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Pushing the Boundaries: Drug-Coated Balloons to Treat a Calcified and Thrombotic Lesion in Acute Coronary Syndrome

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Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
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Funds Collection G

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Patient: Male, 72-year-old
Final Diagnosis: NSTEMI
Symptoms: ACS • NSTEMI
Medication: —
Clinical Procedure: —
Specialty: Cardiology

Objective: Unusual clinical course

Background: Use of drug-coated balloons (DCB) is an important research topic. Many companies are quickly developing new, cutting-edge technologies and means to deliver drugs. Moreover, interest is growing in use of sirolimus-coated balloons, a promising technology in the "leaving nothing behind" era. This, in combination with interest in lesion preparation and intravascular imaging, creates a promising future for DCB for years to come.

Case Report: A 72-year-old patient presented with NSTEMI. Coronary angiography showed a subtotal stenosis of the right coronary artery (RCA). PCI was performed on the native RCA and, given the patient's failure to adhere to the drug regimen, he was treated with a metal-free PCI strategy. After using a novel lesion preparation technique with cutting balloon and high-pressure non-compliant balloon, a novel Sirolimus DCB was used. Final angiography and OCT run showed good luminal gain despite diffuse dissections. To assess vascular healing, we performed coronary angiography 5 weeks later, which demonstrated an excellent result, with absence of residual dissection and further luminal gain compared to the index procedure.

Conclusions: The use of a novel lesion preparation technique (cutting balloon and high-pressure highly non-compliant balloon) in combination with guidance by intravascular imaging and the use of a new sirolimus-coated balloon may attract attention in the interventional cardiology community and stimulate discussion on lesion preparation and use of drug-coated balloons.

Keywords: Acute Coronary Syndrome • Coronary Artery Disease • Tomography, Optical Coherence • Angioplasty, Balloon, Coronary • Percutaneous Coronary Intervention

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Background

The use of drug-coated balloon (DCB) may overcome some of the limitations of the drug-eluting stent (DES) era, by releasing a vessel-antigrowth drug without leaving a permanent implant. This may prevent some of the known adverse outcomes of DES, like in-stent restenosis (ISR) and stent thrombosis (ST), which remain of concern, especially in calcified and complex lesions [1,2].

DCB has several advantages, such as preservation of coronary vasomotion, possibility of positive vessel remodeling, short dual anti-platelet treatment duration, and option of performing coronary artery bypass surgery at a later time [3-5].

Case Report

A 72-year-old patient presented with NSTEMI 10 years after PCI with DES implantation to the left circumflex artery (LCx). Coronary angiography showed patent stents on the LCx but a subtotal stenosis (**Figure 1A**) of the right coronary artery (RCA). PCI was performed on the native RCA and given poor patient compliance, we intended to avoid stent implantation. Optical coherence tomography (OCT, OPTIS™ system, Abbott Vascular, Santa Clara, CA, USA) was used to guide the PCI.

This demonstrated a plaque rupture with presence of mainly white thrombus (**Figure 1B**). Sequential predilatations with a 3.25×10 mm cutting balloon (Wolverine, Boston Scientific, Natick, MA) and 4.0×20 mm OPN balloon (SIS Medical AG, Frauenfeld, Switzerland) up to 30 atm pressure were performed. Subsequently, a 4.0×30 mm Selution™ DCB (6 atm, 120 s) was used. Final angiography (**Figure 1C**) and OCT run showed good luminal gain (6.30 mm^2, **Figure 1D**) despite presence of diffuse dissections (**Figure 2**). Fractional flow reserve (FFR) was performed to assess the distal lesion and was satisfactory (FFR 0.87). The patient was placed on short DAPT (1 month) with aspirin and ticagrelor because of serious patient failure to adhere to the drug regimen.

To assess vascular healing, we performed a planned coronary angiography 5 weeks later, which demonstrated an excellent result, with absence of residual dissection and further luminal gain compared to the index procedure (**Figure 1E**).

Vascular healing following spontaneous coronary artery dissection has been well documented. However, little is known about vascular healing after treatment of thrombotic and/or calcified lesions with DCBs. In this patient, we observed rapid resolution of all dissections and, more importantly, early positive remodeling leading to a marked increase of minimal luminal area (MLA) at 5-week follow-up (12.29 mm^2, **Figure 1F**).

Discussion

Going into a metal-free future when treating coronary artery disease (CAD) is promising, but several challenges need to be overcome. Mid- and long-term outcomes with metallic stents, even with newer and last-generation DES, still present risks of target lesion failure (TLF), in-stent restenosis (ISR), stent thrombosis (ST), and neoatherosclerosis [6]. Without the metallic struts and physical properties, lesion preparation with subsequent optimal acute luminal gain becomes of paramount importance. Avoiding flow-limiting dissections, especially in highly complex and calcified CAD population, becomes extremely challenging and currently there are no precise guidelines on optimal lesion preparation. Recent studies showed good results and performance of DCBs in the setting of small vessel disease and ISR [7,8] but in large vessel stable coronary disease and ACS setting there is limited evidence.

Finally, an adapted and shorter DAPT regimen in this context has been explored and speculated on but actual guidelines still do not integrate them [3,9-12].

In our case we used a novel strategy. Firstly, we used a cutting balloon to create controlled micro-dissections and entry ports for the drug [13]. Secondly, a highly non-compliant balloon was used to maximize luminal gain. OCT at the index procedure showed a relatively large MLA and, compared to the lumen, a small dissection burden. This was later confirmed at follow-up, with complete vascular healing, no residual dissections, and further luminal gain at OCT. Additionally, and given the extreme patient failure to adhere to the drug regimen, we performed a shorter DAPT without observing ischemic complications during the clinical follow-up.

DCBs may therefore overcome some of the limitations of the DES era, but future studies will have to characterize which patients and which lesions should be treated with DCB. Additionally, we need to understand how to best prepare the lesion, achieve luminal gain and, lastly, which drug/drug carrier is more suitable for which lesion.

Long-term data in all-comers, highly complex, and ACS patients treated with DCB are therefore needed before a "metal-free" strategy can become clinical routine.

Conclusions

A DCB-only strategy in an ACS setting with a mixed calcified and thrombotic lesion appears feasible. Importantly, lesion preparation and the use of intravascular imaging appear essential. In our case the OCT images showed that the dissections completely healed with time and lumen gain is a process that still

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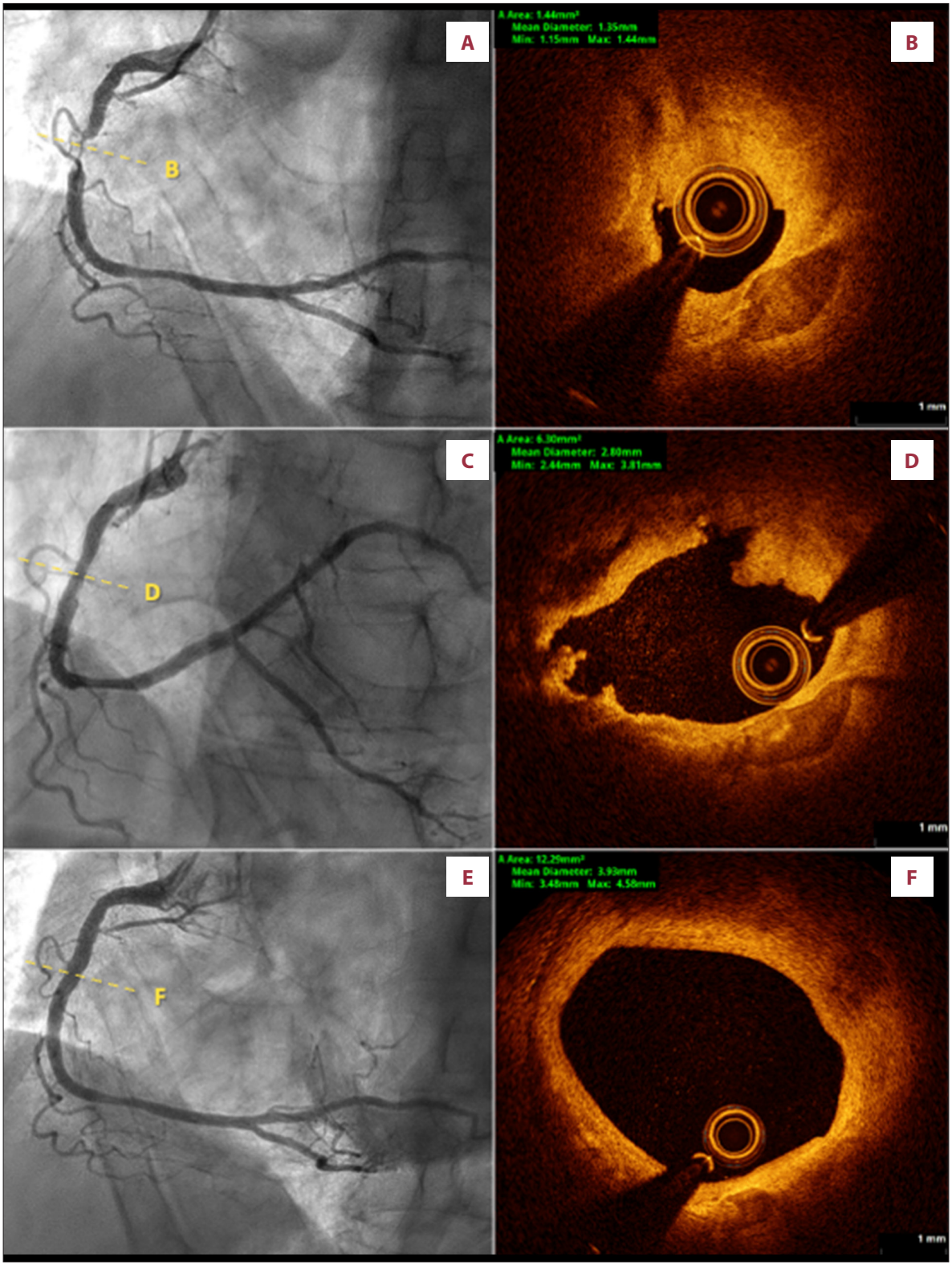

Figure 1. Subtotal stenosis of the RCA; **A** – Initial angiography with subtotal stenosis of the mid-RCA; **B** – OCT demonstrated a plaque rupture with presence of thrombus; **C, D** – Final angiography and OCT showing good luminal gain (6.30 mm^2) despite presence of dissections; **E** – 5 weeks follow-up angiography result, absence of residual dissection and further luminal gain; **F** – OCT showed rapid resolution of all dissections and further increase of MLA.

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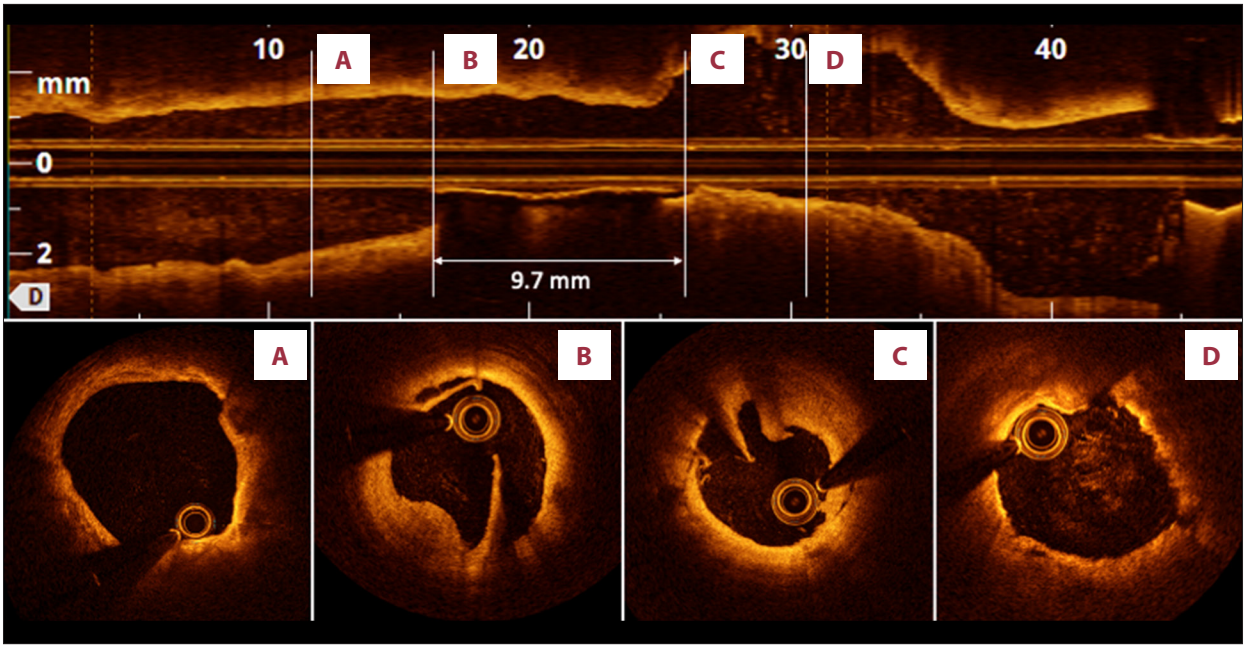

Figure 2. Final OCT pullback at the end of the index procedure; *Above* – Longitudinal section showing a 9.7 mm longitudinal dissection; **B, C** – flap dissections of the treated segment; **A, D** – distal and proximal segment 5 mm off the dissection.

takes place after weeks. Therefore, studies are needed to assess and define an optimal lesion preparation strategy, intravascular imaging parameters, and short- and long-term outcomes in all-comer patients treated with DCB.

Declaration of Figures' Authenticity

All figures submitted have been created by the authors who confirm that the images are original with no duplication and have not been previously published in whole or in part.

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