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CLINICAL RESEARCH

CORONARY

Angiographic and Clinical Outcomes After Everolimus-Eluting Stenting for Unprotected Left Main Disease and High Anatomic Coronary Complexity

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ABSTRACT

OBJECTIVES This study determined angiographic and clinical outcomes after everolimus-eluting stent (EES)–supported percutaneous coronary intervention for unprotected left main disease (ULMD) and high SYNTAX (SYNergy between PCI with TAXus and Cardiac Surgery) trial score (≥33).

BACKGROUND The SYNTAX trial has shown the superiority of coronary surgery over percutaneous coronary intervention (PCI) in patients with ULMD and complex coronary anatomy. It has been hypothesized that, if newer generation drug-eluting stents had been used in the SYNTAX trial, there would have been a significant reduction in clinical events.

METHODS Patients had angiograms scored according to the SYNTAX score algorithm and were divided into 2 groups: those with SYNTAX score of ≥33 and those with <33. The main endpoints were ULMD restenosis and 3-year cardiac mortality.

RESULTS From May 2008 to July 2014, 393 patients underwent EES implantation for ULMD (181 patients had a SYNTAX score ≥33, whereas 212 patients had a SYNTAX score <33). Overall, the restenosis rate was 4.9% (6% in SYNTAX patients scoring ≥33 and 4.1% in SYNTAX patients scoring <33; $p = 0.399$). On multivariate analysis, the only variable related to restenosis was stent length (odds ratio [OR]: 1.06; 95% confidence interval [CI]: 1.02 to 1.09; $p = 0.002$). Three-year cardiac survival rates were 99 ± 1% and 98 ± 2% in patients with European system for cardiac operative risk evaluation (EuroSCORE) <6 and SYNTAX <33 and ≥33, respectively, and 90 ± 3% and 87 ± 3% in patients with a EuroSCORE >6 and SYNTAX score <33 and ≥33, respectively. EuroSCORE was strongly related to cardiac mortality, while the SYNTAX score ≥33 was not both in patients with a EuroSCORE <6 or ≥6, and there were no interactions between EuroSCORE and SYNTAX score ≥33.

CONCLUSIONS For ULMD patients, high anatomical complexity as defined by a SYNTAX score ≥33 is not predictive of clinical outcome after PCI. (TAXUS Drug-Eluting Stent Versus Coronary Artery Bypass Surgery for the Treatment of Narrowed Arteries [SYNTAX]; NCT00114972) (J Am Coll Cardiol Intv 2016;9:1001–7) © 2016 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

CABG = coronary artery bypass graft

CTO = chronic total occlusion

DES = drug-eluting stent(s)

EES = everolimus-eluting stent(s)

EuroSCORE = European system for cardiac operative risk evaluation

MACCE = major adverse cardiac and cerebrovascular event(s)

PCI = percutaneous coronary intervention

TVR = target vessel revascularization

ULMD = unprotected left main disease

Randomized comparison of percutaneous coronary intervention (PCI) with coronary artery bypass graft (CABG) for unprotected left main disease (ULMD) has shown the superiority of CABG in patients with complex coronary anatomy, and guidelines do not recommend PCI in patients with complex coronary anatomy (1–5). The SYNTAX (SYNergy between PCI with TAXus and Cardiac Surgery) trial introduced an anatomic complexity score and showed that patients with ULMD and high SYNTAX score had a higher major adverse cardiac and cerebrovascular event (MACCE) rate if treated with PCI than those treated with CABG, that is, at 5-year follow-up, MACCE rates were 46.5% and 29.7%, respectively ($p < 0.0001$) (3). It has been hypothesized that if newer generation drug-eluting stents (DES) had been used in the SYNTAX trial, there would have been a significant reduction in clinical events. This hypothesis is supported by registry studies (6,7), and 2 ongoing trials will compare PCI with surgery by using everolimus-eluting stents (EES).

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No study of EES has focused on ULMD in patients with complex coronary anatomy. The aim of this study was to describe the angiographic and clinical outcomes after EES-supported PCI for ULMD and high SYNTAX score (≥33).

METHODS

PATIENTS AND TREATMENT. The Florence ULMD PCI registry is a prospective single-center registry that started in 2003 and includes consecutive patients treated with DES supported PCI for ULMD.

Details of this registry have been published previously (6,8,9). From the database, we identified all patients with ULMD who received exclusively EES (either XIENCE; Abbott Vascular, Santa Clara, California; or Promus, Boston Scientific Corp., Natick, Massachusetts) and complex coronary anatomy (SYNTAX score ≥33). Patients underwent PCI instead of coronary surgery because of either the patient's preference or the high risk associated with surgery. High surgical risk was defined as a logistic European system for cardiac operative risk evaluation (EuroSCORE) ≥6 (10). All angiograms were scored according to the SYNTAX scoring algorithm (11).

PCI was performed using standard techniques. For distal left main disease, a single-stent technique was preferred in patients with a normal or diminutive appearing side branch, whereas a double-stent technique was considered in patients with disease of both ostia and proximal segments of left anterior descending artery and circumflex artery. Whatever the stenting technique used, routine final kissing balloon post-dilation with noncompliant balloons had to be performed in all cases. Intravascular ultrasonographic guidance was used at the discretion of the operator. Multivessel disease was defined as stenosis >70% of 1, 2, or 3 major coronary arteries on visual assessment at baseline angiography, other than the LM lesion. Disease of left anterior descending artery and of the circumflex artery included lesions beyond 10 mm from the ostia. Chronic total occlusion (CTO) was defined as a complete occlusion (Thrombolysis In Myocardial Infarction [TIMI] flow grade 0) lasting >3 months. Completeness of revascularization was defined as successful revascularization of all vessels with a stenotic diameter >70% and a diameter >2 mm on visual assessment achieved either during index hospitalization or at any time within 30 days after the first ULMD PCI.

Procedural adjunctive antithrombotic therapy included unfractionated heparin (an initial bolus of 70 U per kg, and additional boluses during the procedure to achieve an activated clotting time of 200 to 250 s), whereas glycoprotein IIb/IIIa inhibitors were prescribed at the discretion of the operator. Chronic antithrombotic treatment included aspirin (300 mg/day, indefinitely) and clopidogrel, 75 mg daily, or prasugrel, 10 mg daily for at least 1 year.

Treatment protocol included routine 6- to 9-month angiographic follow-up. All patients were considered eligible for angiographic follow-up, except for asymptomatic patients with severe renal insufficiency. Unscheduled angiography was allowed on the basis of clinical indication.

ENDPOINTS. The angiographic endpoint of the study was angiographic restenosis, defined as left main binary angiographic in-segment restenosis >50% at the scheduled or unscheduled angiographic follow-up. Left main restenosis was defined as >50% luminal narrowing at the segment site, including the stent and 5-mm proximal and distal to the stent edges of the target vessel on follow-up angiography. Angiographic parameters were assessed using an automated edge-contour detection computer analysis system (Innova 2100IQ, General Electric Healthcare Technologies, Little Chalfont, Buckinghamshire, United Kingdom). Clinical endpoints were 1- and 3-year cardiac mortality rates. Other clinical exploratory endpoints were 1-year MACCE that included cardiac death, nonfatal myocardial infarction, target vessel revascularization (TVR), and stroke; 1-year TVR was defined as repeat