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Editorial

Does the daily risk assessment of adverse outcomes after percutaneous coronary interventions facilitate the personalized medicine approach?

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New-generation drug-eluting stents (DES) comprise of a *heterogenous* group of coronary devices characterized by thin struts, biocompatible durable or biodegradable polymer coatings or polymer-free structure and limus-eluting drugs. Thanks to excellent early and long-term outcomes in patients undergoing percutaneous coronary interventions (PCI), new-generation DES are recommended in almost all patient and lesion subsets. Nevertheless, several limitations have remained. Although DES reduce restenosis, they are also associated with chronic vascular inflammatory process and stent thrombosis (ST) [1].

The manuscript published in this issue of the *International Journal of Cardiology* raises the interesting issue that is the assessment of the daily risk of adverse events after PCI for complex lesions, including unprotected left main (ULM) and coronary bifurcations [2]. In that study all consecutive patients presenting with a critical lesion of ULM or bifurcation treated with very thin struts DES were analyzed (i.e. Promus Element, Boston Scientific; Xience Alpine, Abbott Vascular; Ultimaster, Terumo; Synergy, Boston Scientific; Resolute Onyx, Medtronic). The study population consisted of 2745 patients with the mean age of 68 ± 11 years. In that group 27.2% of treated lesions were ULM, and 88.5% - coronary bifurcations. Authors disclosed that the average daily risk was 0.022% for major adverse cardiovascular events (MACE), 0.005% for target lesion revascularization (TLR) and 0.004% for ST, in the first 12 months. Interestingly, the bimodal distribution of adverse events was observed, especially for TLR, with an early peak in the first 50 days and a late one after 150 days. In another words, after conversion, at 1-year follow-up the MACE rate was 8.03%, TLR rate – 1.8%, and ST – 1.46%. The results were quite reasonable in terms for MACE, but simultaneously, the TLR rate was quite low, whereas the rate of ST was quite high. This needs further elucidation.

The proposed by the authors daily risk assessment approach is relatively new and offers a way of showing data simple and easy to understand for the wide population. Moreover, it provides a versatile way to analyze and represent data, such as calculating the difference in term of events in any desired period of time, or in a continuous manner. Taking advantage of such approach we should consider two issues: the use of biodegradable stents and the issue of a planned angiography after PCI in ULM.

Theoretically stents with biodegradable polymers have some advantages. The concept is based on the hypothesis that the polymer is one of the reasons for DES negative impact on the artery wall. When the drug completely elutes, the polymer still stays on the stent surface, chronically irritating the artery wall and leads to local inflammation impairing proper healing and endothelialization. The idea assumes that the biodegradable polymer would be absorbed from the stent surface following drug elution, leaving only a bare metal stent covered with neointima without further irritation of the artery wall leading better clinical outcomes [1]. However, recent studies did not support this hypothesis not only in stable coronary artery disease, but also in patients with STEMI [3,4] as well as in complex interventions including ULM [5]. Similarly, in this paper daily risk assessment analysis showed no significant difference in the use of permanent vs. biodegradable polymer DES [2]. Moreover, other studies disclosed more important points in the stent design. Iannaccone et al. analyzed fifty-three studies with a total population of 52,006 patients. They showed that strut thickness ≤ 81 nm was associated with a lower TLR rate (2.9% vs. 3.6%) and ST rate (0.8% vs. 1.3%). Interestingly, a mean number of connectors >2.5 also correlated with a lower TLR rate (3.2% vs 3.5%) and ST rate (1.0% vs. 1.3%). However, DES with a mean number of crowns <7.5 did not perform better than DES with a higher mean number of crowns [6]. So, it seems that definitely the type of the polymer does not play any role in term of long-term outcomes in patients after PCI with DES.

Coronary artery disease involving left main still poses a therapeutic challenge mainly due to the large amount of myocardium at risk. Not so long ago, PCI had a class III recommendation for patients with ULM eligible for coronary artery bypass grafting. However, major technical advances, mainly new generation DES, have totally revolutionized the choice of revascularization strategies [7,8]. Nevertheless, the debatable issue is how to manage after the PCI.

Previous practice recommended that the routine control angiography should be performed up to 6 months after PCI in ULM. This was

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based on the historical registry data with bare metal stents [9]. In the DES era this recommendation was sustained based on the assumption that the development of restenosis would peak between 2 and 4 months. However, more recently the analysis of 340 patients was performed to assess the rate and temporal distribution of cardiac sudden death or out-of-hospital myocardial infarction in patients undergoing planned PCI with DES deployment in ULM [10]. That analysis showed that the rate of sudden death, cardiac death and ST were very low and comparable to patients who underwent PCI for non-left main lesions. These findings were one of the main reasons that led to the common resignation from the routine 6-month angiographic follow-up.

In the present study, the daily risk analysis showed that patients with PCI in LM characterized the significantly higher daily risk of MACE at three, six months and one year, a higher daily risk of TLR at six months and one year, and a higher daily risk of ST at six months. The highest daily risk values of MACE, TLR and ST were observed during the first month of follow-up, with values of 0.073%, 0.014% and 0.037%, respectively [2]. This might suggest the need for revisiting the necessity (the comeback) of the planned angiographic control after PCI in LM, especially after complicated cases with 2-stent techniques.

Declaration of conflicts of interest

Nothing to disclose.

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