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Letter to Editor

Drug Coated Balloon and STEMI Patients: Maybe the Right Role has Not be Found Yet

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Abbreviations BMS: Bare Metal Stent; DCB: Drug Coated Balloon; DES: Drug Eluting Stent; ISR: In-Stent Restenosis; LLL: Late Lumen Loss; MACE: Major Adverse Cardiac Event; OCT: Optical Coherence Tomography Image; PCI: Percutaneous Coronary Intervention; PEB: Paclitaxel Eluting Balloon; PES: Paclitaxel Eluting Stent; POBA: Plain Old Balloon Angioplasty; ST: Stent Thrombosis; STEMI: ST Elevation Myocardial Infarction; TLR: Target Lesion Revascularization

Letter to Editor

The introduction of drug coated balloon (DCB) and subsequently modifications of this device from the first to the second generation, improving the mechanism of drug delivery in the coronary segment and release on the vessel walls as well as its trackability have lead to obtain interesting results in the treatment of specific setting of patients.

Along the last years, DCB has obtained important results in the in-stent restenosis (ISR) revascularization: if it's well established how comparison between plain old balloon angioplasty (POBA) and DCB is clearly in favour of the second one as underlined in PEPCAD-DES study [1] in terms of rate of restenosis and clinical follow up, this device represent a valid alternative to repeat DES implantation for the treatment of both bare metal stent (BMS) and drug eluting stent (DES) restenosis (class A, level of evidence I) [2].

In the Isaar Desire 3 trial, Byrne et al analyzed the role of DCB in the treatment of DES restenosis in comparison not only to POBA alone, but repeat DES implantation too. In a randomized population of 402 patients, DCB (SeQuent Please, B Braun, Melsungen, Germany) and repeat DES (Taxus Liberte, Boston Scientific, Natick, MA, USA) showed a superiority than POBA alone after an angiographic follow up of 6-8 months (recurrent binary restenosis of 39 (27%) vs. 34 (24%) vs. 72 (57%) respectively, $p<0.0001$) and a clinical follow up of 12 months (target lesion revascularization-TLR - of 30 (22.1%) vs. 17 (13.5%) vs. 56 (43.5%) $p<0.0001$, with a non inferiority of paclitaxel eluting balloon (PEB) than repeat paclitaxel eluting stent-PES- $p=0.09$), underlining its safety and efficacy in this target of lesions, without the need of further struts layer inside the previous stent [3].

Although optimal results in the treatment of both BMS and DES-ISR [4-8], actually DCB doesn't present indeed any useful results in ST elevation myocardial infarction (STEMI) patients.

In the DEB-AMI trial, DCB was analyzed in association to BMS implantation in 150 patients randomized in three arms (vs. BMS alone and DES), giving similar results to BMS alone treatment and inferior clinical and angiographic outcome than DES implantation (late lumen loss -LLL- 0.64 ± 0.56, 0.74 ± 0.57 and 0.21 ± 0.32 mm respectively, $p<0.01$ and a rate of TLR sharply in favour of third arm). The association of DCB plus BMS failed to demonstrate an angiographic and clinical superiority to BMS alone, loosing clearly the match with DES [9].

However the attractive to use a DCB, releasing the drug without permanent metal struts layers in a coronary segment with an elevated instability as during the index procedure of a STEMI patient revascularization, when the thrombus stratification on vessel walls and the inflammatory process which determines a not truthful vessel caliber, may determine a not adequate stent implantation and apposition, has leading to a further assessment of previous trial with the introduction of a fourth arm of patients about DCB-only treatment. Unfortunately, DCB-only primary percutaneous coronary intervention (PCI) didn't show different results, because the rate of LLL and restenosis were similar to BMS or DCB plus BMS implantation and inferior again to paclitaxel eluting stent (PES) [10].

In the PAPPA pilot study (Paclitaxel-eluting balloon angioplasty in Primary Percutaneous coronary intervention in Amsterdam), one hundred patients presenting with STEMI were prospectively enrolled and treated by DCB (Pantera Lux, Biotronik) alone angioplasty. Bail-out stenting by BMS (Pro-Kinetic Energy, Biotronik) implantation was performed in 41 patients, due to residual stenosis ≥50% and/or C to F type dissection. After 12 months of clinical follow-up, were observed only five major adverse cardiac events (MACE), with three episodes of TLR and two cardiac deaths, showing for the first time, interesting results in this set of patients, even if the restricted population and the high number of bail-out stenting [11].

These considerations may indicate how the real and appropriate role of DCB in STEMI patients was not found yet, rather than is not existing.

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In an unstable situation as the myocardial infarction, whereas in a native coronary segment involved in an acute thrombotic occlusion, the implantation of a stent seems to be necessary to oppose vasoreactivity and elastic recoil during and at the end of index procedure, while due to the high platelet and inflammatory process activation, the role of DCB may be referred to stent thrombosis (ST), due to thrombotic aggregation both in correspondence of uncovered struts of the previous stent or plaque rupture inside the ISR process.

In this condition, in a scenario where the coronary segment has just an implanted stent, rather than treat the STEMI trough the implantation of a second stent, the association of thrombus aspiration followed by DCB treatment along the stent segment involved in the acute occlusion may represent an intriguing option: the previous failed stent represent the scaffolding against elastic recoil and the DCB has just the role to release effectively the drug in these struts and vessel wall.

After removing the occluding thrombus, an homogeneous release of antiproliferative drug without further strut layers (Figures 1A-1E), reducing the inflammatory trigger (increased by a second stent apposition), may allow an adequate neointimal coverage, revealed by a follow up optical coherence tomography (OCT) images (Figure 1F). This treatment option may give finally a role to this device in the acute revascularization setting, avoiding a second metal layer in a stented segment after thrombus resolution.

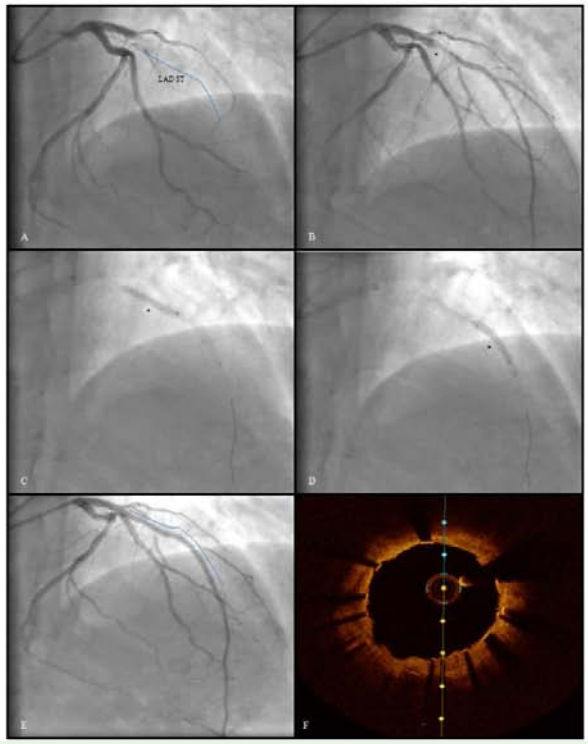

Figure 1: A: ST of left anterior descending artery (LAD): blue line identifies the long middle stent segment with a thrombotic occlusion in correspondence of proximal edge (two DES 3/15 mm and 3/18 mm in overlap in the middle segment of LAD). **B:** partial recanalization of LAD after thrombus aspiration (asterisk underlines the persistent stenosis at proximal edge). **C-D:** dilatation by DCB Restore (Cardionovum, Bonn, Germany) 3/20 mm along the stent segment. **E:** complete recanalization of middle LAD. **F:** 6 months Optical Coherence Tomography (OCT) control with a persistent optimal result after DCB treatment.

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