International Journal of Cardiology 211 (2016) 37–42

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

# Provisional vs. two-stent technique for unprotected left main coronary artery disease after ten years follow up: A propensity matched analysis

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ARTICLE INFO

*Article history:*
Received 17 January 2016
Accepted 28 February 2016
Available online 3 March 2016

*Keywords:*
Unprotected left main
Bifurcation
Stenting
Drug eluting stent

ABSTRACT

*Aims:* There is uncertainty on which stenting approach confers the best long-term outlook for unprotected left main (ULM) bifurcation disease.
*Methods and results:* This is a non-randomized, retrospective study including all consecutive patients with 50% stenosis of the left main involving at least 1 of the arteries stemming from the left main treated with drug-eluting stents (DES) in 9 European centers between 2002 and 2004. Patients were divided into two groups: those treated with provisional stentings vs. those treated with two stent strategy. The outcomes of interest were 10-year rates of target lesion revascularization (TLR), major adverse cardiac events (MACE), and their components (cardiovascular death, myocardial infarction [MI], or repeat revascularization), along with stent thrombosis (ST). A total of 285 patients were included, 178 (62.5%) in the provisional stenting group and 87 (37.5%) in the two stent group. After 10 years, no differences in TLR were found at unadjusted analysis (19% vs 25%, $p > 0.05$) nor after propensity score matching (25% vs 28%, $p > 0.05$). Similar rates of MACE (60% vs 66%, $p > 0.05$), death (34% vs 43%, $p > 0.05$), MI (9% vs 14%, $p > 0.05$) and ST were also disclosed at propensity-based analysis.
*Conclusion:* Even after 10 year follow-up, patients treated with provisional stenting on left main showed comparable rates of target lesion revascularization compared to two stent strategy.


## 1. Introduction

Significant stenosis of unprotected left main coronary artery (ULMCA) has an ominous adverse impact on prognosis [1,2]. While surgical revascularization has represented for many years the treatment of choice, percutaneous coronary intervention (PCI) has obtained comparable results thanks to technological innovation, especially in the presence of isolated disease of ULCMA. [3–5].

Choice between provisional vs. two-stent technique represents one of the most challenging situation for interventional cardiologists [6]. Actually for bifurcations involving coronary artery disease other than ULMCA provisional strategy has shown to reduce rates of subsequent revascularization and of stent thrombosis [6].

For patients treated with provisional stenting on ULMCA, most of the studies similarly showed non-inferior or superior results when compared to two-stent strategy, especially in terms of freedom from target

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http://dx.doi.org/10.1016/j.ijcard.2016.02.136
0167-5273/

lesion revascularization (TLR: 7–9). Shortness of follow-up represents one of the most relevant limits of these reports, due to potential increased risk of restenosis and/or stent thrombosis along with introduction and potential impact of new strategies for treatment of bifurcation. For example, the longest follow-up of the previously reported study is limited to 35 months.

Consequently, we performed the present study to analyze all the patients treated with ULMCA with a follow-up of at least 10 years,

## 2. Methods

### 2.1. Inclusion criteria

This study is a multicenter, non-randomized, single-cohort retrospective study including all patients with ULMCA treated with DES in the 9 participating centers (Dipartimento di Scienze Mediche, Divisione di Cardiologia, Città della Salute e della Scienza, Turin, Italy, Division of Cardiology, Brighton, Scientific Institute S. Raffaele, Milan, Italy, Department of Cardiology, Institut Cardiovasculaire Paris Stud, Hôpital Privé Jacques Cartier, Générale de Santé, Massy, France, Cardiovascular Institute, Hospital Clínico San Carlos, 28040 Madrid, Spain; Servicio de Cardiología, Hospital Marqués de Valdecilla, Santander, Cantabria, Spain (JDLT); Divisione di Cardiologia, Ospedale Mauriziano, Turin, Ospedale Di Rivoli). Consecutive patients with ULM treated from 2002 onwards (year in which DES became commercially available in the participating centers) to 2004 were enrolled. Only patients with a 50% stenosis of the left main involving both left main and the origin of at least 1 of the arteries stemming from the left main were included and divided into two groups: those treated with provisional stentings vs. those treated with two stent strategy.

### 2.2. Data collection

Clinical data were abstracted from clinical records (electronic), while follow-up was performed with clinical examinations or phone calls or formal query to primary care physicians.

Angiographic data were collected after examination of coronary angiographies by at least two dedicated physicians: site of lesions, classifications and elaboration of Syntax score were performed according to Syntax criteria. [11].

### 2.3. Clinical and interventional features

Age, gender, cardiovascular risk factors, serum creatinine, indication for PCI and ejection fraction at discharge from hospital after ULM PCI were recorded for each patient.

For the diagnostic and interventional features of ULM disease, information on site of lesion (ostial, mid, or distal), type of technique for bifurcation disease (provisional vs. two-stent strategies), stent type and stent diameter were recorded.

For the angiographic features on non-ULM stenosis, site of vessel and lesion were appraised. For a subgroup of patients, ($n = 120$) Syntax score was evaluated by two different operators at each center [12].

### 2.4. Procedural management

Coronary angioplasty and stent implantation during index PCI were performed according to established practice and guidelines at the time of each procedure. For patients with ULM disease with a Syntax score of 23–32, after discussion with surgeons and patients, PCI on ULM was chosen. The choice of devices, techniques (including the approach to bifurcation stenting, kissing balloon, and post-dilatation), and drug therapy (including glycoprotein IIb/IIIa inhibitors) for the index procedure was at the operating cardiologist's discretion. Post-procedure, all patients were prescribed lifelong aspirin 75 mg once daily for life and clopidogrel 75 mg for 6–12 months or longer. The choice between angiographic and clinical follow-up was at the operator's and referring physician's discretion, taking into account patient preference and comorbidities. In the majority of cases, angiographic follow-up was recommended 6–12 months after the index PCI irrespective of symptoms or signs of ischemia. Treatment of restenosis was also at the operating cardiologist's discretion, but in the majority of cases was collectively discussed and the final management decision was based on the patient's symptoms and/or signs of ischemia, coronary anatomy, surgical risk, feasibility of PCI, and overall life expectancy. In cases of repeat PCI, the choice of technique and device was also left at the interventionist's discretion.

### 2.5. Study endpoints

Repeat PCI (Re-PCI) TLR on ULM at 10 years was the primary end point, defined as repeat revascularization for in-stent restenosis on ULM. MACE (Major Adverse Cardiac Events) and its single components (cardiovascular death, myocardial infarction, re-PCI) were secondary endpoints, along with re-PCI on non-ULM disease and stent thrombosis which was diagnosed and classified according to Academic Research Consortium (ARC) Classification [13].

Follow-up was performed with in-hospital clinical examination, formal inquiry to primary care physicians and patient phone interview by clinical or interventional cardiologists.

### 2.6. Statistical analysis

Categorical variables were compared with the Fisher's exact test. Parametric distribution of continuous variables (presented as mean ± SD) was tested graphically and with Kolmorogov–Smirnov test, and the appropriate analyses were used in accordance with the results. For propensity score, first logistic regression analysis was done for all baseline features that differed between provisional and two stent groups and those clinically relevant (age, diabetes mellitus, previous surgical or percutaneous revascularization, disease of proximal left anterior descending artery or circumflex) and matching was computed after division into quintiles and methods of nearest neighbor on the estimated propensity score [14]. Calibration was tested with Hosmer–Lermeshow, and accuracy was assessed with Area Under the Curve. Standardized differences were evaluated before and after matching to evaluate performance of the model. All statistical analyses were performed with SPSS 21 and differences were considered significant at $\alpha = 0.0$.

## 3. Results

### 3.1. Baseline clinical and angiographic features

285 patients were enrolled, of whom 178 (62.5%) were treated with provisional stenting and 87 (37.5%) with two stent technique. There

**Table 1**
Baseline features of patients.

| | Patients treated with provisional stenting (174) | Patients treated with two stent technique (85) | p |
|---|---|---|---|
| Age (years) | 66 ± 10 | 65 ± 9 | 0.45 |
| Female gender (%) | 35 [21] | 16 [21] | 0.53 |
| Hypertension (%) | 124 (73) | 58 (71) | 0.34 |
| Hyperlipidemia (%) | 121 (72) | 64 (77) | 0.91 |
| Diabetes mellitus | | | 0.52 |
| - Non-insulin dependent | 49 (31) | 23 (30) | |
| - Insulin dependent | 14 [12] | 5 [6] | |
| Smoker habit, both previous and current (%) | 61 (30) | 15 [21] | 0.01 |
| Previous percutaneous coronary intervention (PCI) | 63 (35) | 15 [21] | 0.01 |
| Previous surgical revascularization | 61 (34) | 19 (32) | 0.02 |
| Creatinine at admission (md/dl) | 0.97 ± 0.4 | 0.90 ± 0.51 | 0.73 |