IVUS-Guided PCI Reduces MACE in Left Main Disease: OPTIMAL Trial

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Percutaneous coronary intervention (PCI) for unprotected left main coronary artery (ULMCA) disease presents a significant challenge, with outcomes historically varying based on imaging guidance.1 The OPTIMAL trial, presented at ACC.26, provides evidence that intravascular ultrasound (IVUS) guidance improves clinical outcomes compared to angiography guidance in this high-risk patient population.

KEY TAKEAWAYS

- The Pivot: IVUS guidance is now demonstrably superior to angiography guidance for PCI in unprotected left main coronary artery disease.
- The Data: IVUS guidance reduced the primary endpoint of major adverse cardiac events (MACE) by 35% (HR 0.65, 95% CI 0.48-0.88, p=0.005).
- The Action: Clinicians performing PCI for ULMCA disease should integrate IVUS guidance as the standard of care.

Unprotected left main coronary artery disease is associated with high morbidity and mortality, necessitating careful revascularisation strategies. Affecting approximately 5-7% of patients undergoing coronary angiography, ULMCA disease carries a particularly poor prognosis if left untreated, with annual mortality rates approaching 50% for severe stenosis. While PCI has emerged as a viable alternative to coronary artery bypass grafting (CABG) in selected patients, optimising procedural outcomes remains critical. Angiography alone provides a two-dimensional lumenogram, which can underestimate plaque burden and vessel size, potentially leading to suboptimal stent deployment. Intravascular ultrasound (IVUS) offers detailed cross-sectional imaging of the vessel wall, allowing for precise assessment of lesion characteristics, vessel sizing, and stent apposition. The OPTIMAL trial sought to definitively compare the clinical efficacy of IVUS-guided PCI versus angiography-guided PCI in this complex anatomical subset.

The OPTIMAL Trial: Design and Findings

The OPTIMAL trial was a prospective, multicentre, randomised controlled trial enrolling 1,970 patients with unprotected left main coronary artery disease undergoing PCI.1 Patients were randomly assigned in a 1:1 ratio to receive either IVUS-guided PCI (N=985) or angiography-guided PCI (N=985).1 The primary endpoint was major adverse cardiac events (MACE), defined as a composite of cardiac death, myocardial infarction (MI), stent thrombosis, or target lesion revascularisation (TLR) at three years.1 Secondary endpoints included individual components of MACE and all-cause mortality.1 The trial employed a rigorous methodology, with adjudication of all MACE events by an independent clinical events committee blinded to treatment assignment. Follow-up was conducted at 1, 6, 12, 24, and 36 months

post-procedure.

Baseline characteristics were well-balanced between the two groups. The mean age of participants was 67.5 years, and approximately 72% were male.1 A significant proportion of patients had comorbidities, including hypertension (85%), dyslipidaemia (78%), and diabetes mellitus (35%).1 The most common left main lesion location was distal bifurcation (70%).1 Patients with acute myocardial infarction within 48 hours, cardiogenic shock, or severe renal impairment were excluded to ensure a relatively stable patient population suitable for elective PCI. The SYNTAX score, a measure of coronary artery disease complexity, was also balanced between the groups, indicating comparable baseline disease severity.

At three years, the primary endpoint of MACE occurred in 10.2% of patients in the IVUS-guided group compared to 15.1% in the angiography-guided group.1 This translated to a statistically significant 35% reduction in MACE with IVUS guidance (Hazard Ratio [HR] 0.65, 95% Confidence Interval [CI] 0.48-0.88, P=0.005).1

Breaking down the composite endpoint, IVUS guidance significantly reduced the incidence of cardiac death (3.1% vs. 5.2%; HR 0.59, 95% CI 0.37-0.94, P=.027) and target lesion revascularisation (4.5% vs. 7.8%; HR 0.56, 95% CI 0.38-0.82, P=.003).1 There was a trend towards lower rates of myocardial infarction (4.8% vs. 6.5%; HR 0.73, 95% CI 0.49-1.08, P=.11) and stent thrombosis (0.8% vs. 1.5%; HR 0.53, 95% CI 0.20-1.40, P=.20), although these did not reach statistical significance individually.1 All-cause mortality was also lower in the IVUS group (4.2% vs. 6.8%; HR 0.61, 95% CI 0.40-0.92, P=.019).1

The procedural characteristics indicated that IVUS-guided PCI was associated with a slightly longer procedural time (mean 78 minutes vs. 65 minutes, P210 mL vs. 195 mL, P=.01).1 However, these differences did not translate into an increased risk of acute kidney injury or other periprocedural complications.1 The mechanism for improved outcomes with IVUS guidance likely involves more accurate vessel sizing, optimisation of stent expansion, and better detection of edge dissections or malapposition, all of which contribute to reduced rates of stent-related complications and subsequent revascularisation.

Limitations and Implications

The OPTIMAL trial provides robust evidence supporting the use of IVUS guidance in ULMCA PCI. A limitation is the open-label design, inherent to procedural trials, which could introduce some bias, though objective endpoints like cardiac death and MI are less susceptible. While the trial was adequately powered for its primary endpoint, the lack of statistical significance for individual components like MI and stent thrombosis suggests that larger trials or meta-analyses might be needed to confirm these specific benefits. The trial's findings align with previous smaller studies and meta-analyses, reinforcing the benefits of IVUS. The observed reduction in MACE, driven by lower rates of cardiac death and TLR, has direct clinical relevance. The increased procedural time and contrast volume associated with IVUS use are minor considerations given the significant improvement in patient outcomes. These data strongly advocate for IVUS as the preferred imaging modality for PCI in unprotected left main coronary artery disease, moving beyond angiography as the sole guide.

CLINICAL IMPLICATIONS

> The OPTIMAL trial's clear demonstration of reduced MACE with IVUS-guided PCI in unprotected left main disease should prompt an immediate re-evaluation of current practice. For too long, the adoption of IVUS has been inconsistent, often viewed as an optional adjunct rather than an essential tool. These data, showing a 35% reduction in MACE and a significant drop in cardiac death, make a compelling case for IVUS to become the standard of care. Guideline bodies like the European Society of Cardiology and the American College of Cardiology must now consider upgrading their recommendations to reflect this evidence, moving from a Class IIa or IIb recommendation to a Class I for ULMCA PCI.
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> The implications for interventional cardiologists are straightforward: if you are performing PCI in the left main, you should be using IVUS. The argument that IVUS adds time or cost is now outweighed by the substantial patient benefit. Hospitals and healthcare systems need to ensure that IVUS equipment is readily available and that operators are adequately trained in its use and interpretation. This is not merely about improving procedural success rates, but about preventing hard clinical endpoints like cardiac death and repeat revascularisation, which carry significant human and economic costs.
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> From an industry perspective, this trial reinforces the value proposition for manufacturers of IVUS catheters and consoles. Companies like Philips and Boston Scientific, who produce these devices, can expect increased demand as adoption rates rise. For patients, this means a higher likelihood of a durable, successful revascularisation, reducing their risk of future adverse events and improving their long-term prognosis. It is a rare instance where a procedural intervention shows such a clear and significant benefit on patient-centric outcomes, making the case for its widespread implementation undeniable.

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REFERENCES

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