

# Clinical Impact of Intravascular Ultrasound Guidance in Drug-Eluting Stent Implantation for Unprotected Left Main Coronary Disease

## Pooled Analysis at the Patient-Level of 4 Registries

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**Objectives** This study sought to investigate the clinical impact of the use of intravascular ultrasound (IVUS) during revascularization of patients with left main coronary artery (LM) disease with drug-eluting stents (DES).

**Background** Whether the use of IVUS during the procedure adds a clinical benefit remains unclear. There is only 1 previous observational study, with relevant limitations, supporting the value of this strategy.

**Methods** We performed a patient-level pooled analysis of 4 registries of patients with LM disease treated with DES in Spain. A propensity score-matching method was used to obtain matched pairs of patients with and without IVUS guidance.

**Results** A total of 1,670 patients were included, and 505 patients (30.2%) underwent DES implantation under IVUS guidance (IVUS group). By means of the matching method, 505 patients without the use of IVUS during revascularization were selected (no-IVUS group). Survival free of cardiac death, myocardial infarction, and target lesion revascularization at 3 years was 88.7% in the IVUS group and 83.6% in the no-IVUS group ( $p = 0.04$ ) for the overall population, and 90% and 80.7%, respectively ( $p = 0.03$ ), for the subgroups with distal LM lesions. The incidence of definite and probable thrombosis was significantly lower in the IVUS group (0.6% vs. 2.2%;  $p = 0.04$ ). Finally, IVUS-guided revascularization was identified as an independent predictor for major adverse events in the overall population (hazard ratio: 0.70, 95% confidence interval: 0.52 to 0.99;  $p = 0.04$ ) and in the subgroup with distal lesions (hazard ratio: 0.54, 95% confidence interval: 0.34 to 0.90;  $p = 0.02$ ).

**Conclusions** The results of this pooled analysis show an association of IVUS guidance during percutaneous coronary intervention with better outcomes in patients with LM disease undergoing revascularization with DES. (J Am Coll Cardiol Intv 2014;7:244–54) © 2014 by the American College of Cardiology Foundation

Percutaneous revascularization of unprotected left main coronary artery (LM) disease has been a controversial subject during recent years. Even though LM treatment has been traditionally reserved for surgery, there have been numerous registries with drug-eluting stents (DES) that have shown favorable outcomes (1–5). Randomized studies have shown that percutaneous coronary intervention (PCI) of these lesions with paclitaxel and sirolimus-eluting stents, respectively, may offer results comparable to surgery up to 3 years, as long as the complexity and extent of the coronary disease are not high (6–8). In a meta-analysis of randomized trials, PCI with DES was associated with nonsignificantly different 1-year rates of major adverse cardiac and cerebrovascular events, a lower risk of stroke, and a higher risk of target vessel revascularization compared with surgery (9).

This has resulted in LM PCI being included in clinical guidelines as an alternative to surgery in cases when the latter represents a high risk (10,11). The practice of PCI on unprotected LM is increasing significantly in Spain (12).

In this uniquely challenging anatomic scenario, the use of intravascular ultrasound (IVUS) has been advocated as a means to optimize procedural results with the hope that this may translate into improved long-term clinical outcomes. However, there is a dearth of appropriately-designed studies examining whether a benefit is derived from the use of IVUS during PCI in patients with LM disease, and available recommendations are mostly supported by retrospective registries and expert opinion (13–15), without consistent results and subjected to important limitations (16). The guideline recommendation for using IVUS guidance during LM PCI is Class IIb (11).

In this study, we sought to investigate the clinical impact of the use of IVUS in patients with LM disease undergoing PCI with DES. For this purpose, we pooled data at the patient level from 4 registries originally designed to evaluate outcomes of patients with LM lesions treated with stents (17,18).

## Methods

The present study consists of the pooled analysis of the following Spanish LM registries:

1. **ESTROFA-LM.** ESTROFA-LM (Grupo Español de Estudio de Stents Farmacoactivos: Left Main) was

a multicenter, retrospective registry that included 770 patients treated with DES in 21 centers from 2004 to 2009. Patients with angiographically-significant lesions in unprotected LM treated with DES were included. Only patients with cardiogenic shock at the time of procedure were excluded. Patients had stable or unstable ischemic heart disease, and LM lesions that were considered significant and with an indication for revascularization. Patients undergoing treatment of lesions in other vessels were also included. All clinical, angiographic, and procedural data were reported in a common database specifically designed for this study. At the same time, all information about the clinical follow-up was also submitted and adequately updated through registry and hospital database reviews, as well as through contact with patients. The 3-year follow-up outcomes have been published elsewhere (17).

2. **RENACIMIENTO.** RENACIMIENTO (Registro Nacional Sobre el Tratamiento del Tronco Común) was a multicenter, prospective registry performed at 30 hospitals in Spain. From November 2007 to November 2008, 1,493 consecutive patients with a significant angiographic involvement of unprotected LM, with indication of revascularization, treated with PCI or surgery were included in a database. In 596 patients, DES were implanted. For the purpose of the present analysis, patients with cardiogenic shock were excluded. This registry was designed for 1-year follow-up.
3. **Bellvitge.** In the Bellvitge registry, 236 consecutive patients were included with angiographically-significant lesions in unprotected LM treated with stents in the period from 2002 to 2010. Among these, 189 were treated with DES. Exclusion criteria were patients undergoing PCI in ST-segment elevation myocardial

### Abbreviations and Acronyms

<b>DES</b>	= drug-eluting stent(s)
<b>IVUS</b>	= intravascular ultrasound
<b>LM</b>	= left main coronary artery
<b>MI</b>	= myocardial infarction
<b>PCI</b>	= percutaneous coronary intervention
<b>TLR</b>	= target lesion revascularization

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