



Short Communication

Short and long terms clinical outcomes of Paclitaxel drug-eluting balloons applied for de-novo coronary artery lesions in the context of acute coronary syndrome: A real world experience



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ABSTRACT

A single-centre retrospective observational study aimed at observing the outcomes of using DEB in ACS patients. All-comer ninety patients were included with a follow-up of 12–36 months. DEBs were deployed successfully yielding TIMI 3 without significant coronary dissection. MACE was 1.1% and 3.3% for 30 days and 12–36 months respectively.

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1. Introduction

The efficacy of drug-eluting balloon (DEB) compared with the standard stenting technique has been questioned in several studies.^{1,2} Authors aimed to study the safety and efficacy of DEB in treating de novo lesions in Acute coronary syndrome (ACS) in real-world and the short and long-term clinical outcomes.

2. Methods

A cross-sectional retrospective observational study conducted in a single centre in England. Data was collected as a part of the British Cardiovascular Interventional Society national audit. All-comer ninety patients were included who had a percutaneous coronary intervention (PCI) with DEBs (Paclitaxel coated) between 11/2015 and 04/2019. Patients were admitted with non-ST-elevation-ACS for urgent non-elective PCI. The follow-up period was for 12–36 months. Patients with in-stent restenosis were

excluded. The primary outcome was a composite of major adverse cardiac events (MACE) in the first 30 days and 12–36 months.

3. Results

Ninety patients were involved. Mean age was (64.65 ± 10.48 years) [Table 1](#). Mean DEB size was 2.73 ± 0.63 mm. Mean DEB length was 18.14 ± 3.62 mm. Mean target-vessel size was 2.70 ± 0.59 mm [Table 2](#).

1:1 balloon to vessel size strategy was used. Vessels were sized based on angiographic appearance for the majority of the cases. Intracoronary imaging with ultrasound and optic coherent tomography were used to size the vessels and post-angioplasty assessment for vessels ≥ 3.5 mm in size (n = 20). Balloon inflation time was 30–140sec (mean 79.09 ± 29.16), and inflation pressure was 6–18atm (mean 11.0 ± 2.64) guided by manufacturer recommendations. 105 balloons of different sizes were used. Twenty-one patients received 2 DEB to two different vessels. DEBs were deployed in all the patients yielding excellent outcomes, TIMI 3 in all patients without significant coronary dissection. No further drug-eluting stent was required. 44.76% of DEBs were used in 2.27–4 mm vessels, whereas 55.23% were used in smaller vessels,

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Table 1

Demonstrates the epidemiological data about the past medical history of the involved patients.

Total participants n (%)	90 (100%)
Male	79 (87.7%)
Female	11 (12.3%)
British white	81 (90%)
Previous myocardial infarction	25 (27.7%)
Previous CABG	8 (8.8%)
Previous PCI	43 (47.7%)
Diabetes mellitus (any type)	25 (27.7%)
Hypertensive	53 (59.89%)
Smoker	65 (72.2%)
LVEF > 50%	78 (86.67%)
LVEF ≤ 35%	3 (3.33%)
Statins	88 (97.7%)
ACEI	69 (76.7%)
Beta-blockers	62 (68.9%)

Table 2

Shows the number of balloons of different sizes.

Balloon size	Number of balloons used
2 mm	27
2.25 mm	3
2.5	28
2.75	2
3.0	25
3.5	9
4.0	11
Total	105

2.0–2.5 mm 52% of the lesions were shorter than 20 mm; the rest were longer. 4.45% were bifurcations, and none were used to treat left main disease, heavy calcified lesions or trifurcation. Only diseases in the native vessels were treated with DEB in patients with previous Coronary Artery Bypass Surgery.

MACE was observed in one patient (1.11%) in 30 days and 3 (3.3%) in 12–36 months of follow up. Sadly, two patients died secondary to severe aortic stenosis, and advanced heart failure respectively and (n = 1) was non-cardiac death. No patients were readmitted for target lesion revascularisation.

4. Discussion

MACE happened in 1.1% and 3.3% for 30-days and 12–36 months. No patient was readmitted with target lesion revascularisation even though the acute angiographic results of the DEB may be suboptimal, and this could be because the inferior immediate gain achieved with DEB was balanced by the prolonged late lumen gain³. Despite the promising results, this study is of small sample size, non-randomised and single-centre. The use of intra-coronary imaging for the large vessels was done based on the operator preferences; there is no local protocol for that in our centre.

5. Conclusions

DEBs seem to be safe and effective in managing de-novo coronary lesions in the context of ACS.

5.1. Key message

What is already known? – Limited available data with regard to using DEB in de novo coronary lesions, particularly in the context of the acute coronary syndrome.

What this study adds: DEB is a safe and effective alternative approach in the management of de-novo coronary lesions in the context of acute coronary syndrome.

Authors' contributions

All authors have read and approved the manuscript. AA-conception and design, drafting the chapter, data extraction; SS-conception and design, drafting the chapter, data extraction; JM-conception and design, revising the chapter critically for important intellectual content; AS-conception and design, revising the chapter critically for important intellectual content.

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Declaration of competing interest

Authors have no conflict of interest.

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