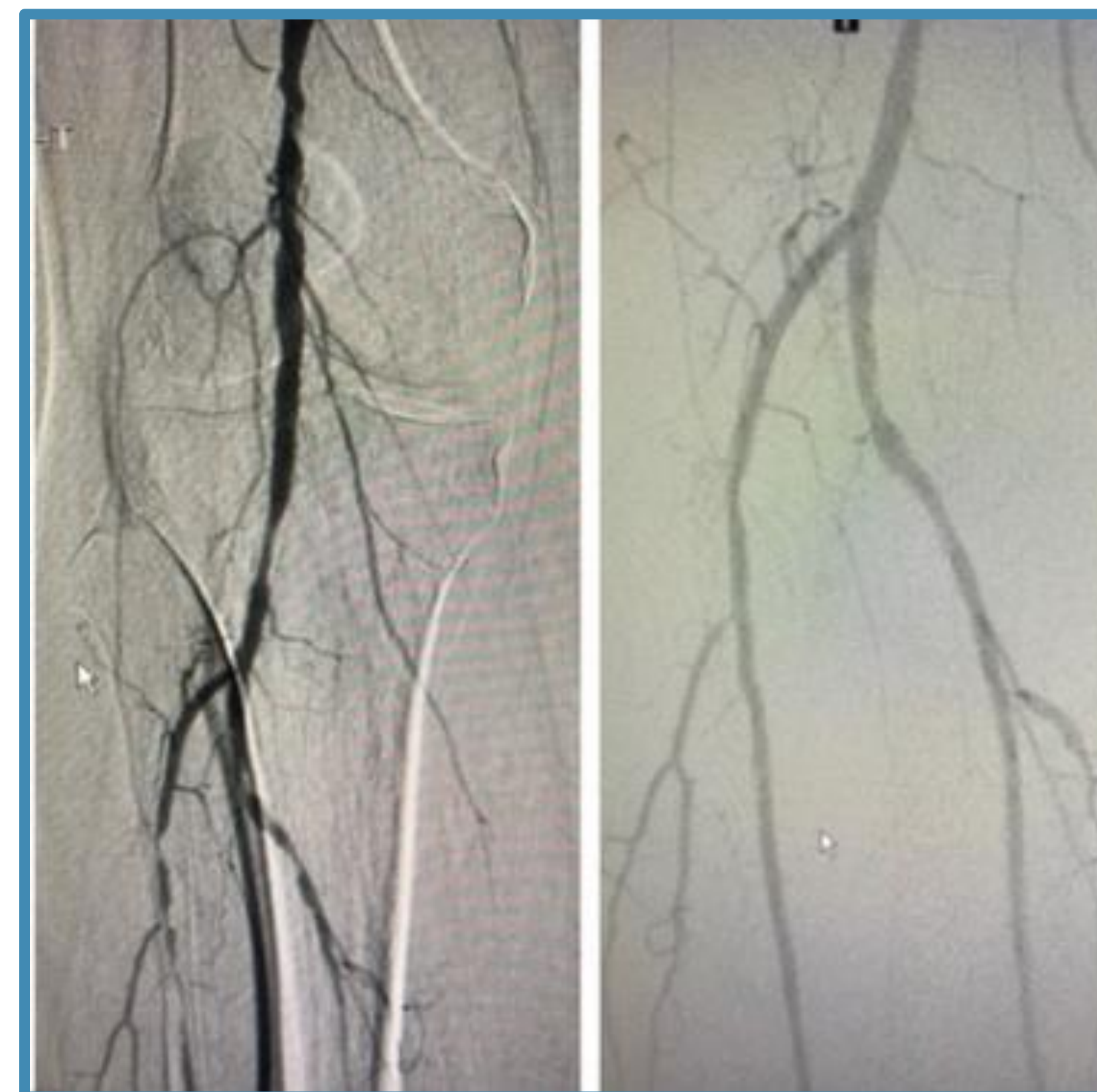
Secondary Study Outcomes

- The secondary outcomes of this study are complication rates for the following over 30 days post-procedure:
 - Hematomas, pseudoaneurysm, radial aneurysm, asymptomatic radial artery thrombosis, RP bleed, embolization, access site bleed, and perforation

RESULTS

Patients

- Forty-seven patients, ages 44 to 91, underwent a transradial peripheral atherectomy from July 1, 2018 through June 30, 2019.
- Baseline characteristics are shown in **Table 1** and **Table 2**
- The arteries successfully revascularized are presented in **Table 3**.



High-grade lesions in the left popliteal, left anterior tibial, and left posterior tibial arteries treated with 1.25 mm solid crown orbital atherectomy.

RESULTS

Table 1: Baseline Characteristics

	Mean (std)	Median (IQR)	Range (min, max)
Age (years)	72.5 (10.5)	72.8 (65.5, 81.3)	(44.9-91.3)
Weight (kg)	80.6 (16.9)	82.0 (67.0, 94.0)	(46.0, 108.0)
Height (cm)	169.6 (10.8)	167.0 (160.0, 180.0)	(152.0, 187.0)

Table 2: Additional Baseline Characteristics

		Count (%)
Sex	Male	26 (55.3%)
	Female	21 (44.7%)
Glycemic Status	Non-Diabetic	23 (48.9%)
	Type 1 Diabetes	4 (8.5%)
	Type 2 Diabetes	20 (42.6%)
HTN Hx	No	1 (2.1%)
	Yes	46 (97.9%)
Smoking Status	Current Smoker	5 (10.6%)
	Former Smoker	22 (46.8%)
	Never Smoker	20 (42.6%)
CAD Hx	No	9 (19.1%)
	Yes	38 (80.9%)
Rutherford Classification	Severe Claudication (Rutherford Grade 3)	22 (46.8%)
	Ischemic Rest Pain (Rutherford Grade 4)	6 (12.8%)
	Minor Tissue Loss (Rutherford Grade 5)	6 (12.8%)
	Ulceration or Gangrene (Rutherford Grade 6)	13 (27.7%)
	Staged Procedure	Yes
	No	44 (93.6%)
Access Site Location	Left	45 (97.8%)
	Right	1 (2.2%)
Secondary Access Sites	Anterior Tibial	3 (43%)
	Posterior Tibial	4 (57%)

CAD, coronary artery disease; HTN, hypertension; Hx, history

Table 3: Revascularized Artery Breakdown

Revascularized Artery	Location	Count (%)
Common Femoral Artery	Left	2 (4%)
	Right	3 (6%)
Anterior Tibial Artery	Left	5 (11%)
	Right	1 (2%)
Superficial Femoral Artery	Left	15 (32%)
	Right	12 (26%)
Peroneal Artery	Left	3 (6%)
	Right	3 (6%)
Common Iliac Artery	Left	2 (4%)
	Right	2 (4%)
Popliteal Artery	Left	7 (15%)
	Right	4 (9%)
Posterior Tibial Artery	Left	1 (2%)
	Right	3 (6%)
Other	Left	2 (4%)
	Right	4 (9%)

RESULTS

Objectives

- All procedures (n=47) resulted in clinical success as displayed in **Table 4**.
- The procedure time, fluoroscopy time, and time to discharge are displayed in **Table 5**.

Table 4: Primary Objective- Success Rate

	Procedures completed (n=47)
Success Rate	47 (100%)

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

Time Per Number Of Vessels Revascularized Per Procedure	Mean (std)	Median (IQR)	Range (min, max)
Total Procedure Time (min)			
All Revascularizations	76.6 (27.3)	70.0 (60.0, 90.0)	(25.0, 160.0)
1 Vessel Revascularized	78.9 (32.7)	70.0 (60.0, 95.0)	(25.0, 160.0)
2 Vessels Revascularized	70.4 (14.3)	67.5 (60.0, 85.0)	(45.0, 90.0)
3 Vessels Revascularized	81.3 (17.5)	82.5 (67.5, 95.0)	(60.0, 100.0)
Total Fluoroscopy Time (min)			
All Revascularizations	28.3 (15.0)	24.1 (16.8, 36.4)	(9.5, 73.5)
1 Vessel Revascularized	28.3 (15.8)	23.8 (16.8, 36.4)	(9.5, 73.5)
2 Vessels Revascularized	23.2 (7.6)	23.1 (16.6, 25.7)	(13.7, 42.5)
3 Vessels Revascularized	46.3 (18.4)	45.6 (32.8, 59.7)	(24.9, 68.9)
Time to Discharge (hr.)			
All Revascularizations	55.3 (98.7)	6.5 (4.7, 47.5)	(2.8, 402.0)
1 Vessel Revascularized	42.7 (76.4)	5.8 (4.7, 21.4)	(2.8, 316.0)
2 Vessels Revascularized	65.8 (131.1)	9.1 (4.7, 28.4)	(3.6, 402.0)
3 Vessels Revascularized	110.0 (120.1)	85.3 (14.9, 205.1)	(5.4, 264.0)

Secondary Objectives

- No complications occurred in the 47 patients.

CONCLUSIONS

- For patients with severe PAD (Rutherford Grade 3-6), utilizing a MáLEI-transradial approach for peripheral atherectomies is a safe alternative to the transfemoral method.
- Findings from this analysis demonstrate that performing orbital atherectomies in the lower extremities is an efficacious and safe method with minimal complications.

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DISCLOSURES

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