Are Paclitaxel-Eluting Stents Better in Unprotected Left Main Coronary Artery Disease? Three-Year Clinical and Intravascular Imaging Results From a Randomized Study

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Key words: *drug-eluting stents; paclitaxel; left main stenting; long-term; intravascular ultrasound.*

Summary. *Background and Objective. Recent publications have demonstrated superior outcomes in unprotected left main patients after paclitaxel-eluting stent (PES) implantation. Long-term data in these patients are limited. The aim of this study was to evaluate if intravascular ultrasound (IVUS)-guided PES implantation is superior to bare metal stent (BMS) implantation in unprotected left main disease after lesion pretreatment with cutting balloon during long-term follow-up.*

Material and Methods. Unprotected left main patients were randomized to BMS (n=50) or PES implantation (n=53). All interventions were IVUS-guided and cutting balloon pretreatment before stenting was performed in all patients. All patients were scheduled for 6-month and 3-year follow-up. Subgroups of patients who underwend IVUS and OCT imaging at 3-year follow-up were analyzed. The primary endpoint was the major adverse cardiac events (MACEs) defined as death, Q-wave myocardial infarction, or target lesion revascularization.

Results. Baseline characteristics were similar in both the groups with a mean SYNTAX score of 31.4±14.5 in BMS and 32.6±11.7 in PES patients (P=0.718). At 3 years, MACEs occurred in 18 patients (36.0%) in the BMS and 7 patients (13.2%) in the PES group (P=0.011). By IVUS, percent neointimal volume obstruction at 3 years was reduced from 18.1%±8.7% with BMSs to 10.0%±5.4% with PESs (P<0.001). The total number of uncovered stent struts per OCT image and IVUS image was 0.4±0.8 and 1.2±1.5, respectively (P<0.001).

Conclusions. The current study demonstrated that IVUS-guided PES implantation was superior to BMS implantation after cutting balloon pretreatment in unprotected left main disease at 3 years. If compared with IVUS, OCT was more precise in the assessment of stent endothelization.

Introduction

Although coronary artery bypass grafting (CABG) is the gold standard for the treatment of unprotected left main coronary artery (ULMCA) disease (1), many patients are scheduled for percutaneous coronary intervention (PCI). Initial studies on balloon angioplasty for ULMCA disease reported poor short- and long-term results (2, 3). Bare-metal stents (BMS) reduced the rates of procedural complications; however, the rates of repeat revascularization because of restenosis remained high (4–7). Recent progress in interventional cardiology, including the use of drug-eluting stents (DESs), intravascular ultrasound (IVUS) imaging, debulking before stenting, and effective antiplatelet agents, have resulted in the decreased restenosis rate (8, 9).

Several recent publications have demonstrated superior short- and mid-term outcomes in patients with left main artery disease after DES versus BMS implantation (10, 11) and similar survival rates after DES versus CABG (12–16). The main restriction is that long-term data with both BMS and DES in this subset of patients are limited (15, 17–22). Moreover, some reports have raised concern about incomplete or delayed neointimal coverage of DES with a subsequent increase in late stent thrombosis (23).

Therefore, in this randomized study, IVUS-guided BMS and paclitaxel-eluting stent (PES) implantation after lesion pretreatment with cutting balloon for ULMCA stenosis was evaluated. The aim of the study was to determine whether PES was superior to BMS during the long-term clinical, angiographic, and intravascular follow-up.

Material and Methods

The design and detailed methods of this randomized trial were reported elsewhere (11). In brief, 103 patients were randomly assigned to receive bare-metal Express or Liberte stent or Taxus Express paclitaxel-eluting stent (Boston Scientific Corporation, Natick, Mass, USA) for unprotected left main coronary artery disease. Patients were eligible for the study if they had stable or unstable angina pectoris, or silent ischemia, >50% diameter

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stenosis of ULMCA, which could be treated with stent implantation. All patients were good candidates for CABG. The major exclusion criteria included coronary artery bypass grafts to left anterior descending or left circumflex artery branches, life expectancy less than 1 year, or planned noncardiac surgery in 6 months. All patients provided written informed consent before randomization.

Percutaneous Coronary Intervention Procedure. All patients undergoing PCI were pretreated with aspirin (100 mg) plus clopidogrel (loading dose, 300 mg). After the procedure, aspirin was continued indefinitely, while clopidogrel was prescribed for at least 6 months. Low-molecular-weight heparin or unfractionated heparin was administered in the catheterization lab. The use of periprocedural glycoprotein IIb/IIIa inhibitors was at the discretion of the operator. All interventions were performed using IVUS guidance and cutting balloon pretreatment for atherosclerotic plaque modification before stenting. Methods of cutting balloon intervention and stent implantation were described previously. If any segment on the treated vessel did not meet success criteria, additional balloon dilatations with noncompliant balloon were performed.

Quantitative Coronary Angiography, Intravascular Ultrasound, and Optical Coherence Tomography Protocol. Quantitative coronary angiography (QCA), IVUS, and optical coherence tomography (OCT) measurements were performed off-line at the Riga core lab by independent observers blinded to the treatment arm. After intracoronary nitrate administration, coronary angiograms obtained at baseline, after stenting, at 6 months and 3 years were analyzed using a computer-based QCA-CMS system, version 4.0 (MEDIS Medical Imaging Systems Inc., Leiden, Netherlands). Measurements were obtained in the stented segments as well as their margins 5 mm proximal and distal to the stent. Angiographic restenosis was defined as diameter stenosis ⩾50% at follow-up. Following intracoronary nitrate administration, IVUS images were acquired using automated pullback at 0.5 mm/s with a commercially available imaging system GALAXY II (Boston Scientific Corporation, Natick, Mass, USA) at baseline as well as 6 months and 3 years. Two-dimensional and volumetric IVUS analysis was performed using a computer-based quantitative analysis system (QCU-CMS version 4.14 MEDIS Medical Imaging Systems Inc., Leiden, Netherlands) according to the previously published protocol. The lesion segment was classified as a culprit lesion with 5 mm of proximal and distal reference (most normal appearing) segments. In-stent late loss in lumen diameter (or lumen area) was calculated as the postprocedural lumen dimensions (minimum lumen diameter [MLD] or minimum lumen area [MLA]) minus the follow-up dimensions (MLD or MLA). Volume index was calculated as volume divided by stent length to adjust volume measurement for stent length. Percent neointimal volume obstruction was defined as the ratio of the volume of neointimal hyperplasia to the volume of the stent multiplied by 100.

The OCT images were analyzed with a computer-based quantitative analysis system (QCU–CMS version 4.14 MEDIS Medical Imaging Systems Inc., Leiden, Netherlands) designed for IVUS analysis. The areas and diameters of stent, lumen, and neointimal hyperplasia were measured every 1 mm within the stented segment. The neointimal coverage of stent struts was assessed every 1 mm within the stented segment. OCT and IVUS images were analyzed by side-by-side viewing of follow-up studies, review of landmarks and pullback speed, and frame-by-frame comparison for matching segments. The representative OCT and IVUS images obtained during the follow-up angiography are shown in Fig. 1. Unlike OCT, there was no visually detectable neointimal proliferation in the IVUS image.

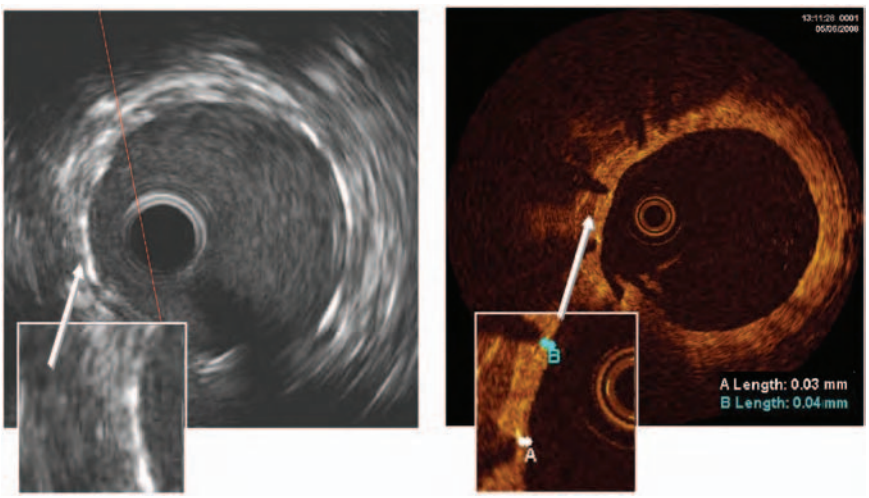

Fig. 1. Corresponding images by intravascular ultrasound and optical coherence tomography 3 years after drug-eluting stent implantation

Follow-Up. The patients were asked to return for clinical follow-up to assess adverse events and to perform stress testing at 1, 3, 6, and 12 months and then annually thereafter. Follow-up angiography with quantitative coronary angiography and intravascular ultrasound was performed at 6 months and 3 years. At 3 years, angiographic and IVUS follow-up was performed in all patients alive who did not experience target vessel revascularization during the 6-month follow-up and did not refuse to undergo the procedure. At the 3-year follow-up, additional OCT was performed for patients who consented to the investigation.

Definitions. The primary endpoint of the study was the major adverse cardiac event (MACE)-free survival. MACE was defined as the occurrence of death, Q-wave myocardial infarction, or target lesion revascularization during follow-up period. Patients with more than one event were assigned to the highest rank event. Death was defined as death from any cause. All deaths were considered to be of cardiac origin unless a noncardiac origin was identified. Q-wave myocardial infarction was defined as documentation of a new abnormal Q wave after the index treatment. Target lesion revascularization (TLR) was defined as any repeat surgical or percutaneous intervention to treat a luminal stenosis in the stent or within the 5-mm segments adjacent to the stent, including the ostium of the left anterior descending artery and/or circumflex artery. Procedural success was defined as the minimum lumen area of $\geqslant$9.0 mm^2 by IVUS or residual angiographic stenosis of <10% (if the minimal luminal reference vessel size by IVUS was smaller than 9.0 mm^2).

Statistical Analysis. Statistical analysis was performed using the SPSS 12.0 for Windows (SPSS Inc., Chicago, IL, USA). Continuous variables are presented as mean ± standard deviation and were compared using the unpaired Student *t* test or Mann-Whitney rank-sum test depending on data distribution. Categorical variables were compared by ×2 statistics or the Fisher exact test as appropriate. All statistical tests were 2-sided, and a *P* value <0.05 was considered statistically significant. The major adverse cardiac event-free survival was analyzed by the Kaplan-Meyer analysis, and differences between groups were analyzed with the log-rank test. All data for QCA and IVUS refer to the offline analysis.

Results

A total of 103 patients with ULMCA disease underwent IVUS-guided PCI with PES (n=53) or BMS (n=50) implantation after cutting balloon pretreatment.

Baseline clinical, lesion, and procedural characteristics of the study population were published elsewhere (11). Overall, there were no significant differences in baseline characteristics except for a significantly longer mean stent length, shorter mean stent diameter, and higher maximal stent implantation pressure in the group treated with PES. Coronary lesion complexity was similar in both the groups with a mean SYNTAX score of 31.4±14.5 in the BMS and 32.6±11.7 in the PES patients (*P*=0.718). The procedural success was 100% in both the groups.

Clinical Follow-Up. The flow of patients through the trial is shown in Fig. 2. A total of 93 patients completed the clinical long-term follow-up. During this period (906±346 days), 7 patients (14.0%) in the BMS group and 3 patients (5.7%) in the PES group died (*P*=0.193). Deaths from cardiac causes occurred in 4 patients (8.0%) in the BMS group and 3 patients (5.7%) in the PES group (*P*=0.710). Deaths from noncardiac causes in the BMS group occurred due to lung cancer, stomach cancer, and non-Hodgkin lymphoma. No patient was lost to follow-up. During this follow-up period, only 1 patient (2.0%) in the BMS group and 3 patients (5.7%) in the PES group experienced Q-wave myocardial infarction (*P*=0.618). No cases of definite or probable stent thrombosis were observed. Ten patients (20.0%) in the BMS group underwent TLR (9 repeat PCI and 1 CABG); in contrast, only 3 patients (5.7%) in the PES group needed repeat PCI (*P*=0.038). MACEs at follow-up occurred in 18 patients (36.0%) and 7 patients (13.2%) in the BMS and PES groups, respectively (*P*=0.011). Cumulative clinical outcomes at the three-year follow-up are summarized in Table 1 and Fig. 3.

Angiographic and Intravascular Ultrasound Follow-Up. Angiographic follow-up was performed in 74 patients. Of the 93 patients alive at 3 years after the index procedure, 9 patients who had TLR during the 6-month follow-up were not scheduled to undergo angiography. Ten patients refused to undergo coronary angiography. Two patients were excluded from IVUS analysis due to incomplete image acquisition. Analyzable serial IVUS images were acquired in 72 patients. The IVUS analyses revealed good apposition of the implanted stents. At 3 years, significant differences in the lumen area and lumen diameter late loss were observed between the BMS and PES groups. The MLA late loss in the PES group was 1.1±0.9 vs. 3.4±1.6 in the BMS group (*P*<0.001), and the MLD late loss in the PES group was 0.2±0.2 vs. 0.5±0.2 in the BMS group (*P*<0.001). Moreover, the neointimal volume index and percentage of neointimal volume obstruction at 3 years were significantly lower in the PES group compared with the BMS group (1.2±1.0 vs. 2.0±0.9, *P*=0.015; and 10.0±5.4 vs. 18.1±8.7, *P*<0.001, respectively). The comparison of neointimal vol-

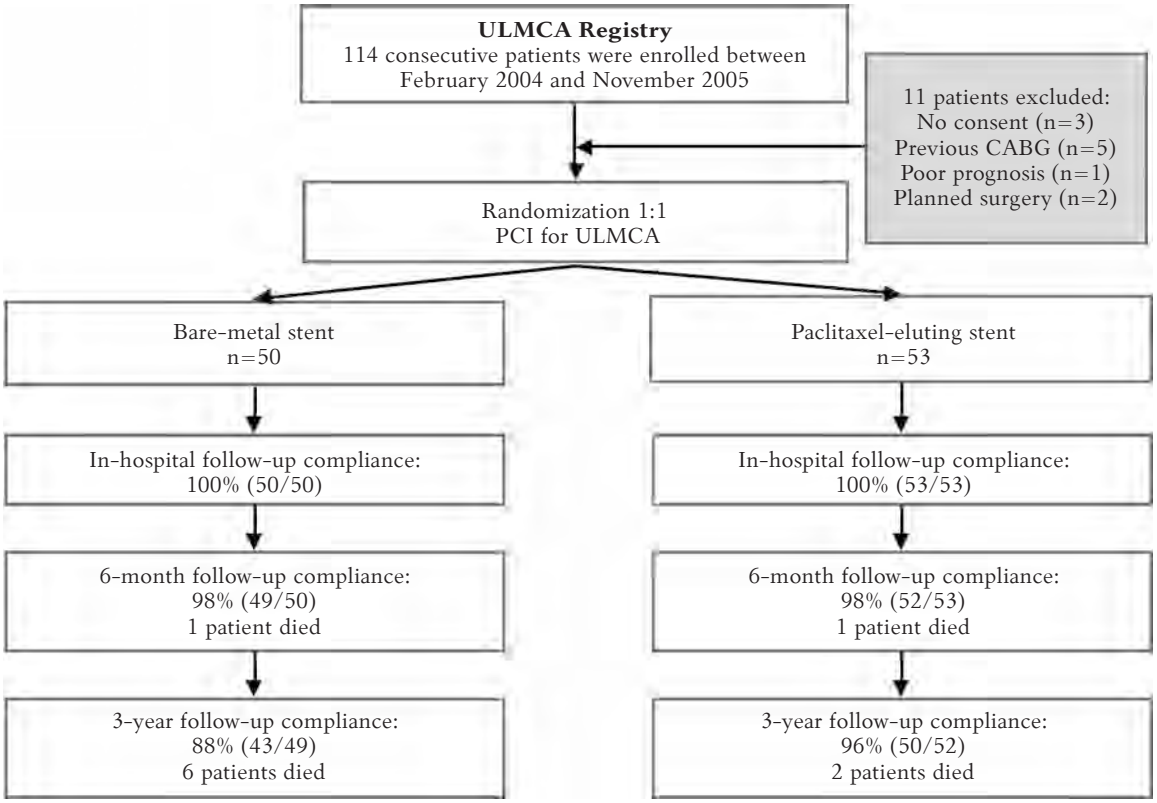

Fig. 2. Flow of patients through the trial

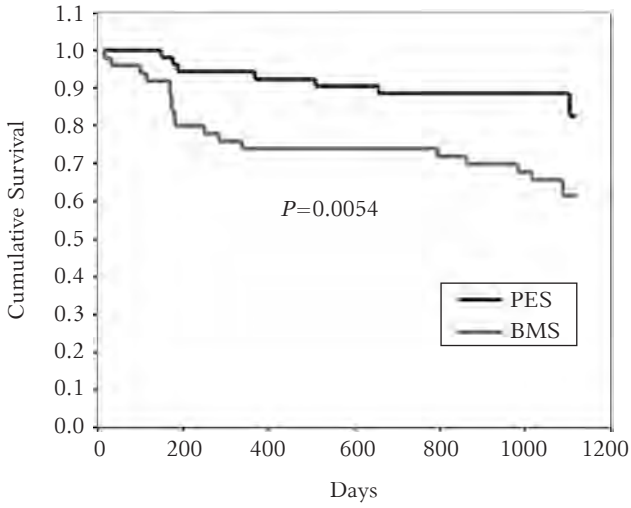

Fig. 3. Kaplan-Meier curves (freedom from death, Q-myocardial infarction, and target lesion revascularization)

Table 1. Cumulative Clinical Outcomes at 3-Year Follow-Up

Outcome	All (n=103)	BMS (n=50)	PES (n=53)	*P*
Total death, n (%)	10 (9.7)	7 (14.0)	3 (5.7)	0.193
Cardiac death, n (%)	7 (6.8)	4 (8.0)	3 (5.7)	0.710
Q-MI, n (%)	4 (3.9)	1 (2.0)	3 (5.7)	0.618
TLR, n (%)	13 (12.6)	10 (20.0)	3 (5.7)	0.038
TLR PCI, n (%)	12 (1.7)	9 (18.0)	3 (5.7)	0.067
TLR CABG, n (%)	1 (1.0)	1 (2.0)	0 (0)	0.485
Total MACEs, n (%)	25 (24.3)	18 (36.0)	7 (13.2)	0.011

BMS, bare metal stent; CABG, coronary artery bypass grafting; MACE, major adverse cardiac event; PCI; percutaneous coronary intervention; PES, paclitaxel-eluting stent; Q-MI, Q-wave myocardial infarction; TLR, target lesion revascularization.

ume obstruction at 6 months and 3 years showed a progression in neointimal hyperplasia in the PES group (9.8±8.7 at 6 months vs. 10.0±5.4 at 3 years, P=0.001), while changes in the BMS group were not significant (16.9±10.7 vs. 18.1±8.7, P=0.261). IVUS results are reported in Table 2.

Comparison of Intravascular Ultrasound and Optical Coherence Tomography at Follow-Up. OCT images were acquired in 20 patients with left main disease and compared with IVUS images obtained during the same angiography procedure. Two patients were excluded from OCT analysis because of incomplete image acquisition. Analyzable OCT images were acquired in 18 patients. A total of 200 corresponding IVUS and OCT cross-sectional images were compared. The mean minimum lumen diameter was 3.2±0.4 mm by both IVUS and OCT. The mean minimum lumen area was 8.1±1.8 mm^2 by IVUS and 8.1±2.2 mm^2 by OCT. The correlations between IVUS and OCT measurements were strong and significant (Figs. 4 and 5). However, when the degree of stent endothelization by IVUS and OCT

Table 2. Intravascular Ultrasound Results at Three Years Follow-Up

	BMS (n=35)	PES (n=37)	*P*
Postintervention			
MVD, mm	4.7±0.5	4.5±0.5	0.291
EEM area, mm^2	19.4±4.3	16.8±3.4	0.035
MLD, mm	3.2±0.4	3.2±0.3	0.900
MLA, mm^2	9.4±1.7	8.5±1.5	0.078
Malapposition, n (%)	0 (0)	0 (0)	–
At 6 months			
MVD, mm	4.8±0.5	4.7±0.5	0.521
EEM area, mm^2	19.7±4.0	18.0±3.4	0.096
MLD, mm	2.9±0.6	3.0±0.4	0.501
MLA, mm^2	7.2±2.8	7.3±2.0	0.892
Late loss in lumen diameter, mm	0.5±0.3	0.2±0.3	0.012
Late loss in lumen area, mm^2	3.0±1.4	1.3±1.2	<0.001
Neointimal volume index, mm^3/mm	1.9±1.2	1.0±0.8	0.002
Neointimal volume obstruction, %	16.9±10.7	9.8±8.7	0.011
Malapposition, n (%)	0 (0)	0 (0)	–
At 3 years			
MVD, mm	4.8±0.5	4.9±0.5	0.644
EEM area, mm^2	18.4±4.0	18.9±4.0	0.642
MLD, mm	2.8±0.5	3.0±0.4	0.108
MLA, mm^2	6.6±2.5	7.5±1.7	0.153
Late loss in lumen diameter, mm	0.5±0.2	0.2±0.2	<0.001
Late loss in lumen area, mm^2	3.4±1.6	1.1±0.9	<0.001
Neointimal volume index, mm^3/mm	2.0±0.9	1.2±1.0	0.015
Neointimal volume obstruction, %	18.1±8.7	10.0±5.4	<0.001
Malapposition, n (%)	0 (0)	0 (0)	–

Values are mean ± standard deviation unless otherwise indicated. BMS, bare-metal stent; EEM, external elastic membrane; MLA, minimum lumen area; MLD, minimum lumen diameter; MVD, minimum vessel diameter; PES, paclitaxel-eluting stent.

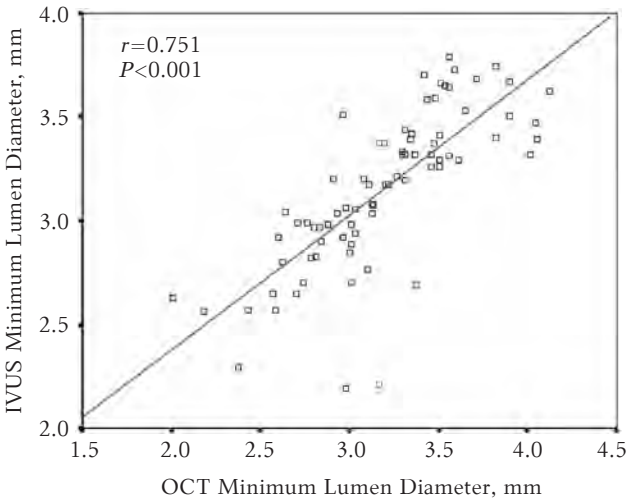

Fig. 4. Correlation of intravascular ultrasound (IVUS) minimum lumen diameter versus optical coherence tomography (OCT) lumen diameter

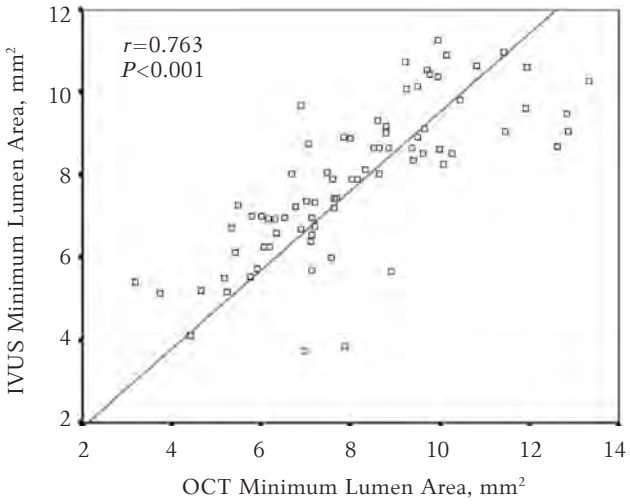

Fig. 5. Correlation of intravascular ultrasound (IVUS) minimum lumen area versus optical coherence tomography (OCT) lumen area

was compared, the total number of uncovered stent struts per image was 0.4±0.8 by OCT and 1.2±1.5 by IVUS (P<0.001).

Discussion

The main finding of this randomized long-term follow-up study was that both PES and BMS implantation were safe and feasible in patients with ULMCA stenosis. The benefit of PES implantation was observed up to 3 years at clinical, angiographic, and IVUS follow-up with an acceptably low incidence of recurrent events: 5.7% of total and 5.7% of cardiac deaths in the PES group compared with 14.0% of total and 8.0% of cardiac deaths in the BMS group and with the overall MACE incidence of 13.2% and 36.0% (P=0.011) in the PES and

BMS subgroups, respectively. Regarding death rate, natural aging of the patients has to be considered (at enrolment stage, the mean age was 62.56±11.45 in the BMS group and 61.08±10.28 in the PES group). At the 3-year follow-up, the oldest patient was already 89 years old.

There is little information from long-term follow-up studies regarding the efficacy of drug-eluting stents in patients with lesions located at the left main coronary artery (19–22) with especially scarce long-term data available from angiographic studies (17, 18). However, to the best of our knowledge, no long-term data are available in the literature from IVUS follow-up studies in the same patient group.

Long-Term DES Registries. In the long-term analysis of the DELFT (Drug-Eluting stent for LeFT main) registry (n=358, with lesion location in distal bifurcation in 73.7% of patients), the 3-year incidence of cardiac death and TLR was 9.2% and 5.8%, respectively (20), while the MACE rate was 32.1%. Chieffo et al. in a multicenter registry analyzing nonbifurcational lesions that involved unprotected left main coronary artery at 3-year follow-up found a MACE rate of 7.4% in elective patients who underwent intervention with DESs (18). In our study, the MACE rate was 13.2% in the PES group, where 81% of cases had an involvement of bifurcation.

Drug-Eluting Stents vs. Bare-Metal Stents. Palmerini et al. recently published a 2-year clinical follow-up study with DESs versus BMSs in a real-world registry of ULMCA. This multicenter observational study showed promising results with 2-year survival and survival free from cardiac death rates of 90.1% and 93.1% in the DES group and 75.9% and 82.4% in the BMS group ($P<0.001$) (22). Gao et al. showed that the cumulative MACE rate at 15 months was significantly decreased in the elective patients (n=220) who received DESs as compared with patients (n=224) treated with BMSs (9.5% vs.16.5%, $P=0.029$) derived from the Chinese registry of unprotected LM stenting, despite the fact that more complex patients and lesions were included in the DES group (24). These data are consistent with our study.

Stents vs. CABG Long-Term Outcomes. The first randomized trial (the LE MANS study) of 52 PCI (35% with DES) and 53 CABG patients showed that the MACCE (cardiac death, acute myocardial infarction, stroke, repeat intervention, and in-stent thrombosis)-free 1-year survival was similar in both groups (71.2% for PCI vs. 75.5% for CABG, $P=0.29$) (19). Data from the largest ongoing prospective multicenter randomized SYNTAX trial of 705 patients with ULMCA showed that the overall MACCE (death, myocardial infarction, stroke, and repeat revascularization) rate at 1-year follow-up in the PCI group was comparable with that in the CABG group (15.8% vs. 13.7%) (25). PCI outcomes were excellent relative to CABG in LM isolated and LM plus one-vessel disease, even though were not statistically different. The PES cohort of our study showed similar results to the SYNTAX 1-year MACCE data. Long-term data from the SYNTAX trial are awaited, while the LE MANS study showed the similar MACCE-free survival during 28.8±9.9-month follow-up in both the groups (53.9% in the PCI vs. 56.6% in the CABG group; F-Cox test, $P=0.47$). Despite the intermediate SYNTAX score in the LE MANS study and our study (25.2% and 32.0%, respectively), the MACE-free survival was lower in our study – 75.7% in both BMS and DES patients at 3-year follow-up.

Another recently published large observational study (the MAIN-COMPARE) evaluated data from 1102 patients with ULMCA disease who underwent stent implantation (28.9% received BMSs and 71.1% DESs) and 1138 patients who underwent CABG at 12 medical centers in Korea (21). There were no significant differences in the rates of death or the composite endpoint of death, Q-wave myocardial infarction, or stroke in the PCI and CABG groups. However, by the third year of study, the survival free from target-vessel revascularization (TVR) was significantly lower in the stent groups: 82.5% in the BMS and 90.7% in the DES groups vs. 97.4% in the CABG group (21). In our study, repeat TLR rates with PESs and BMSs were 5.7% 20.0%, respectively, that were found to be similar to the MAIN-COMPARE study.

Despite the large number of patients with distal LM stenosis (81% in the PES group and 68% in the DES group) and high SYNTAX scores (32.6% and 31.3%, respectively) in our study, the low MACE incidence at the 3-year follow-up, especially in the PES group (13.2%), compared with other studies was achieved. We tend to claim that it could be reached due to a 100% use of plaque debulking with cutting balloon as well as use of IVUS guidance in stenting procedure. However, randomized trials of unprotected LM stenting with cutting balloon plague modification versus without debulking as well as with IVUS guidance versus without one are required to establish benefits of these techniques.

Intravascular Ultrasound. IVUS is an important tool for confirming the presence of significant left main disease and also for guiding selection of stent size, assessing the presence of calcification, and documenting the involvement of the distal left main vessel and its branches. IVUS minimum lumen diameter and area stenosis were found to be the most important quantitative predictors of cardiac events (8). Our study is the first report of long-term serial IVUS analysis of patients with ULMCA treated with PESs vs. BMSs. The percentage of neointimal vol-

ume obstruction at 3 years was significantly lower in the PES group compared with the BMS group (10.0%±5.4% vs. 18.1%±8.7%, $P<0.001$). However, the comparison of neointimal hyperplasia for serial patients at 6 months and 3 years showed a significant progression of neointima in the PES group ($P=0.001$), while changes in the BMS group were not significant ($P=0.261$)

Optical Coherence Tomography. A strong correlation between IVUS and OCT parameters was observed in our study. It corresponds to the findings in other trials (26). However, when stent strut coverage with neointimal tissue was compared, there were more uncovered struts per one IVUS image compared with OCT. We can assume that often the assessment of stent endothelization is below the resolution of IVUS. Although OCT was superior to IVUS in visualization of microscopic structures of the coronary arteries, an important limitation of this technique is the need to displace blood during OCT image acquisition and substantial signal attenuation of the OCT source light, and low penetration of the signal. Therefore, in our small subset of patients with large vessel (left main) disease, a complete image acquisition was impossible in 2 patients (10%).

In spite of fast development of new intravascular imaging technologies, the clinical impact of these tools is insufficiently explored. Park et al. in their MAIN-COMPARE study showed that elective stenting with IVUS guidance, especially in the placement of drug-eluting stent, might reduce the long-term mortality rate for unprotected left main coronary artery stenosis when compared with conventional angiography guidance (27). Compared with angiography, IVUS has the unique ability to assess suboptimal results of stenting, which may result in target lesion failure. OCT can give us more precise information regarding small dissections and malapposed stent struts if compared with IVUS. If we want to do the job to the best of our ability, we must embrace imaging techniques such as IVUS and OCT, especially if treating such a high-risk lesion cohort as left mains.

Stent Thrombosis. Stent thrombosis (ST) is one of the major concerns for the use of DESs due to the potentially fatal consequences. The real-world DES registries with long-term follow-up have reported an overall incidence of mortality related to ST lower than 10% (28). In our study, the definite ST did not occur. All the patients were taking dual antiplatelet therapy at least up to 6 months after intervention. Some individuals were continually administered dual antiplatelet therapy until 3 years and others were continually administered aspirin therapy only. This finding shows that the use of both PESs and BMSs is safe under appropriate antiplatelet therapy even in left main. Moreover, we connect this favorable outcome to our technique of left main stenting (using debulking devices such as cutting balloon) and IVUS guidance. This finding is consistent with the LE MANS Prospective Randomized study, where no ST was documented in the PCI group at 1-year follow-up (19).

With this long-term follow-up study, we tried to answer the question whether we should use PESs in all unprotected LM cases. The present prospective, randomized 3-year follow-up study suggests that PES is superior to BMS in terms of MACEs as well as in terms of IVUS parameters.

Study Limitations. The present study was carried out in a single center and had an open label design. The modest sample size and open-label nature of this trial led to differences between the two arms in the vessel size, stent length and diameter, and inflation pressure. The extent to which these differences contributed to the observed results is unknown. Larger registries and randomized trials are required to explore the optimal technique of left main stenting, especially when the distal bifurcation is involved, including a one- vs. two-stent technique, and the utility of IVUS guidance and plaque modification.

Conclusions

Based on the results of our study, we conclude that patients with unprotected left main disease treated with paclitaxel-eluting stents using cutting balloon plague pretreatment and intravascular ultrasound guidance had favorable late outcomes in comparison with bare metal stents. The results of long-term follow-up demonstrated a significant benefit of paclitaxel-eluting stents versus bare metal stents in terms of both clinical and intravascular ultrasound parameters. Optical coherence tomography is more accurate tool for the evaluation of stent endothelization compared with IVUS. Therefore, the use of intravascular ultrasound and optical coherence tomography should be encouraged in comparison studies aimed at revealing significant neointimal differences in small sample size populations.

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Statement of Conflict of Interest

The authors state no conflict of interest.

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