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 restenosis 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 Passao, 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

Results

<table>
<thead>
<tr>
<th>Characteristics of CLI Cohort by Rutherford Classification</th>
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<tbody>
<tr>
<td>Total (56)</td>
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<tr>
<td>Hypertension</td>
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<tr>
<td>Diabetes</td>
</tr>
<tr>
<td>Heart Disease</td>
</tr>
<tr>
<td>Kidney Disease</td>
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<tr>
<td>Current/Past Smoker</td>
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<tr>
<td>Multilevel Disease</td>
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<tr>
<td>Mean Treated Lesion Length (cm)</td>
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- 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