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EDITORIAL COMMENT

# Will Optical Coherence Tomography Become the Standard Imaging Tool for Percutaneous Coronary Intervention Guidance?*

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In the last 3 decades, intravascular ultrasound (IVUS) and, more recently, optical coherence tomography (OCT) have been increasingly used to guide percutaneous coronary intervention (PCI). Although there are randomized trials, registries, and meta-analyses suggesting better outcomes using IVUS to guide PCI (1-3), data on the clinical impact of OCT are still missing. In the United Kingdom, consecutive data of all PCI procedures must be prospectively entered in the registry organized by the British Cardiovascular Interventional Society, endorsed by the United Kingdom Department of Health, with tracking of events based on the complete and unquestionable national statistics. One of the main findings stemming from this large observational study conducted between 2005 and 2015 in London is that the rate of use of intravascular imaging in daily practice remains low (4). Angiography-alone PCI was performed in 75,046 patients (86.1%), IVUS-guided PCI in 10,971 patients (12.6%), and OCT-guided PCI in 1,149 patients (1.3%). The imaging-guided PCI procedures lead to a better outcome than the angiography-guided procedures, with angiography guidance achieving the worst results (15.7% 1-year failure) with a significant difference also in propensity score-selected subgroups (hazard ratio: 0.39; 95% confidence interval: 0.21 to 0.77; $p = 0.0008$). Imaging was more likely used in the largest teaching hospitals during elective day procedures performed by the best operators. Diffuse distal disease, cardiogenic shock, severe comorbidities (severe chronic obstructive pulmonary disease, cognitive impairment) limiting patient tolerance were unlikely to be considered for imaging with the OCT procedures also excluding renal insufficiency and aortio-ostial lesions. These unbalanced clinical and angiographic conditions are confounding factors very unlikely to be fully caught and then to be corrected also in the sophisticated multivariate statistical analysis. The absence of clear indications on how often the strategy was changed (longer or larger stents and balloons, higher pressure) and how much the final result was improved (minimal stent area increase) is another major weakness of this registry. We also do not know which lesions were preferentially treated under imaging guidance, with left main disease and restenotic lesions receiving the strongest recommendations in the guidelines (5).

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There is a lower overall rate of use of intravascular imaging globally than in the 9 participating cardiac centers across London, with the exception of Japan, Korea, and in part, the United States. Time and cost are the most frequent reasons put forward to justify this reduced use but the real explanations are more fundamental questions on the efficacy of IVUS/OCT to improve outcome. Many expert interventional cardiologists suggest that intravascular imaging is good only in a learning phase, but once you have learned how to use a new device or practiced the technique to treat a complex bifurcational lesion, you can skip doing intravascular imaging and simply rely on

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angiography. Despite the better outcome of this very large registry in the imaging group, it is unlikely that this study will overcome these resistances.

The other interesting finding in this registry is the good outcome of the OCT-guided group. The difference in unadjusted mortality between patients who underwent OCT- and IVUS-guided PCI (7.7% vs. 12.2%) became nonsignificant after adjustment (hazard ratio: 0.85; 95% confidence interval: 0.63 to 1.34; $p = 0.43$). There is already clear evidence showing that OCT, like IVUS, modifies the procedural strategy, using both conventional second-generation drug-eluting stents (DES) (6) and biodegradable scaffolds (7,8). OCT enables accurate evaluation of the thickness of subintimal calcification, underestimated with angiography but also not measurable with IVUS, allows a rapid automatic measurement of the proximal and distal reference to select the most appropriate stent diameter and length, and unveils poor stent expansion and geographical miss showing also edge dissections, in-stent tissue protrusion, and strut malapposition. There is evidence that gross underexpansion and malapposition lead to stent failure, including thrombosis and OCT that show crisp images easier to interpret than IVUS. Software advancements available in most OCT systems include automated contour analysis, 3-dimensional reconstruction and color-coded display of unapposed struts, coregistration with angiography. Except for the last (coregistration is also provided by most IVUS vendors), these are unique advantages of OCT to facilitate interpretation and make it less subjective and dependent on the presence of local experts. OCT was expected to take over at the time of the rise of bioresorbable scaffolds because the lack of shadowing beyond polymer struts makes it the best imaging technique for the evaluation of the immediate BVS results and the resorption process (9). The worse late results compared with metallic second-generation stents require device changes to optimize the resorption process, but OCT is likely to survive this fall of interest for the main target of its use.

In the pivotal ILUMIEN I (Observational Study of Optical Coherence Tomography [OCT] in Patients Undergoing Fractional Flow Reserve [FFR] and Percutaneous Coronary Intervention) (10), the operator decision-making was modified by OCT in more than one-half of the procedures before the intervention and in 27% of all cases post-PCI. This finding is consistent with the observations of the ILUMIEN III: OPTIMIZE PCI (Optical Coherence Tomography [OCT] Compared to Intravascular Ultrasound [IVUS] and Angiography to Guide Coronary Stent Implantation: a Multicenter Randomized Trial in PCI) (11) study, which demonstrated that OCT for PCI guidance resulted in similar minimum stent area to that of IVUS-guided PCI. In the OPINION (Optical Frequency Domain Imaging vs. Intravascular Ultrasound in Percutaneous Coronary Intervention) randomized trial, the noninferiority of OCT in comparison to IVUS was demonstrated in 829 patients with a clinical primary endpoint of target vessel failure at 12 months follow-up (5.2% vs. 4.9%; p for noninferiority $<0.05$) and a secondary endpoint of binary restenosis, also similar in the 2 groups (12). In the OPINION trial, there was a small, but significant, difference in the average stent size (OCT $2.92 \pm 0.39$ mm vs. IVUS $2.99 \pm 0.39$ mm; $p = 0.005$), but this did not translate into differences in angiographic in-stent minimal lumen area at 8-month angiographic follow-up. Like for IVUS, the optimal method and goal for stent expansion remains unclear, with the ILUMIEN III: OPTIMIZE PCI trial (11) using a pre-stenting OCT measurement of the elastic lamina of the distal reference, possible in most cases in their experience, and the OPINION trial using a lumen-based criterion.

We need more data in order to confirm that OCT-guided PCI is superior to angiography alone. The ILUMIEN IV (OCT guided PCI vs. angiography: An outcome study) multicenter randomized trial appears sufficiently large to address outcome differences and establish whether the claimed superiority of OCT to angiography is confirmed. We also need evidence to support superiority of OCT in comparison to angiography and IVUS in specific anatomic settings such as bifurcation involvement requiring a complex stenting strategy where OCT is also able to identify the optimal crossing of the wire in the more distal cell at the site of the side branch ostium (13). The OCTOBER (European Trial on Optical Coherence Tomography Optimized Bifurcation Event Reduction) is an ongoing randomized trial specifically assessing whether systematic OCT-guided revascularization of patients with complex bifurcation lesions provides superior 2-year clinical outcome compared with standard revascularization by PCI, including liberal use of IVUS (NCT03171311).

What to do while awaiting these results? The indications of the most recent guidelines push even the sceptics to a more liberal use of these imaging techniques.

The so-called experts in IVUS and OCT guidance should come up with a proposal of simple criteria for

optimization. A number is enough to determine lesion severity with fractional flow reserve or instantaneous wave-free ratio. We should aim at a similar simplification for the intravascular imaging tools with automated analysis of the key predictive parameters.

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**KEY WORDS** coronary imaging, OCT, PCI