

INTRODUCTION

- Peripheral arterial disease (PAD) manifests itself clinically as intermittent claudication or more severely as critical limb ischemia (CLI).
- The treatment approaches include conservative management, medical management, endovascular and surgical interventions.
- The optimal treatment for PAD has not yet been determined. Bare-metal stents (BMS) have reported superior results over plain balloon angioplasty, however the implantation of long stents has an increased incidence of in-stent restenosis and occlusion, which is challenging to treat.
- Drug-coated balloons (DCB) have been reported to have superior results over plain balloon angioplasty in several recent studies. However, evidence in the literature comparing their performance against BMS is limited.
- The purpose of this study is to compare Freedom from Target Lesion Revascularization (TLR) in femoropopliteal disease using DCB versus BMS at 1, 2 and 3 years follow up.**

METHODOLOGY

We have designed a retrospective, single centre study comparing the efficacy of DCB with BMS in treating symptomatic femoropopliteal disease. Patient characteristics such as age, gender, hypertension, diabetes, smoking status and hyperlipidemia were documented. We also documented lesion length, location, TASC, Rutherford classification and multi-level disease.

For this study, patients were followed in Meditech, a computer program at our centre that stores imaging, procedural and clinic visit information. Patient follow up clinic visits to the vascular surgeon were documented along with any open surgery or subsequent endovascular therapy after their initial intervention for CLI.

Primary outcome is Freedom from target lesion revascularization (TLR) in patients who underwent treatment of femoropopliteal disease at 1, 2, and 3 years. **Secondary outcomes** are major events such as above or below the knee amputation or death.

Statistical Analysis

- Baseline characteristics between the groups were compared using analysis of variance for continuous data or a chi-square test for categorical data.
- Propensity scores were built through a binary logistic regression using baseline covariates (CLI, TASC C+D, multifocal disease, popliteal involvement and prior stenosis) in order to adjust for any measured differences.
- Threshold for statistical significance was $p < 0.05$
- Deaths were excluded as they were considered competing risks.

RESULTS

We identified 401 patients treated for symptomatic, femoropopliteal disease (Rutherford ≥ 3) between December 2009 and December 2015.

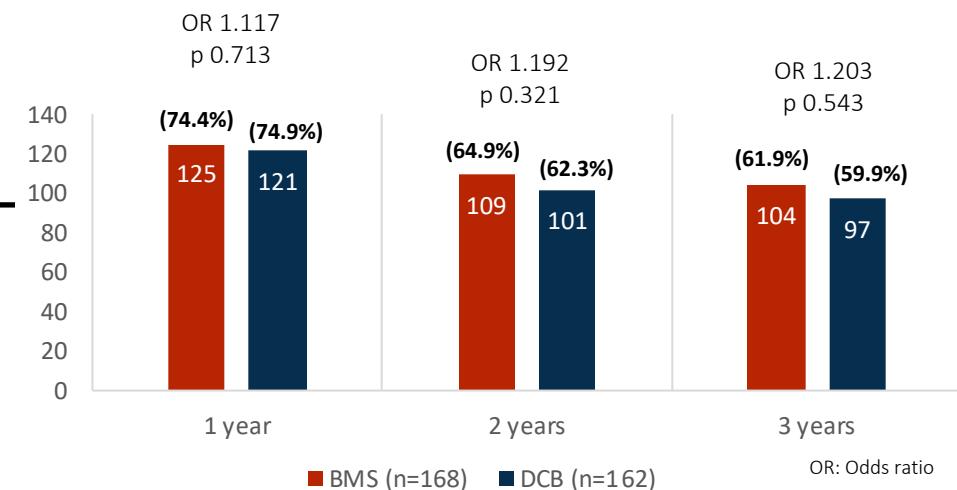
- In the BMS cohort, 31 (15.4%) died within the first two years and 2 (1%) in the third year, leaving 168 (67 +/- 10.4 years, 132 male) in the BMS cohort.
- In the DCB cohort, 38 (19%) died in the first two years and 0 (0%) in the third year, leaving 162 (67 +/- 9.6 years, 96 male) in the DCB cohort.

Patient Characteristics	BMS (n=168)	DCB (n=162)	p value
Hypertension	128 (76.2%)	131 (80.9%)	0.349
Hyperlipidemia	89 (53.0%)	129 (79.6%)	0.000
Past/current smoker	115 (68.5%)	135 (83.3%)	0.002
Diabetes Mellitus	97 (57.7%)	100 (61.7%)	0.501
Renal insufficiency	34 (20.2%)	52 (32.1%)	0.017
CLI	91 (54.2%)	63 (38.9%)	0.006

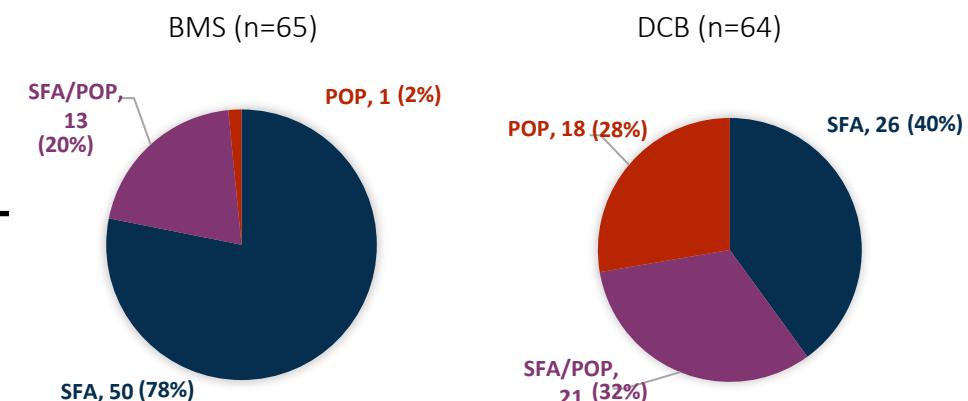
Lesion Characteristics	BMS (n=168)	DCB (n=162)	p value
Lesion length, cm	11.5 (6.8%)	11.92 (7.1%)	0.609
Recurrent/In-stent	4 (2.4%)	40 (24.7%)	0.000
Popliteal involvement	33 (19.6%)	80 (49.4%)	0.000
Total occlusion	58 (34.5%)	47 (29.0%)	0.290
Multilevel Disease	68 (40.5%)	61 (37.7%)	0.652
TASC C+D	59 (35.1%)	62 (38.3%)	0.570

TLR	BMS (n=168)	DCB (n=162)	p value
0 - 12 months	43 (25.6%)	41 (25.3%)	1
12 - 24 months	16 (9.5%)	20 (12.3%)	0.481
24 - 36 months	5 (3.0%)	4 (2.5%)	1

Freedom from TLR at 1, 2 and 3 years



Comparison of TLR at 3 years by Lesion Location



DISCUSSION

Limitations

- TLR is a crude assessment of re-stenosis rates
- Non-randomized study: operators chose which modality to use
- Limited access to some health records

Future Directions

- Survival analysis
- Risks of mortality of using Paclitaxel coated devices
- Analysis of TASC C+D

Conclusions

The results from our experience show no statistical difference between rates of restenosis in DCB and BMS in symptomatic femoropopliteal disease. DCB provides the freedom to treat without permanently implanting stents and has a role in the treatment of complex lesions specifically involving popliteal lesions and in-stent restenosis.