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Editorial comment

Fewer stents for STEMI. Are DCBs ready for prime time?

Menos *stents* para el IAMCEST: ¿está listo el balón farmacoactivo para su gran momento?

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Coronary lesions in patients with acute coronary syndrome (ACS) are frequently characterized by plaque erosion or plaque rupture. A dynamic alteration of the culprit vessel, mainly due to vasoconstriction and thrombus burden, may lead to inappropriate stent sizing or apposition and is associated with worse outcomes. Drug-coated balloons (DCB) appear to be an attractive therapeutic option, especially for young patients with ST-segment elevation myocardial infarction (STEMI).[1] Experimental data show a reduction in local inflammation after treatment with paclitaxel DCB.[2]

The recent European Society of Cardiology (ESC) guidelines on the management of chronic coronary syndromes no longer recommend DCB for the treatment of in-stent restenosis.[3] Until recently, DCB therapy was considered a first-line treatment for in-stent restenosis.[4] The rationale for this downgrade remains controversial. Specifically, the current guidelines emphasize target lesion revascularization as the primary endpoint, while placing less weight on hard outcomes such as myocardial infarction and death. In contrast, avoidance of additional stent layers may favor DCB therapy with respect to these endpoints.[5] Furthermore, the guidelines maintain that DCB should not be used for de novo coronary lesions.[4] Nonetheless, DCB therapy continues to receive considerable attention and remains a major focus of international scientific discussion.

Sanz-Sánchez et al.[6] deserve to be congratulated for their contribution to the growing clinical evidence of DCB therapy. In their recent article published in *Revista Española de Cardiología*, these authors present the study design of the COPERNICAN trial, a prospective, investigator-initiated randomized clinical trial aiming to compare a DCB-based with a conventional DES revascularization strategy in patients with STEMI from 16 Spanish centers. Successful guidewire crossing of the culprit lesion with restoration of flow was required before randomization. This inclusion criterion was chosen because a large thrombus burden may limit drug transfer into the vessel wall.[7]

The COPERNICAN trial applies the criteria of the international DCB consensus group for successful lesion preparation, namely TIMI grade III flow, absence of type C or higher dissection, and residual stenosis $\leq$ 30%.[8] Proper one-to-one sizing of both the lesion preparation devices and the DCB is considered essential.[9] This algorithm underpins the combined use of DCB and DES, referred to as the "reduced stent strategy" in the COPERNICAN trial. Lesions with potentially flow-limiting dissections or significant elastic recoil are treated with DES. In contrast, lesions treated with DCB avoid permanent implants, thereby allowing restoration of natural vascular function, including vasomotion,[10] late lumen enlargement,[11] and local regression of atherosclerosis.[12,13]

The acceptance of a certain proportion of cross-over to DES within the DCB arm reflects the principles of a strategy trial. In this context, the combination of DCB and DES is not regarded as treatment failure but as an integral component of the "reduced stent strategy," which represents a strength of the study design. A limitation, however, is the lack of detailed specification of the DCBs used. Even among paclitaxel-based DCBs, important technological differences exist, precluding the assumption of a uniform class effect.

The classification of coronary dissections still relies on the old American Heart Association scheme. According to this scheme, type A and B dissections carry a low risk of vascular occlusion, whereas type C and higher are associated with higher event rates.[14] The question, however, is whether this classification remains valid in the era of contemporary lesion preparation techniques and potent platelet inhibition. From an angiographic perspective, the preservation of flow and clear dominance of the true lumen seem to provide a more reliable guarantee of vessel patency. The requirement for restored blood flow prior to randomization in the COPERNICAN study is fully in line with this concept.

The COPERNICAN trial will provide important clinical evidence on the use of DCB in ACS.[6] In the PEPCAD NSTEMI trial, a DCB-only strategy was noninferior to both BMS and DES with respect to target lesion failure at 9 months in patients with non–ST-segment elevation myocardial infarction.[15] In STEMI patients, the REVELATION trial demonstrated noninferiority of DCB compared with DES in terms of fractional flow reserve at 9 months and sustained at 2 years.[16,17] In a cohort of 1139 STEMI patients, DCB-only treatment was comparable to DES regarding all-cause mortality after a median follow-up of more than 3 years (propensity score-matched analysis).[18] Similarly, a prespecified subgroup analysis of ACS patients in the BASKET-SMALL 2 trial showed no differences in major adverse cardiac event rates and all-cause mortality at 3 years between DCB and DES, irrespective of clinical presentation.[19] Beyond the treatment of flow-limiting vulnerable plaques, novel perspectives are also emerging in the field of preventive therapy.[20]

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