

Title: ILUMIEN IV: OCT Vs Angiography

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Date: 28/08/23

Dr Ziad Ali

"Hi, I'm Ziad Ali from St Francis Hospital and Heart Centre in New York, the Cardiovascular Research Foundation in New York, and the New York Institute of Technology. I'm here to talk about the first global multicenter randomised control trial comparing OCT guidance to angiography guidance for PCI, the ILUMIEN Four Optimal PCI Study.

Rationale Behind the Study

So PCI's most commonly guided by angiography globally, but angiography has a number of well-recognised limitations. We can overcome these limitations by using intravascular imaging and OCT is a very high-resolution intravascular imaging modality. We've shown previously in ILUMIEN Three that OCT guidance can improve stent expansion and reduce procedural complications like malaposition and major dissection.

But what we didn't know is whether those improvements in acute procedural success can actually lead to an improvement in clinical outcomes, particularly in complex patients.

Patient Cohort and Study Design

So we enrolled specifically patients who were high risk, defined as medication-treated diabetes, or patients with complex coronary lesions, defined as lesions that were greater than 28 millimetres of intended total stent length in one vessel or more vessels.

People had a recent myocardial infarction acute coronary syndromes, severe calcification bifurcations with two stents, a chronic total occlusion or diffuse or multifocal instant restenosis. So we really tried to encompass this high-risk patient population

because we think those patients are the most likely to benefit from imaging coupled with the most likely value for money.

Key Findings

For the catheter devices, the take-home messages were that OCT increases the minimal stent area, improves stent expansion and reduces major complications, major dissection, major malaposition, major tissue protrusion and untreated focal reference segment disease. Even angiographic core lab adjudicated complications were significantly less common in the OCT-guided group.

Overall, that translated to a very strong 66% reduction in stent thrombosis, which was statistically significant. That was coupled with a reduction in target vessel myocardial infarction and ischemia-driven target vessel revascularization overall, pointing towards the fact that OCT can dramatically improve safety. We did not see a difference in the two-year primary clinical endpoint of target vessel failure and that was largely because of equipoise ischemia-driven revascularization.

We do believe that was strongly impacted by the COVID-19 pandemic when patients couldn't get to the hospital and if they were having experiencing angina, they were more likely to manage it at home or have difficulty with resources for hospitalization and that tends to bias findings towards the mean.

Next Steps

ESC did an amazing job of putting together the hotline session which incorporated four major studies the ILUMIEN Four study, the October study which showed a significant benefit of about 4% for bifurcations guided by OCT versus angio.

The OCTIVUS study, which shows that OCT and IVUS were non inferior in terms of clinical outcomes at one year. And then, very importantly, a real-time network meta-analysis presented by Dr. Stone, which showed a robust benefit in almost every clinical endpoint a benefit in terms of target vessel failure, major adverse cardiovascular events,

stent thrombosis, death, cardiac death, target lesion revascularization, MI, target vessel MI, stent thrombosis the list goes on and on. So this robust data of almost 20,000 patients really is the nidus to move the guidelines as they should be for multiple randomised controlled trials and meta-analyses towards a one A.”