Outcomes of endovascular treatment of patients with intermittent claudication due to femoropopliteal disease

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Abstract

Objective: Our objective was to evaluate the outcomes of endovascular treatment in patients with moderate and severe claudication due to femoropopliteal disease, that is, disease of the superficial femoral and popliteal arteries.

Methods: A retrospective review of all patients with moderate and severe claudication (Rutherford 2 and 3) undergoing endovascular treatment for FP disease between January 2012 and December 2017 at two university-affiliated hospitals was performed. All procedures were performed by vascular surgeons. Primary outcomes were mortality, freedom from reintervention, major adverse limb events defined as major amputations, open surgical revascularization, or progression to chronic limb-threatening ischemia (CLTI) at 30 days, 1 year, 2 years, and last follow-up. Unadjusted odds ratios were calculated to identify variables associated with adverse outcomes, and Kaplan–Meier survival curves were used to determine mortality and freedom from reintervention.

Results: Eighty-five limbs in 74 patients were identified on review. Mean age was 69.6 ± 9.8 years and 74.3% were males. At a median follow-up of 49.0 ± 25.5 months, all-cause mortality rate was 8.1% (6 patients) with 16.7% being due to cardiovascular causes. Reintervention rates were 1.2%, 16.5%, and 21.2% at 30 days, 1 year, and 2 years, respectively. Major adverse limb events occurred in 3 patients and rates were 0%, 1.2%, and 2.4% at 30 days, 1 year, and 2 years, respectively. Progression to CLTI was 0%, 1.2%, and 1.2% at 30 days, 1 year, and 2 years, respectively. Claudication had improved or resolved in 55.6% (n = 34 patients), stable in 38.9% (n = 21 patients), and worse in 5.6% (n = 3 patients) Age ≥ 70 years (OR = 4.09 (1.14–14.66), p = 0.027), TASCII A lesion (OR = 4.67 (1.14–19.17), p = 0.025), and presence of 3-vessel runoff (OR = 3.70 (1.18–11.59), p = 0.022) predicted symptoms’ improvement. TASCII A lesions were less likely to require reintervention (OR = 0.23 (0.06–0.86), p = 0.020). Reintervention within 1 year (OR = 11.67 (0.98–138.94), p = 0.017), reintervention with a stent (OR = 14.40 (1.19–173.67), p = 0.008) and more than one reintervention (OR = 39.00 (2.89–526.28), p < 0.001) predicted major adverse limb events.

Conclusions: Careful patient selection is important when planning endovascular treatment in patients with intermittent claudication and FP disease. This could result in symptomatic improvement in more than half of the patients. Adverse outcomes such as major adverse limb events, progression to CLTI, and amputations occur at low rates.

Keywords
claudication, endovascular, revascularization, outcomes

Introduction

It is estimated that peripheral arterial disease (PAD) affects 200 million individuals worldwide.¹ Symptomatic PAD most commonly manifests with intermittent claudication (IC) and has a relatively benign prognosis compared to the more severe chronic limb-threatening ischemia (CLTI).² It is an important marker and predictor of adverse cardiovascular morbidity and mortality.³⁻⁵ Guidelines recommend
optimal medical therapy (OMT) with antiplatelet agents, statins, and risk factors modification in all patients with PAD to reduce adverse cardiovascular events. Moreover, supervised exercise therapy (SET) is recommended as adjunct therapy for patients with IC. Serious challenges exist in both availability and accessibility of SET even in high-income countries. Revascularization through endovascular treatment (ET) in patients with IC can provide improvement for those with disabling symptoms. There are concerns about progression to CLTI and increased risk of limb loss as a result of the procedure. Our objective was to evaluate whether ET in patients with moderate and severe IC due to femoropopliteal (FP) disease results in increased adverse limb outcomes.

Methods

Study design

We conducted a retrospective review of all patients with moderate and severe IC resulting from FP disease undergoing ET between January 2012 and December 2017. This took place in two tertiary care university-affiliated health centers in Montreal, Quebec, Canada. Patients presenting with moderate or severe IC defined as Rutherford 2 and 3 grade, respectively, associated with FP disease on computerized tomography, magnetic resonance, angiography, or duplex ultrasonography were included. If a patient underwent ET in both legs, each leg was analyzed independently. Patients with CLTI, concomitant aorto-iliac, common femoral, and/or tibial vessel procedures were excluded. Necessary ethics approval was obtained through centralized research ethical board reviews. Demographic data and anatomical data were collected from each institute’s electronic health records. All angiograms were evaluated by the first author (senior vascular surgery resident) and an attending vascular surgeon. In addition, noninvasive vascular laboratory results were retrieved from our standard postoperative surveillance protocol records which is ankle-brachial index (ABI) and arterial duplex at 6 weeks postoperatively, ABI and arterial duplex every 4 months for 1 year, and then ABI and arterial duplex every 6 months thereafter. Time to intervention was defined as time from diagnosis of IC to ET. Primary outcomes were mortality, reintervention rates, major adverse limb event (MALE) (defined as major amputation or open surgical revascularization), Major adverse cardiovascular events (MACE; defined as nonfatal myocardial infarctions, nonfatal stroke, or cardiac-related deaths), minor amputations and progression to CLTI (defined as ischemic rest pain, or tissue loss). Secondary outcomes included adherence to OMT, improvement in symptoms defined as subjective reduction in pain with walking or increased walking endurance, factors associated with symptom improvement, factors associated with reintervention, and factors associated with MALE.

Results

Eighty-five limbs in 74 patients were identified on review (Figure 1). Mean age of the population was 69.6 ± 9.8 years, and 74.3% were males. The most commonly encountered comorbidities were hypertension (74.3%), dyslipidemia (67.6%), and history of smoking (66.2%) (Table 1). Lesions were characterized as TASC II A in 29.8%, B in 46.4%, and C in 23.8%. There were no TASCII D lesions treated. Forty-three patients (51.2%) were treated with a stent in their index procedure. The stents used were bare metal nitinol stents. Sizing was done via preoperative CT measurements, intraoperatively visual estimation or use of the hybrid room software. For patients who needed a stent as an adjunct to plain balloon angioplasty (PBA), the stent used was 1 mm larger than the balloon, that is, 6 mm stent post 5 mm PBA. One patient was treated with a drug-coated balloon (DCB). No patients received treatment with an atherectomy device. Intravascular ultrasound is not available in our practice (Table 2).

Figure 1. Results of retrospective review through 897 patients undergoing ET between January 2012–December 2017.
Table 1. Characteristics of patients undergoing ET for intermittent claudication.

| Characteristic                          | Value                                      |
|-----------------------------------------|--------------------------------------------|
| Mean age in years, mean (SD)            | 69.6 (9.8), range = 53–91                 |
| Sex, % (n)                              | Male 74.3% (n = 55/74)                     |
|                                        | Female 25.7% (n = 19/74)                  |
| Comorbidities, % (n)                    | Hypertension 74.3% (n = 55/74)            |
|                                        | Diabetes mellitus 35.1% (n = 26/74)       |
|                                        | History of smoking 66.2% (n = 49/74)      |
|                                        | Dyslipidemia 67.6% (n = 50/74)            |
|                                        | Coronary artery disease 29.7% (n = 22/74) |
|                                        | Stroke 16.2% (n = 12/74)                  |
|                                        | Chronic kidney disease 1.2% (n = 1/74)    |
|                                        | Active or previous cancer 14.9% (n = 11/74)|
|                                        | Severe comorbidities a 59.5% (n = 44/74)  |
| Rutherford classification, % (n)        | II 3.6% (n = 3/84)                         |
|                                        | III 96.4% (n = 81/84)                     |
| Previous revascularization, % (n)       | Ipsilateral 2.4% (n = 2/84)               |
|                                        | Contralateral 14.3% (n = 12/84)           |
| Medications, % (n)                      | Antiplatelet 68.9% (n = 51/74)            |
|                                        | Statin 64.9% (n = 48/74)                  |
|                                        | Anti-hypertensive 81.8% (n = 45/55)       |
|                                        | Anti-diabetic 65.4% (n = 17/26)           |
|                                        | OMT b 23.0% (n = 17/74)                   |

a Defined as presence of three of the following: hypertension, diabetes mellitus, dyslipidemia, coronary artery disease, and stroke.
bOMT: optimal medical therapy defined as use of antiplatelets, statin, and non-smoking.

Table 2. Anatomical and ET procedure details.

| TASC II Classification, % (n)          | Location                                      |
|----------------------------------------|-----------------------------------------------|
| A                                      | Proximal SFA 19% (n = 16/84)                 |
| B                                      | Mid SFA 45.2% (n = 38/84)                    |
| C                                      | Distal SFA 70.2% (n = 59/84)                 |
| D                                      | Above-knee popliteal 16.7% (n = 14/84)       |
|                                        | Below-knee popliteal 2.4% (n = 2/84)         |
| Infra-popliteal runoff, % (n)          | 3 vessels 46.2% (n = 40/83)                  |
|                                        | 2 vessels 37.3% (n = 31/83)                  |
|                                        | 1 vessel 14.1% (n = 12/83)                   |
| Primary procedure type, % (n)          | Plain balloon angioplasty (PBA) 95.2% (n = 80/84)|
|                                        | Drug-coated balloon (DCB) 1.2% (n = 1/84)    |
|                                        | Stent 3.6% (n = 3/84)                        |
| Angiogram findings, % (n)              | Subintimal recanalization 37.8% (n = 31/82)  |
|                                        | Residual stenosis 51.9% (n = 42/81)          |
|                                        | Vessel dissection 38.8% (n = 31/80)          |
|                                        | Embolization 3.8% (n = 3/79)                 |
| Adjunct procedure required, % (n)      | 66.7% (n = 56/84)                            |
| Adjunct procedure type, % (n)          | PBA 21.4% (n = 12/56)                        |
|                                        | Stent 76.8% (n = 43/56)                      |
|                                        | Others a 1.8% (n = 1/56)                     |
| Mean stent length used in mm, mean (range) | 162.8 ± 81.1 (37–350)                      |
| Closure device success, % (n)          | 92.4% (n = 73/79)                            |

a Tibioperoneal trunk thrombolysis for embolization.
There were no mortalities recorded up to 2 years. At a median follow-up of 49.0 ± 25.5 months, all-cause mortality rate was 8.1% (6 patients). Figure 2 shows Kaplan–Meier survival estimates for overall survival. Cardiovascular causes accounted for 16.7%. Reintervention rates were 1.2%, 16.5%, and 21.2% at 30 days, 1 year, and 2 years, respectively (Figure 3). MALE occurred in 3 patients and rates were 0%, 1.2%, and 2.4% at 30 days, 1 year, and 2 years, respectively. The first patient’s index ET was an superficial femoral artery (SFA) angioplasty for a TASC II B lesion. Six months later, symptoms recurred with evidence of recurrent stenosis in the SFA and above-knee popliteal segments; this was stented. 2 years elapsed before the SFA stent thrombosed and the patient presented with CLTI grade 4 (rest pain). He underwent a femoral below-knee popliteal bypass. The second patient underwent SFA stenting which occluded 2 months later and presented with rest pain. He underwent a femoral above-knee bypass 10 months post
The third patient had an initial SFA stent for a TASC II C lesion which occluded 15 months later and required angioplasty and stenting. This itself occluded 7 months later and ET was not possible. He underwent a femoral below-knee popliteal bypass 24 months after the index ET.

The rate of progression to CLTI was 0%, 1.2%, and 1.2% at 30 days, 1 year, and 2 years, respectively. Median ABI improvement was 0.11 and 0.29 at 1 year and 2 years, respectively. Claudication had improved or resolved in 55.6% (n = 54 patients), stable in (n = 21 patients), and worse in 5.6% (n = 3 patients) at a median follow-up of 49.0 +/- 25.5 months (Table 3).

Patients with symptomatic improvement had lower mean ABI prior to revascularization (0.58 vs 0.69, p = 0.014) and were more likely to have 3-vessel runoff (69% vs 38%, p = 0.022). Table 4 summarizes differences between the improved and stable/worse symptoms cohorts. Factors associated with improved symptoms were age ≥ 70 years (OR = 4.09 (1.14–14.66), p = 0.027), a TASC II A lesion (OR = 4.67 (1.14–19.17), p = 0.025), and presence of 3-vessel runoff (OR = 3.70 (1.18–11.59), p = 0.022). Medical comorbidities and adherence to OMT did not predict symptoms’ improvement (Table 5).

Patients undergoing ET for TASCII A lesions were less likely to require reintervention (OR = 0.23 (0.06–0.86), p = 0.020). Factors such as age, sex, comorbidities profile, and adherence to OMT did not predict reinterventions (Table 6). Moreover, adverse outcomes were more likely to occur in patients requiring reinterventions. Factors such as early reintervention within 1 year (OR = 11.67 (0.98–138.94), p = 0.017), reintervention with a stent (OR = 14.40 (1.19–173.67), p = 0.008), and more than one reintervention (OR = 39.00 (2.89–526.28), p < 0.001) predicted MALE (Table 7).

**Table 3.** Outcomes in claudicants undergoing endovascular procedures for femoropopliteal disease.

| Mortality rate, % (n) | 30 days | 0% |
|-----------------------|---------|----|
| 1 year                | 0%      |
| 2 years               | 0%      |
| Overall               | 8.1% (n = 6/74) |

| Cause of death, % (n) | Cardiovascular | 16.7% (n = 1/6) |
|-----------------------|-----------------|
| Non-cardiovascular    | 66.7% (n = 4/6) |
| Unknown               | 16.7% (n = 1/6) |

| Reintervention rates, % (n) | 30 days | 1.2% (n = 1/85) |
|-----------------------------|---------|
| 1 year                      | 16.5% (n = 14/85) |
| 2 years                     | 21.2% (n = 18/85) |
| More than 2 years           | 29.4% (n = 25/85) |

| Median ABI, Mean ± SD (range) | Preintervention | 0.64 ± 0.16 (0.27–1.00) |
|-------------------------------|-----------------|
| At 1 month                    | 0.95 ± 0.18 (0.48–1.35) |
| At 2 months                   | 0.96 ± 0.16 (0.48–1.14) |
| At 6 months                   | 0.84 ± 0.17 (0.51–1.00) |
| At 12 months                  | 0.75 ± 0.18 (0.42–1.00) |
| At 18 months                  | 0.80 ± 0.20 (0.40–1.02) |
| At 24 months                  | 0.93 ± 0.16 (0.50–0.99) |
| At 60 months                  | 0.85 ± 0.21 (0.68–1.21) |

| Major adverse limb events (MALE), % (n) | 30 days | 0% |
|-----------------------------------------|---------|
| 1 year                                  | 1.2% (n = 1/85) |
| 2 years                                 | 2.4% (n = 2/85) |
| Overall                                 | 3.5% (n = 3/85) |

| Progression to CLTI, % (n) | 30 days | 0% |
|----------------------------|---------|
| 1 year                     | 1.2% (n = 1/85) |
| 2 years                    | 1.2% (n = 1/85) |
| Overall                    | 3.5% (n = 3/85) |

| Minor amputations, % (n) | 30 days | 0% |
|--------------------------|---------|
| 1 year                    | 0%      |
| 2 years                   | 0%      |
| Overall                   | 1.2% (n = 1/85) |

| Median follow up in months, mean ± SD (range) | 49.0 ± 25.5 (0–92.0) |
| Reported symptoms at last vascular follow-up % (n) | Improved or resolved symptoms 55.6% (n = 30/54) |
| Stable                 | 38.9% (n = 21/54) |
| Worse                  | 5.6% (n = 3/54) |

Discussion
This study reflects a contemporary Canadian experience with ET in patients with moderate-to-severe IC at two...
university centers. Our patients’ demographics including age, male predominance, and comorbidity profile were similar to already published randomized and non-randomized trials.11,12 Both the Society for Vascular Surgery and American College of Cardiology/American Heart Association (ACC/AHA) guidelines stress the importance of OMT with antiplatelets, statins, and smoking cessation.2,6 In our cohort, 68.9% of patients were on antiplatelets (aspirin, clopidogrel, or both) and 64.9% were on statins. This seemingly low adherence to OMT is similar to previous larger-scale studies that reported statin use as low as 11%.12,13 When analyzing use of antiplatelets, statins, and non-smoking status, only 23% were considered to be on OMT. SET is an important pillar in management of patients with IC with reported improvement in maximal walking distance, pain-free walking up to 15 months compared to OMT alone.16–18 In our practice, we advise home exercise therapy (HET) for all patients as there are no hospital-associated SET programs available within our province. While lacking the supervision involved in SET, HET has been shown to improve symptoms in a recent network meta-analysis involving 42 trials and 3515 patients.19 All patients are prescribed a single antiplatelet agent preoperatively and postoperatively. Moreover, patients who receive a stent of

| Table 4. Comparison of patients with improved symptoms versus stable or worse symptoms. |
|------------------------------------------|---------------------------|-----------------------------|
| Improved symptoms (n = 30) | Stable or worse symptoms (n = 24) | p value |
| Mean age in years, mean (SD) | 70.0 (10.5) | 66.7 (8.4) | 0.243 |
| Male sex, % | 69% | 75% | 0.667 |
| Mean preintervention ABI, mean (SD) | 0.58 (0.14) | 0.69 (0.15) | 0.014 |
| HTN, % | 73% | 80% | 0.585 |
| DM, % | 42% | 40% | 0.875 |
| Smoking, % | 62% | 65% | 0.809 |
| Dyslipidemia, % | 65% | 85% | 0.133 |
| CAD, % | 27% | 50% | 0.108 |
| Stroke, % | 19% | 10% | 0.388 |
| CKD, % | 4% | 0% | 0.375 |
| Active or previous cancer, % | 8% | 10% | 0.783 |
| Severe comorbidities, %a | 54% | 80% | 0.065 |
| Medications, % | | | |
| Antiplatelet agent | 85% | 75% | 0.415 |
| Statin | 73% | 70% | 0.818 |
| Previous intervention | 0% | 4% | 0.259 |
| TASC II classification, % | A 40% | A 13% | 0.065 |
| | B 40% | B 67% | |
| | C 20% | C 21% | |
| Presence of three vessel runoff, % | 69% | 38% | 0.022 |
| Reintervention within 1 year, % | 13% | 25% | 0.273 |
| Reintervention within 2 years, % | 17% | 38% | 0.083 |
| Mean ABI at 12 months, mean (SD) | 0.74 (0.09) | 0.84 (0.14) | 0.343 |

*aDefined as presence of three of the following: hypertension (HTN), diabetes mellitus (DM), dyslipidemia, coronary artery disease (CAD) and stroke SD: standard deviation; CKD: chronic kidney disease; TASC: Trans Atlantic Inter-Society Consensus.

| Table 5. Unadjusted odds ratio for factors associated with improved symptoms in patients undergoing endovascular treatment. |
|-----------------------------|-----------------------------------------------|-----------------------------------------------|
| Factor | Unadjusted OR (95% CI) | p-value |
| Age ≥ 70 | 4.09 (1.14–14.66) | 0.027 |
| Male sex | 0.75 (0.20–2.78) | 0.667 |
| Severe comorbiditiesa | 0.29 (0.08–1.11) | 0.065 |
| OMTb | 1.80 (0.49–6.55) | 0.373 |
| TASCII A lesion | 4.67 (1.14–19.17) | 0.025 |
| Subintimal recanalization | 0.63 (0.20–1.95) | 0.422 |
| Residual stenosis | 1.13 (0.38–3.38) | 0.829 |
| Vessel dissection | 0.89 (0.30–2.66) | 0.829 |
| Use of stent in index ET | 1.10 (0.38–3.26) | 0.854 |
| 3-Vessel runoff | 3.70 (1.18–11.59) | 0.022 |
| Reintervention | 1.27 (752–2.15) | 0.349 |
| Time to intervention > 12 weeks | 1.68 (1.08–2.62) | 0.065 |

*Defined as presence of three of the following: hypertension, diabetes mellitus, dyslipidemia, coronary artery disease, and stroke.

bOMT: optimal medical therapy defined as use of antiplatelets, statin, and non-smoking.

ET: endovascular treatment; CI: confidence intervals
Table 6. Unadjusted odds ratio for factors associated with reintervention in patients undergoing endovascular treatment.

| Factor                        | Unadjusted OR (95% CI) | p-value |
|-------------------------------|------------------------|---------|
| Age ≥ 70                      | 0.93 (0.33–2.59)       | 0.887   |
| Male sex                      | 0.74 (0.24–2.32)       | 0.604   |
| Severe comorbidities*         | 2.59 (0.82–8.13)       | 0.098   |
| OMT*                          | 1.27 (0.36–4.48)       | 0.711   |
| TASCII A lesion               | 0.23 (0.06–0.86)       | 0.020   |
| 3-Vessel runoff               | 0.62 (0.24–1.61)       | 0.327   |
| Use of stent in index ET      | 1.11 (0.38–3.26)       | 0.854   |

ET: endovascular treatment; CI: confidence intervals
*Defined as presence of three of the following: hypertension, diabetes mellitus, dyslipidemia, coronary artery disease, and stroke.
*OMT: optimal medical therapy defined as use of antiplatelets, statin, and non-smoking.

Table 7. Unadjusted odds ratio for factors associated with major adverse limb events in patients undergoing endovascular treatment.

| Factor                        | Unadjusted OR (95% CI) | p-value |
|-------------------------------|------------------------|---------|
| TASCII A or B                 | 7.00 (0.60–81.68)      | 0.076   |
| No 3-vessel runoff            | 1.90 (0.17–21.83)      | 0.600   |
| Vessel dissection             | 1.60 (0.10–26.55)      | 0.741   |
| Adjunct intervention in index OR | 1.00 (0.09–11.53) | 1.000   |
| Use of stent in index ET      | 1.95 (0.17–22.38)      | 0.585   |
| Reintervention within 1 year | 11.67 (0.98–138.94)    | 0.017   |
| Reintervention with stent     | 14.40 (1.19–173.67)    | 0.008   |
| Multiple reinterventions      | 39.00 (2.89–526.28)    | < 0.001 |

ET: endovascular treatment; CI: confidence intervals.

any kind are discharged on dual antiplatelet agents for 3 months, followed by a lifelong single antiplatelet agent.

Our FP anatomy and distribution of disease were comparable to previous studies with more TASC II A/B than TASC II C/D lesions. Previous studies show that long complex lesions involving below-knee popliteal segments fare worse and have lower patency. In our cohort, only 2.4% of the patients had below-knee popliteal artery involvement.

Intermittent claudication is an important marker of overall cardiovascular health with reported mortality of 10–15% in claudicants at 5 years. Our cohort had no procedure-related mortality, and 8.1% (6 patients) mortality at a median of 49.0 ± 25.5 months (0–92.0). Cardiovascular-related death was identified in one patient where death was due to congestive cardiac failure (16.7%) 6 years after the intervention. Two patients (33.3%) died secondary to lung cancer at 3 years post intervention, one patient with sepsis related to pneumonia 4 years post intervention (16.7%), and one patient with massive hemoptysis (16.7%) 7 years later. A cause could not be determined in the sixth patient who died 3 years post intervention. Overall, 66.7% of the deaths were non-cardiovascular in comparison to 33–57% reported in the literature.

Despite numerous studies examining ET in IC, the balance between improvement in quality of life on one hand and procedure-related complications on the other is unclear. Our cohort had a reintervention rate of 1.2%, 16.5%, and 21.2% at 30 days, 1 year, and 2 years follow-up, which is lower than the 26–49% reintervention rate reported in the literature. A number of factors could contribute to the high reintervention rate in the reported literature including a tendency toward less stent use when the initial indication for revascularization was IC although stenting in FP disease improves primary patency. In our cohort, 46 limbs (54.8%) received stenting in their index procedure. It was primary, that is, intention to stent beforehand, in 6.5% (3 limbs) in comparison to the remainder 93.5% (43 limbs) who had a stent after balloon angioplasty was deemed suboptimal. Factors such as complex FP anatomy (17.9% in our cohort), more extensive subintimal recanalization (37.8%), and post-angioplasty dissection (38.8%) were indications for stenting but the association between intra-op findings and patency could not be ascertained by statistical interrogation in our cohort. These same factors reportedly contribute to reduced patency and increased adverse outcomes and reinterventions.

A DCB was used in one patient with a distal SFA occlusion and severe IC in our cohort. In our institution, DCB and drug-eluting stents are usually reserved for CLI for economic reasons. In our cohort, adverse outcomes occurred in 3 patients and were comparable to larger-scale reports. MALE rates were 0%, 1.2%, and 2.4% at 30 days, 1 year, and 2 years, respectively. This is similar to the 1.6–4% incidence reported with ET.

Progression to CLI was seen in 3.5% of the limbs undergoing ET, which is comparable to the reported natural history of patients with IC without intervention. A 2017 meta-analysis of randomized trials by Pandey et al. did not show an increase in amputations with ET in comparison to OMT and SET. A recently published experience with revascularization for IC by both open surgery and ET showed that patients’ comorbidities determine adverse outcomes such as CLI and MALE. In our cohort that was treated exclusively by ET, we found that anatomical factors rather than patients’ baseline characteristics determined worse outcomes. Symptoms improvement was more likely in patients ≥70 years, TASC II A lesions, and limbs with 3-vessel run-off. Reintervention was less likely with TASC II A lesions, and MALE was more likely in patients with early and multiple reinterventions.

**Limitations**

This is a retrospective, non-randomized study with a small cohort of 85 limbs. It represents a real-world description of
outcomes in a system where SET is not available. There is no validated quality of life outcomes reported in our study.

**Conclusion**

Careful patient selection is important when planning ET in patients with IC and FP disease. This could result in symptomatic improvement in more than half of the patients. Adverse outcomes such as MALE, progression to CLTI, and amputations occur at low rates.

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**References**

1. Fowkes FGR, Rudan D, Rudan I, et al. Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. *Lancet Lond Engl* 2013; 382(9901): 1329–1340.
2. Hirsch AT, Haskal ZJ, Hertzer NR, et al. ACC/AHA 2005 Practice Guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report from the American association for vascular surgery/society for vascular surgery, society for cardiovascular angiography and interventions, society for vascular medicine and biology, society of interventional radiology, and the acc/aha task force on practice guidelines (writing committee to develop guidelines for the management of patients with peripheral arterial disease): endorsed by the american association of cardiovascular and pulmonary rehabilitation; national heart, lung, and blood institute; society for vascular nursing; transatlantic inter-society consensus; and vascular disease foundation. *Circulation* 2006; 113(11): e463–654.
3. de Lemos JA and Kumbhani DJ. Lessons From the Heart. *J Am Coll Cardiol* 2014; 63(15): 1539–1541.
4. Kumbhani DJ, Steg PG, Cannon CP, et al. Statin therapy and long-term adverse limb outcomes in patients with peripheral artery disease: insights from the REACH registry. *Eur Heart J* 2014; 35(41): 2864–2872.
5. Mozaffarian D, Mozaffarian D, Benjamin EJ, et al. Executive summary: heart disease and stroke statistics—2016 update: a report from the American heart association. *Circulation* 2016; 133(4): 447–454.
6. Conte MS, Pomposelli FB, Clair DG, et al. Society for vascular surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: management of asymptomatic disease and claudication. *J Vasc Surg* 2015; 61(3): 2S–41S.
7. Makris GC, Lattimer CR, Lavida A, et al. Availability of supervised exercise programs and the role of structured home-based exercise in peripheral arterial disease. *Eur J Vasc Endovasc Surg* 2012; 44(6): 569–575.
8. Cheetham DR, Burgess L, Ellis M, et al. Does supervised exercise offer adjuvant benefit over exercise advice alone for the treatment of intermittent claudication? A randomised trial. *Eur J Vasc Endovasc Surg* 2004; 27(1): 17–23.
9. Gelin J, Jivegard L, Taft C, et al. Treatment efficacy of intermittent claudication by surgical intervention, supervised physical exercise training compared to no treatment in unselected randomised patients I: one year results of functional and physiological improvements. *Eur J Vasc Endovasc Surg* 2001; 22(2): 107–113.
10. Ahern TM, Kheirelseid EAH, Boland M, et al. Supervised exercise therapy in the management of peripheral arterial disease – an assessment of compliance. *Vasa* 2017; 46(3): 219–222.
11. Pandey A, Banerjee S, Ngo C, et al. Comparative efficacy of endovascular revascularization versus supervised exercise training in patients with intermittent claudication: meta-analysis of randomized controlled trials. *JACC Cardiovasc Inter* 2017; 10(7): 712–724.
12. Soga Y, Yokoi H, Urakawa T, et al. Long-term clinical outcome after endovascular treatment in patients with intermittent claudication due to Iliofemoral artery disease. *Circ J* 2010; 74(8): 1689–1695.
13. Miura T, Soga Y, Miyashita Y, et al. Five-year prognosis after endovascular therapy in claudicant patients with Iliofemoral artery disease. *J Endovasc Ther* 2014; 21(3): 381–388.
14. Aihara H, Soga Y, Mii S, et al. Comparison of long-term outcome after endovascular therapy versus bypass surgery in claudication patients with trans-atlantic inter-society consensus-II C and D Femoropopliteal disease. *Circ J* 2014; 78(2): 457–464.
15. Golledge J, Moxon JV, Rowbotham S, et al. Risk of major amputation in patients with intermittent claudication undergoing early revascularization. *Br J Surg* 2018; 105(6): 699–708.
16. Gardner AW and Poehlman ET. Exercise rehabilitation programs for the treatment of claudication pain. A meta-analysis. *JAMA* 1995; 274(12): 975–980.
17. Leng GC, Fowler B and Ernst E. Exercise for intermittent claudication. *Cochrane Database Syst Rev* 2000; 2: CD000990.
18. Stewart KJ, Hiatt WR, Regensteiner JG, et al. Exercise training for claudication. *N Engl J Med* 2002; 347(24): 1941–1951.
19. Thanigaimani S, Phie J, Sharma C, et al. Network meta-analysis comparing the outcomes of treatments for intermittent claudication tested in randomized controlled trials. *J Am Heart Assoc* 2021; 10(9): e019672.
20. O’Brien-Inr MS, Harris LM, Dosluoglu HH, et al. Endovascular intervention for treatment of claudication: is it cost-effective?. *Ann Vasc Surg* 2010; 24(6): 833–840.

21. Schneider PA. Evolution and current use of technology for superficial femoral and popliteal artery interventions for claudication. *J Vasc Surg* 2017; 66(3): 916–923.

22. Tepe G, Zeller T, Albrecht T, et al. Local delivery of paclitaxel to inhibit restenosis during angioplasty of the leg. *N Engl J Med* 2008; 358(7): 689–699.

23. Fakhry F, Spronk S, van der Laan L, et al. Endovascular revascularization and supervised exercise for peripheral artery disease and intermittent claudication: a randomized clinical trial. *JAMA* 2015; 314(18): 1936.