Should we rely on OCT to assess the improvements of new generation drug-eluting stents?

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Received: 10 October 2011 / Accepted: 17 October 2011 / Published online: 1 November 2011
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Drug-eluting stents have changed the landscape of interventional cardiology. Since their introduction, over a decade ago, their primary and ultimate effect—the ability to decrease neointimal proliferation—still remains undisputable. The reduction of restenosis after drug-eluting stents pushed the borders of percutaneous coronary intervention towards the treatment of patients with complex anatomies, while improving the durability of the procedure. However, the intense modulation of vascular healing by drug-eluting stents may also have potential drawbacks, namely impaired re-endothelialization. Newer generation drug-eluting stents, therefore, face the challenge of maintaining the efficacy levels of early stent formulations, and, at the same time, improving the quality of tissue response to these devices.

Several new drug-eluting stents have already been released for clinical use, providing theoretical improvements in the platform, coating, and the drug. In practice, however, proving the superiority of newer stents is not an easy task. First-generation drug-eluting stents are associated with a low frequency of clinical complications. Particularly, the odds of stent thrombosis, perhaps the most feared safety event commonly

do not surpass 3% during an observation period of several years. Therefore, a conclusive clinical trial would need the inclusion of thousands of patients, followed-up for a long period of time, in order to be powered to confirm a decrease in thrombosis.

Surrogate endpoints are important tools to overcome the difficulties in assessing low-frequency adverse events. Optical coherence tomography (OCT) imaging has been recently introduced in interventional cardiology as a candidate method to evaluate the subtleties of the stent-to-vessel wall interaction. Indeed, stent apposition, strut coverage, and abnormal intraluminal tissue all seem to be reliably assessed by OCT. In the present issue of the *International Journal of Cardiovascular Imaging*, Jung-Sun Kim et al. show that the newer zotarolimus-eluting ResoluteTM stent was less prone to present uncovered or malapposed stent struts and intracoronary thrombus than the sirolimus-eluting CypherTM stent at 9 months, by OCT imaging. Taken together, in theory, these results would imply in an improved vascular response for the zotarolimus stent.

Previous studies have shown that new-generation biolimus-eluting stents had better strut coverage at 9 months by OCT than sirolimus-eluting stents [1], but were not associated with a clear improvement in stent thrombosis after 2 years [2]. Conversely, new-generation zotarolimus-eluting stents had similar 13-month OCT findings compared to new-generation everolimus stents [3], but tended to have more definite thrombotic events at 12 months [4]. These somewhat

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contradictory findings highlight the difficulties in demonstrating the link between OCT-derived surrogate parameters and future clinical outcomes.

Although intuitive, the value of OCT to assess the vascular healing process and, ultimately, to predict subsequent outcomes is still to be constructed. Developments in OCT technologies, as well as the standardization and validation of the analytic process may all help in better defining the role of OCT as a clinical method to evaluate coronary stents.

Conflict of interest I have no conflicts of interest related to this manuscript.

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