

Background

- Critical Limb Ischemia (CLI) is the most severe form of peripheral artery disease (PAD), leading to limb loss and death.
- Treatment of complex long femoro-popliteal lesions remains a challenge, due to high re-stenosis rates and failure of long-term patency following plain balloon angioplasty and stents.
- Several recent studies have shown favourable results following drug-coated balloon (DCB) angioplasty in shorter femoro-popliteal lesions.
- Most of these studies on DCBs mainly reflect TASC Types A & B lesions with a relative paucity of data on Types C & D lesions.

Objective: To assess clinical outcomes for SFA/Pop TASC Types C & D PAD in patients with CLI using DCBs

Methods

- Single-centre retrospective study, including patients treated for femoro-popliteal disease with Paclitaxel DCBs (Biotronic LUX Passeo, Medtronic IN.PACT, and Bard Lutonix DCBs) from Dec 2012 to Dec 2016.
- Data Collection:
 - Patient age, sex, and comorbidities
 - Treated lesion length, Rutherford classification, Lesion type (de novo, recurrent, in-stent stenosis), Multilevel disease (iliac or below-knee intervention)
 - Repeat interventions, bypass surgery, amputations, death within 18 months of original DCB intervention

- Exclusions:
 - Major Adverse Limb Event (MALE) or death in 30d



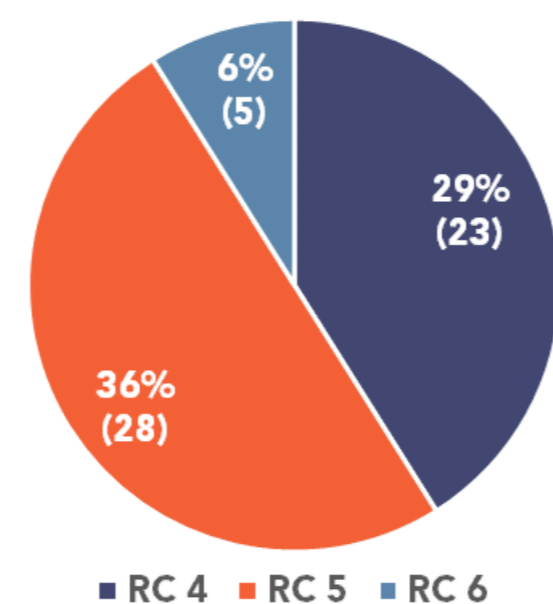
- Outcomes:
 - Primary: Freedom from TLR (defined as no bypass or re-intervention) within 18-months
 - Secondary: Major amputation (ATK/BTK), Death

Results

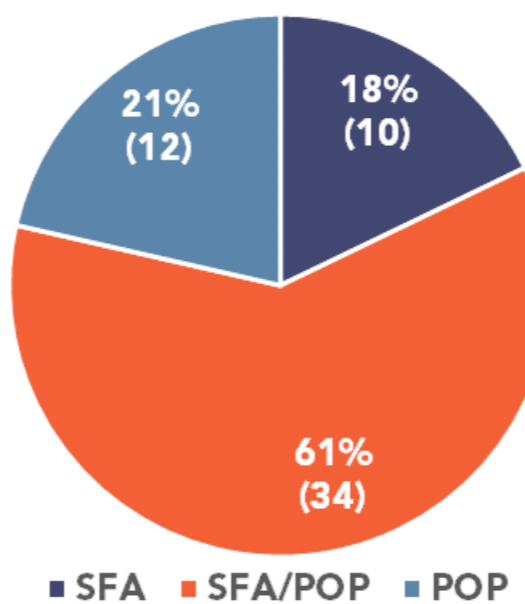
Characteristics of CLI Cohort by Rutherford Classification

	Total (56)	RC 4 (23)	RC 5 (28)	RC 6 (5)
Hypertension	44 (79%)	17 (74%)	23 (82%)	4 (80%)
Diabetes	41 (73%)	15 (65%)	23 (82%)	3 (60%)
Heart Disease	31 (55%)	9 (39%)	19 (69%)	3 (60%)
Kidney Disease	15 (27%)	4 (17%)	7 (25%)	4 (80%)
Current/Past Smoker	40 (71%)	21 (91%)	17 (61%)	2 (40%)
Multilevel Disease	44 (79%)	15 (65%)	25 (89%)	4 (80%)
Mean Treated Lesion Length (cm)	19.0	17.8	19.8	19.4

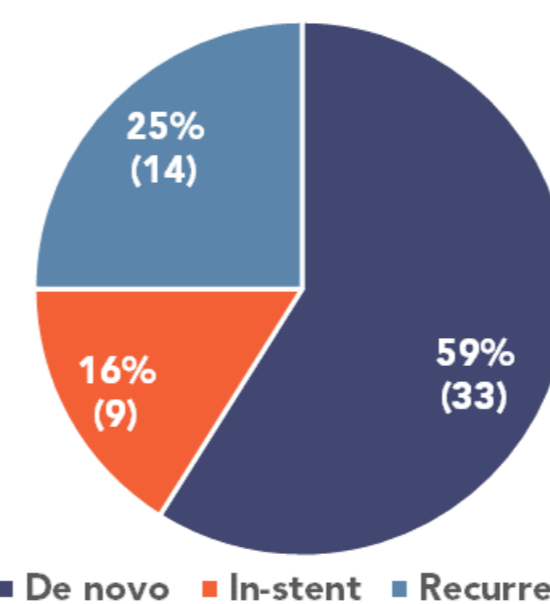
Cohort by Rutherford Class



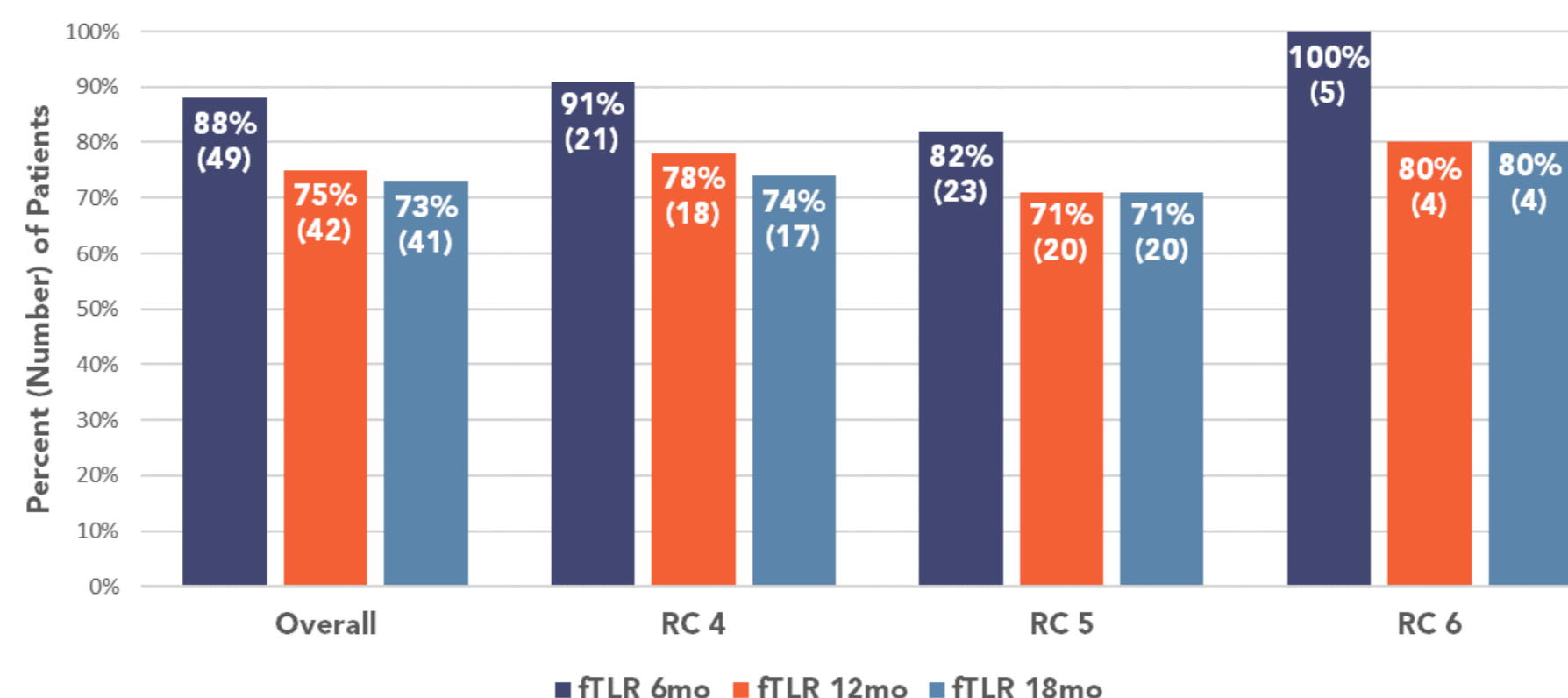
Cohort by Lesion Location



Cohort by Lesion Type



Freedom from TLR at 6, 12, and 18mo for All CLI Patients by Rutherford Class



Results

- The average patient age was 70 ± 10 years.
- The average treated lesion length was 19 ± 6 cm.
- 79% had multilevel disease.
- 55% had infrapopliteal disease.
- 43% required other intervention simultaneously.

Primary Outcomes: At 18-months, 25% of patients had reintervention, 5% had a bypass surgery. Freedom from TLR at 18-months was 73%.

Secondary Outcomes: At 18-months, 1 (2%) patient required a major amputation, 11 (20%) deaths occurred in this cohort within 18mo after the procedure, mostly attributable to stroke, cancer, or coronary artery disease.

Discussion

- In our experience, we had a cohort of elderly patients with complex femoro-popliteal lesions with multilevel disease, which is common in real-world practice.
- These patients are not suitable for surgical bypass, the currently accepted treatment for CLI.
- Several trials and studies are working to find an ideal solution for this problem.

Conclusions: Freedom from TLR at 18mo in a complex cohort of patients with Critical Limb Ischemia from this single-centre experience was 73%.

DCBs have a role in treating complex fem-pop lesions in patients with multiple comorbidities who are poor surgical candidates.

- Limitations:**
- TLR as crude assessment of follow-up
 - Absence of some records of outcomes
 - Single centre study