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Don't think twice: BMS is never nice

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Percutaneous coronary intervention (PCI) with stent implantation is the gold standard therapy in primary PCI. While European guidelines state a preference for new-generation drug-eluting stents (DES) over bare metal stents (BMS) as the default device in primary PCI (Class I recommendation, Level of Evidence A)[1], US guidelines give equal weight to both therapies (Class I recommendation, Level of Evidence A)[2]. In addition, the most recent National Institute for Health and Care Excellence (NICE) guidance in the UK still supports the use of BMS in preference to DES in certain lesions[3].

This raises the question as to whether there are certain situations in which BMS might be preferred to new-generation DES in patients undergoing primary PCI. In theory, there are two situations where such an approach might be justifiable: first, if BMS were to allow a shorter duration of dual antiplatelet therapy compared with DES, and second, if BMS were to offer equivalent efficacy to conventional DES, with the advantage of lower cost. In reality, however, the first situation is largely irrelevant, in that both European and US practice guidelines give a class I recommendation for 12 months of dual antiplatelet therapy, irrespective of the device used[1,2,4]. In terms of the second situation, previous concerns regarding first-generation DES use in STEMI – on account of higher rates of late stent thrombosis – have not been borne out in studies of new-generation DES. In fact, randomised trials have confirmed the superiority of new-generation DES over BMS, in terms of both efficacy (mainly driven by reduced rates of target lesion revascularisation [TLR]) and safety, with DES showing significantly lower rates of ST in one trial[5] and a trend towards lower ST in another[6].

But are there patient or lesion subsets that might do just as well with BMS implantation in the setting of STEMI? In other words, does the advantage of DES over BMS apply equally to patients known to be at lower risk of in-stent restenosis (ISR) and adverse events, such as non-diabetics, those with short culprit lesions or culprit lesions in large vessels[7,8]? This was exactly the question posed by Baumbach et al[9] in a pooled analysis of the EXAMINATION and COMFORTABLE-AMI randomised trials published in this issue of the journal.

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The investigators compared rates of cardiac death, target vessel myocardial infarction, and clinically indicated TLR at one year in STEMI patients treated with new-generation DES versus BMS, stratified according to their perceived risk of adverse outcomes. Patients were stratified using a risk score from 0-2, depending on the presence or absence of the following factors: lesion length >15 mm, target vessel diameter <3.0 mm, and diagnosis of diabetes (0=no risk factors; 1=1 risk factor; and 2=≥2 risk factors). The majority of patients fell into the low-risk category, with only one fifth of patients having a score of 2. Patients in the high-risk group also had a generally less favourable cardiac risk profile.

The main finding was that of lower event rates in patients treated with DES across all risk scores, although this only reached statistical significance in patients with risk scores of 0 and 1 and not in those at highest risk of adverse events. This may well be due to lack of power in the high-risk group. The reduction in events was driven by significantly lower TLR across all groups. Thus, even patients with none of the specified risk factors still derived a TLR advantage from DES. In addition, stent thrombosis rates (a secondary endpoint) were lower with DES compared with BMS in all groups, but this only reached statistical significance in patients with a risk score of 1, which was probably the only group big enough to show a significant difference in rates of such a rarely occurring event.

The authors should be commended for reporting an important analysis based on individual patient data from two contemporary large-scale clinical trials. In total, data from 2,655 patients were available for analysis. Furthermore, the question regarding feasibility of selective BMS use in STEMI patients at low risk of adverse events is a potentially important one in terms of cost impact since – at least in the current analysis – these patients comprise approximately 80% of treated patients.

However, some limitations must be taken into account when interpreting the results of this study. First, the analysis only takes into account the factors chosen for the risk score used. The addition of other risk factors for adverse events, such as complex lesion morphology[8] or bifurcation lesions (which accounted for 8.4% of lesions in COMFORTABLE-AMI, for example) might, potentially, improve the predictive ability of such a score. Second, there are some important differences between the two included trials, resulting in heterogeneity of the included population, a factor which may have influenced results. The COMFORTABLE-AMI

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trial included only patients undergoing primary PCI, whereas the EXAMINATION trial also included patients undergoing rescue PCI and patients presenting up to 48 hours after symptom onset. This may help to explain differences in baseline TIMI flow between the trials: the rate of TIMI 3 flow was much higher in the EXAMINATION trial than in COMFORTABLE-AMI, presumably due to the impact of thrombolysis in patients undergoing rescue PCI and spontaneous recanalisation in some patients presenting late, while rates of TIMI 0-1 flow were much higher in COMFORTABLE-AMI. Despite this, the proportion of patients presenting in Killip class II-IV was higher in EXAMINATION (10.4% vs. 6.6% in COMFORTABLE-AMI). Third, the study and control stents differed between the trials, with the EXAMINATION trial investigating the XIENCE V® everolimus-eluting durable polymer stent vs. the MULTI-LINK VISION® BMS (both Abbott Vascular, Santa Clara, CA, USA) and the COMFORTABLE-AMI trial investigating the BioMatrix™ biolimus-eluting biodegradable polymer stent vs. the Gazelle™ BMS (both Biosensors, Morges, Switzerland). Indeed, when the present analysis was performed individually for each trial, results for the COMFORTABLE-AMI trial were consistent with the present analysis, whereas there was no significant difference in event rates between treatment groups in the EXAMINATION trial, suggesting that results were driven by the former.

So, does this analysis help us to identify patient or lesion subsets that might do just as well with BMS in the setting of STEMI? The current study shows that risk stratification to identify patients in whom BMS may be preferred for primary PCI is of no value, since the advantage of new-generation DES over BMS in reducing adverse events applies even to patients perceived to be at lower risk of such events. Thus, in STEMI, new-generation DES should be the default device.

Conflict of interest statement

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