



Brief report

Comparison of Drug Coated Balloon With Drug Eluting Stent for Isolated Ostial Side-Branch Coronary Artery Bifurcation Lesions



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A Medina 001 coronary bifurcation lesion (CBL) is associated with the highest rate of target lesion failure (TLF) of any Medina classification CBL.¹ Isolated side branch (SB) disease can be more complex to treat, due to the proximity of a main vessel not requiring PCI as well as the fibrocalcific nature of ostial lesions and higher risk of significant recoil and vessel threatening dissection. There is also a risk of geographic miss possibly resulting in bail out to a two stent strategy. With the use of drug coated balloons (DCB) increasingly utilized in de novo coronary disease, and recent evidence supporting their use in the SB as part of a main vessel DES strategy in a CBL,^{2,3} we sought to explore their use in a 001 Medina CBL.

All patients undergoing PCI for a Medina 001 CBL in the SPARTAN registry⁴ with either a DCB-only strategy or a drug eluting stent (DES)-only strategy were identified from 2015 to 2019. The primary endpoint was a bifurcation oriented composite endpoint (BOCE) of cardiovascular death (CD), target lesion revascularization (TLR) and target lesion MI. Nationally obtained clinical outcome databases were utilized to determine endpoints and ethical and institutional approval were obtained. Data was analyzed by an independent data scientist using R4.3.1 with RStudio Server 2024. The significance level was determined as 0.05. Univariate Cox regression was undertaken for all variables against the composite endpoint to identify correlation. Cumulative hazard plots were created with a log-rank test to determine significant differences between the arms. Multivariate Cox regression models were created using significant variables identified in the univariate analysis.

Of 203 patients with 001 CBLs, 122 were treated with a DCB and 81 with a DES. The median age was 67 (59 to 73) and all clinical presentations were included. There were no significant differences in the baseline patient characteristics and the lesion characteristics were largely well balanced with the exception of vessel diameter (median 2.5 [2.5 to 3.0] in DCB and 3.0 [2.5 to 3.5] in DES), as outlined in Table 1.

The median follow-up time was 3.4 (2.5 to 5.1) years. There was a significant increase in BOCE with DES (14%) compared to DCB (4.1%), HR: 3.5 (1.29 to 9.9), $p = 0.01$ (Figure 1). On univariate analysis, older age, presence of COPD, lower eGFR and smaller vessel diameter were adversely associated with the endpoint.

The association with DCB/DES after multivariate analysis remained significant (HR: 3.3 [1.0 to 10.8], $p = 0.04$), although no other variables were adversely associated with the outcome. Whilst numerically lower event rates were observed in the individual components of the endpoint with DCB compared to DES, there was no statistical significance. Cardiovascular death occurred in 9.9% of DES patients compared to 3.3% of DCB (HR: 3.1 [0.9 to 10.3], $p = 0.05$). TLR occurred in 3.7% of DES patients compared to 0.8% of DCB patients (HR: 4.6, [0.5 to 45], $p = 0.18$), and target lesion MI in 1.2% of DES patients compared to 0% of DCB, $p > 0.99$. Furthermore, there was no statistically significant difference in all-cause mortality (15% in DES compared to 7.4% in DCB, HR: 1.3 [0.5 to 3.2], $p = 0.56$).

These findings show, in the setting of a single center registry, a significant reduction in event rate when treating a 001 CBL with a DCB compared to a DES. This may be due to the fact there is less risk of carina shift when treating with a DCB.⁵ Furthermore, assuming adequate lesion preparation and lumen gain of the ostial SB lesion, there is less risk of stent related consequences beyond carina shift, such as geographical miss or size mismatch when adopting a

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Table 1
Baseline patient and procedural characteristics

Baseline/procedural characteristics	DCB (n = 122)	DES (n = 81)	p-value
Age*	70 (60–74)	64 (57–72)	0.07
Female*	18 (15)	14 (17)	0.63
Dyslipidaemia	33 (27)	18 (22)	0.44
Hypertension	55 (44)	34 (42)	0.66
Previous CVE	3 (2.5)	1 (1.2)	>0.99
Previous PCI	17 (14)	6 (7.4)	0.15
Previous MI	23 (19)	10 (12)	0.22
Diabetes	27 (22)	21 (26)	0.53
COPD*	3 (3)	3 (4)	
Clinical presentation*			0.10
STEMI	29 (24)	27 (33)	
NSTEMI/UA	55 (45)	39 (48)	
Stable angina	38 (31)	15 (19)	
eGFR*	77 (64–85)	73 (63–85)	0.56
Vessel treated*			0.14
LAD	47 (39)	25 (31)	
Circumflex	66 (54)	54 (67)	
RCA	9 (7)	2 (3)	
Heavy calcification*	24 (20)	16 (20)	0.99
Baseline LVEF	60 (53–63)	58 (53–61)	0.27
Vessel diameter*	2.5 (2.5–3)	3 (2.5–3.5)	0.001
Lesion length	20 (15–25)	18 (16–24)	0.39
TIMI flow			0.21
Pre PCI			
0	24 (20)	26 (32)	
1	4 (3)	7 (9)	
2	9 (7)	8 (10)	
3	85 (70)	40 (49)	
Post PCI			0.98
0	0 (0)	0 (0)	
1	0 (0)	0 (0)	
2	3 (2)	4 (5)	
3	119 (98)	77 (95)	
Dissection (post DCB)	0		
A	17 (14)		
B	26 (21)		
C	1 (1)		
D–F	0 (0)		
Peri-procedural MI	0 (0)	0 (0)	>0.99
Length of stay (days)	1 (1.0–2.0)	2 (1.0–3.0)	0.02

DCB = drug coated balloon; DES = drug eluting stent; COPD = chronic obstructive pulmonary disease; CVE = cerebrovascular event; eGFR = estimated glomerular filtration rate; LAD = left anterior descending; LVEF = left ventricular ejection fraction; MI = myocardial infarction; NSTEMI = non-ST elevation myocardial infarction; PCI = percutaneous coronary intervention; RCA = right coronary artery; STEMI = ST-elevation myocardial infarction; TIMI = thrombolysis in myocardial infarction; UA = unstable angina.

Data for continuous variables age, eGFR, LVEF, vessel diameter, lesion length and length of stay are median with 25th to 75th percentiles. All other variables are expressed as counts (%).

All variables marked with * are included in the multivariable analysis.

Bold values highlight statistical significance.

stentless strategy. Similar to the work by Mohammed et al.¹ the BOCE was predominantly driven by rates of CD. Although event rates did not achieve statistical significance ($p = 0.05$), the numbers and events of the individual component may have been too small.

The limitations include the significant selection bias with a registry. Whilst there was no significant difference in the baseline characteristics of the two groups, the intended treatment strategy cannot be determined in this registry and the lesions with significant recoil after lesion preparation not suitable for a DCB cannot be identified. Similarly we cannot definitively identify those cases initially planned for a single SB DES that had to bail out to a 2 DES strategy. Furthermore, this is a center with experience and expertise in DCB use, which may limit the generalizability of the results.

In a retrospective, single-center analysis, DCB use was associated with reduced BOCE in the treatment of Medina 001 or isolated side-branch lesions.

Disclosures

Vassilios Vassiliou reports speaker fees from Sanofi and Daichii-Sankyo and received grants for investigator-initiated research from B Braun and Medtronic. Simon Eccleshall received speaker fees and acts as a consultant for B Braun, Medtronic and MedAlliance and Cordis, and received grants for investigator-initiated research from B Braun. Dr Natasha Corballis receives an NIHR doctoral research fellowship grant.

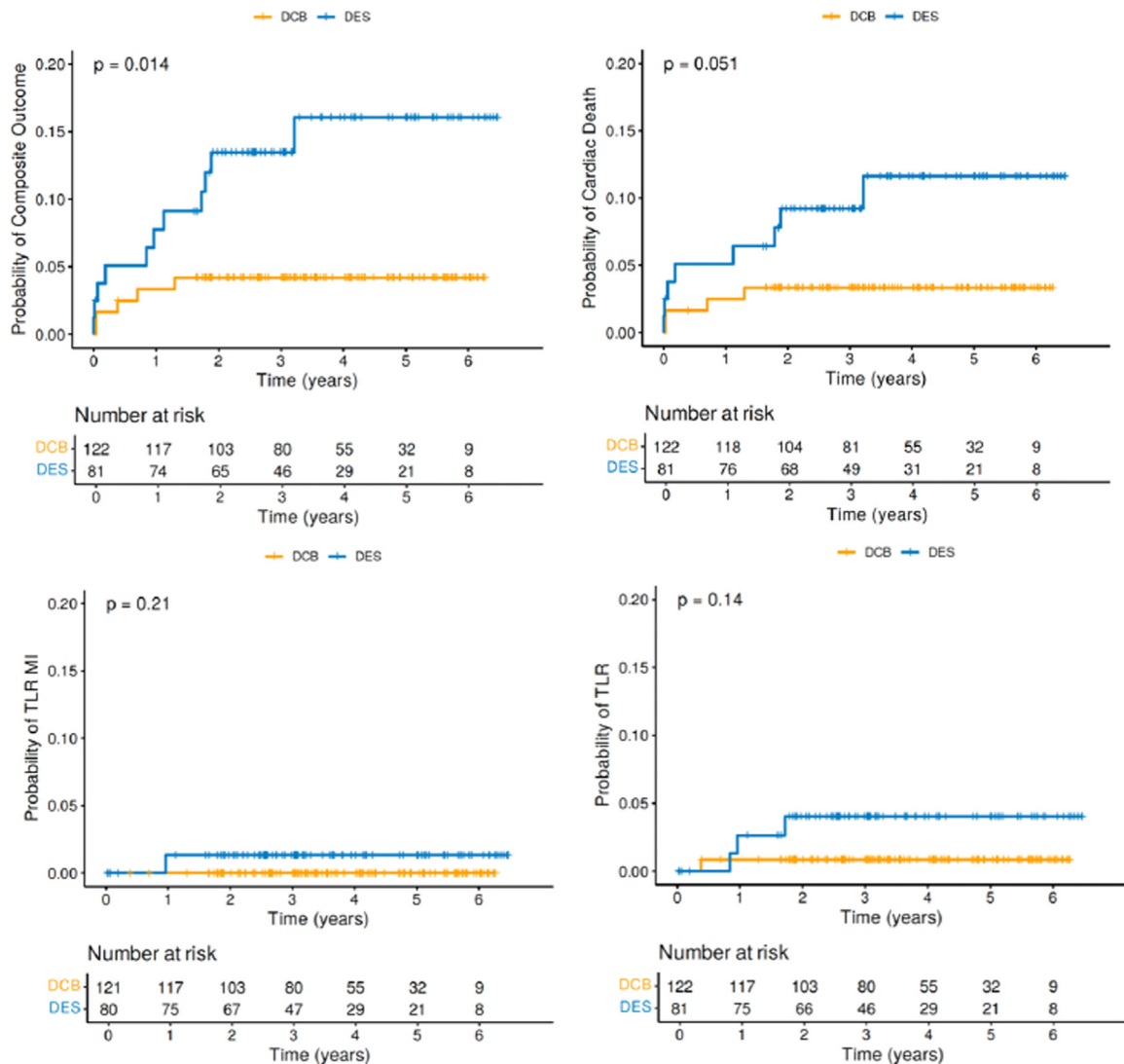


Figure 1. Cumulative hazard plots of events comparing DCB with DES. Cumulative hazard plots showing the difference in event rates between DCB and DES with A) bifurcation oriented composite endpoint of cardiac death, target lesion MI and target lesion revascularisation, B) cardiac death, C) target lesion MI and D) target lesion revascularisation.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Natasha Corballis reports financial support was provided by National Institute of Health and Medical Research. Vassilios Vassiliou reports a relationship with Sanofi-Aventis that includes: speaking and lecture fees. Vassilios Vassiliou reports a relationship with Daiichi-Sankyo that includes: speaking and lecture fees. Vassilios Vassiliou and Simon Eccleshall reports a relationship with B Braun SE that includes: funding grants. Simon Eccleshall reports a relationship with Medtronic Inc that includes: consulting or advisory. Simon Eccleshall reports a relationship with Cordis that includes: consulting or advisory. Simon Eccleshall reports a relationship with Medalliance Medical Health Services Inc that includes: consulting or advisory. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

CRediT authorship contribution statement

Natasha Corballis: Writing – original draft, Methodology, Formal analysis, Data curation, Conceptualization. **Ioannis Merinopoulos:** Writing – review & editing, Data curation. **U. Bhalraam:** Formal analysis. **Rajkumar Natarajan:** Writing – review & editing, Data curation. **Tharusha Gunawardena:** Data curation. **Vassilios S. Vassiliou:** Writing – review & editing, Supervision, Funding acquisition. **Simon Eccleshall:** Writing – review & editing, Supervision, Conceptualization.

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