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LONG-TERM CLINICAL RESULTS FOR RANDOMISED COMPARISON OF PACLITAXEL-ELUTING VERSUS BARE-METAL STENTS IN UNPROTECTED LEFT MAIN CORONARY ARTERY DISEASE

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To optimise percutaneous coronary intervention (PCI) strategy for unprotected left main (ULMCA) disease we performed a randomised study: IVUS-guided bare metal stent (BMS) versus paclitaxel-eluting stent (PES) implantation after lesion pre-treatment with cutting balloon (CB) for unprotected LM lesions. The purpose of this randomized study was to evaluate six-month and three-year clinical results. Several recent publications have demonstrated good short- and mid-term outcomes in patients with left main artery disease after stent implantation. However, data on long-term comparison of BMS and PES for LM lesions are limited. Patients with left main coronary artery disease enrolled at Latvian Centre of Cardiology were randomly assigned to either BMS (n = 50) or PES implantation (n = 53). All interventions were IVUS-guided and CB pre-treatment before stenting was performed in all patients. All patients were scheduled for six-month and three-year follow-up. The primary endpoint was major adverse cardiac events (MACE) defined as death, Q wave myocardial infarction or target lesion revascularisation (TLR). Baseline clinical and procedural characteristics were comparable in both groups. At six months, the MACE-free survival rate was 70% in BMS and 87% in PES patients (P < 0.05). At three years, MACE occurred in 18 patients (36.0%) in the BMS and seven patients (13.2%) in the PES group (P < 0.05). The current study demonstrates the benefit of IVUS guided paclitaxel-eluting stent implantation after cutting balloon pre-treatment in left main coronary artery disease over bare metal stent implantation at six months and three years.

Key words: *drug-eluting stents, paclitaxel, left main stenting, long-term.*

INTRODUCTION

Although coronary artery bypass grafting (CABG) is the gold standard for the treatment of the unprotected left main coronary artery (ULMCA) disease (Smith *et al*., 2006), many patients are currently undergoing percutaneous coronary intervention (PCI). Initial studies of balloon angioplasty for ULMCA disease had poor early and long-term results (O'Keefe *et al*., 1989; Eldar *et al*., 1991). Bare-metal stents (BMS) reduced procedural complications, however rates of repeat revascularisation because of restenosis remained high (Tan *et al*., 2001; Takagi *et al*., 2002; Park *et al*., 1998; Silvestri *et al*., 2000). Recent progress in interventional cardiology, including the use of drug-eluting stents (DES), intravascular ultrasound (IVUS) imaging, debulking before stenting and effective antiplatelet agents, have resulted in decreased restenosis rate (Abizaid *et al*., 1999; Park *et al*., 2001).

Several recent publications have demonstrated superior short- and mid-term outcomes in patients with left main artery disease after DES versus BMS implantation (Park *et al*., 2005; Erglis *et al*., 2007) and similar survival rates after DES versus CABG (Lee *et al*., 2006; Palmerini *et al*., 2007; 2006; Sanmartin *et al*., 2007; White *et al*., 2008). The main restriction is that long-term data with both BMS and DES in this subset of patients are limited (Valgimigli *et al*., 2005; Chieffo *et al*., 2007; Buszman *et al*., 2008; Meliga *et al*., 2008; Palmerini *et al*., 2008; Seung *et al*., 2008; White *et al*., 2008) Moreover, some reports have raised concern about incomplete or delayed neointimal coverage of DES with a subsequent increase in late stent thrombosis (Joner *et al*., 2006).

Therefore, in a randomised study we evaluated IVUS-guided BMS and paclitaxel-eluting stent (PES) implantation after lesion pre-treatment with cutting balloon (CB) for

ULMCA stenosis. The purpose of this study was to determine whether PES is superior to BMS during long-term clinical follow-up.

MATERIALS AND METHODS

Starting from February 2004, 103 patients with ULMCA disease were randomly assigned to receive bare metal Express or Liberte stent (n = 50) or Taxus Express paclitaxel-eluting stent (n = 53) (Boston Scientific Corporation, Natick, Massachussetts, USA). Patients were eligible for the study if they had stable or unstable angina pectoris, or silent ischemia, 50% diameter stenosis of ULMCA which could be treated with stent implantation. All patients were good candidates for CABG. Major exclusion criteria included coronary artery bypass grafts to left anterior descending (LAD) or left circumflex artery branches, life expectancy less than one year or planned non-cardiac surgery in six months. Informed written consents were obtained for all patients.

PCI procedure

Medical protocol. All patients undergoing PCI were pretreated with dual anteplatelet therapy: aspirin (100 mg) and clopidogrel (loading dose, 300 mg). After the procedure clopidogrel was recommended for at least six months, while aspirin — lifelong. Low-molecular-weight heparin or unfractionated heparin was administered in the catheterisation lab depending on the patients weight. Glycoprotein (GP) IIb/IIIa receptor inhibitors were given at the operator's discretion.

All interventions were performed using IVUS guidance and cutting balloon pre-treatment for atherosclerotic plaque modification before stenting.

Cutting balloon intervention. CB intervention was performed with a balloon-to-vessel ratio of 1 : 1, according to the IVUS media-to-media to the vessel at the lesion site. CB intervention was performed to cover the entire lesion length. Balloon inflations were performed three times with increasing pressure throughout the lesion.

Stent implantation. All lesions at the ostium and body were treated with a single stent implantation. If the distal portion of the LM or a bifurcation was involved, the following stenting strategies were used: stenting across the LCX ostium or provisional T stenting (if the LCX ostium and/or proximal part were severely diseased). Final kissing balloon dilatation was performed only in cases with suboptimal result at the LCX ostium. In other cases a good result was achieved by opening the stent strut to the LCX with a small diameter balloon or just after stent implantation.

After stent implantation subsequent IVUS was performed to evaluate stent apposition and residual stenosis. If any segment on the treated vessel did not meet success criteria, additional balloon dilatations with a non-compliant (NC) balloon were performed.

Follow-up. Patients were asked to return for clinical follow-up to assess adverse events and to perform stress testing at one, three, six, and twelve months, and then annually thereafter. Follow-up angiography with quantitative coronary angiography and intravascular ultrasound was performed at six months and three years. At three years, angiographic and IVUS follow-up was performed in all patients alive who did not experience target vessel revascularisation during six months follow-up and did not refuse to undergo the procedure.

Definitions. The primary endpoint of the study was major adverse cardiac event (MACE) — free survival. MACE was defined as the occurrence of death, Q-wave myocardial infarction, or target lesion revascularisation during the 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 non-cardiac origin was diagnosed. Q-wave myocardial infarction was defined as documentation of a new abnormal Q wave after the index treatment. Target lesion revascularisation (TLR) was defined as any repeat surgical or percutaneous intervention to treat a luminal stenosis in the stent or within the 5-mm segment adjacent to the stent, including the ostium of the left anterior descending artery and/or circumflex artery. Procedural success was defined as minimum lumen area ≥ 9.0 mm^2 by IVUS, or residual angiographic stenosis $< 10\%$ (if the minimal luminal reference vessel size by IVUS was smaller than 9.0 mm^2).

Statistics. Statistical analyses were performed using SPSS 12.0 for Windows (SPSS Inc., Chicago, IL, USA). Continuous variables are presented as mean ± standard deviation and compared using an unpaired Student's t-test or Mann-Whitney rank-sum test, depending on variable distribution. Categorical variables were compared by χ^2 statistics or Fisher's exact test as appropriate. All statistical tests were 2-sided, and a P value 0.05 was considered statistically significant. Major adverse cardiac event-free survival was examined by Kaplan–Meyer analysis and differences between groups were determined by log-rank test.

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 are published elsewhere (Erglis *et al.*, 2007). Overall there were no significant differences in baseline characteristics except for 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 groups, with Syntax Score 31.4 ± 14.5 in BMS and 32.6 ±

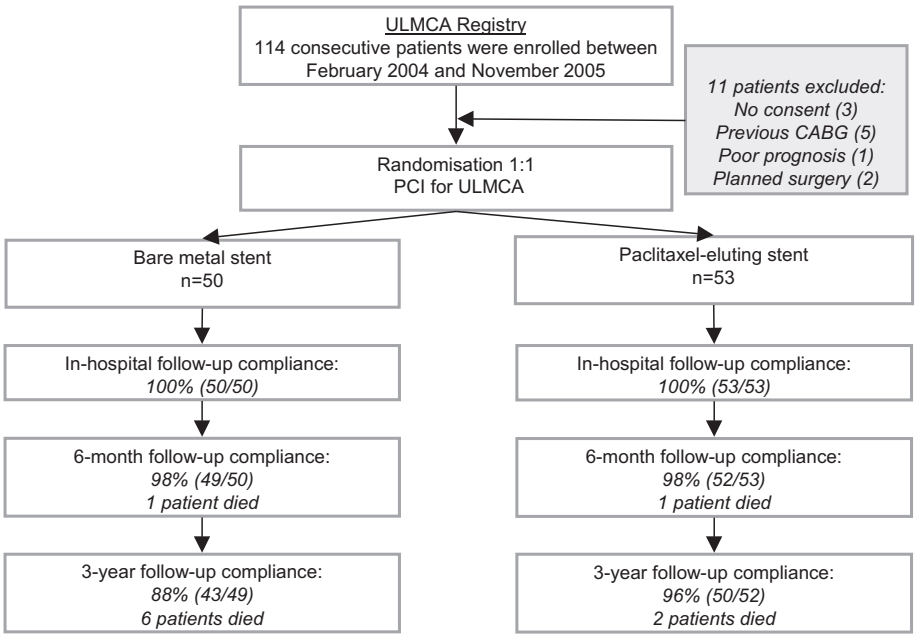

Fig. 1. Flow of patients through the trial.

11.7 in PES patients ($P > 0.05$). The procedural success was 100% in both groups.

Clinical follow-up. The flow of patients through the trial is shown in Figure 1. A total of 93 patients completed clinical long-term follow-up. During this time period (906 ± 346 days) seven (14.0%) patients in the BMS and 3 (5.7%) patients in the PES group ($P < 0.05$) died. Four patients (8.0%) in the BMS group and three patients (5.7%) in the PES group ($P > 0.05$) died from cardiac cause. Non-cardiac deaths in BMS-group patients consisted of lung cancer, stomach cancer and non-Hodgkin lymphoma. No patient was lost to follow-up. During this follow-up period only one patient (2.0%) in the BMS group and three patients (5.7%) in the PES group experienced Q-wave myocardial infarction ($P > 0.05$). No cases of definite or probable stent thrombosis were observed. Ten patients (20.0%) in the BMS group underwent TLR — nine repeat PCI and one CABG, in contrast, only 3 (5.7%) patients in the PES group needed repeat PCI ($P < 0.05$). MACE at follow-up occurred in 18 (36.0%) and 7 (13.2%) patients in the BMS and PES groups, respectively ($P = 0.011$). Cumulative clinical outcomes at three-year follow-up are summarised in Table 1 and Figure 2.

Table 1

CUMULATIVE CLINICAL OUTCOMES AT THREE-YEAR FOLLOW-UP

	BMS (n= 50)	PES (n= 53)	*P* value	All (n=103)
Total death, n (%)	7 (14.0)	3 (5.7)	> 0.05	10 (9.7)
Cardiac death, n (%)	4 (8.0)	3 (5.7)	> 0.05	7 (6.8)
Q-MI, n (%)	1 (2.0)	3 (5.7)	> 0.05	4 (3.9)
TLR, n (%)	10 (20.0)	3 (5.7)	< 0.05	13 (12.6)
TLR-PCI, n (%)	9 (18.0)	3 (5.7)	> 0.05	12 (1.7)
TLR-CABG, n (%)	1 (2.0)	0 (0)	> 0.05	1 (1.0)
Total MACE, n (%)	18 (36.0)	7 (13.2)	0.011	25 (24.3)

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

DISCUSSION

The main finding of this randomised long-term follow-up study is that both PES and BMS implantation are safe and feasible in patients with ULMCA stenosis. The benefit of PES implantation was observed up to three years at clinical follow-up with an acceptably low incidence of recurrent events, 5.7% of total and 5.7% of cardiac death in the PES

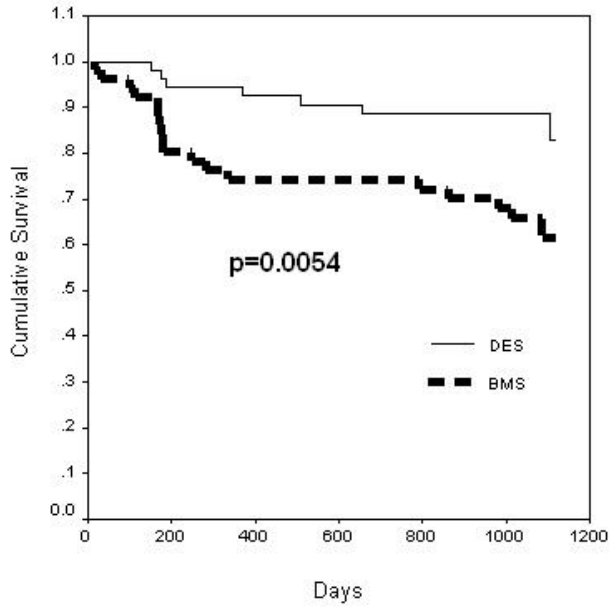

Fig. 2. Kaplan-Meier curves: freedom from death, Q-myocardial infarction and target lesion revascularisation. At three years, the Major Adverse Cardiac Event (MACE) — free survival rate was 75.7% in the study population, 64.0% in the BMS group and 86.8% in the PES group ($P = 0.0054$).

group compared with 14.0% of the total and 8.0% of cardiac death in the BMS group and with the overall incidence of MACE 13.2% and 36.0% ($P = 0.011$) in the PES and BMS subgroups, respectively. Regarding death rate, we have to consider natural ageing of the patients (at enrolment stage mean ages were 62.56 ± 11.45 in BMS group and 61.08 ± 10.28 PES group). At three years 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 (Buszman *et al*., 2008; Meliga *et al*., 2008; Palmerini *et al*., 2008; Seung *et al*., 2008) with especially scarce long-term data available from angiographic studies (Valgimigli *et al*., 2005; Chieffo *et al*., 2007).

DES vs BMS. Palmerini *et al*. (2008) recently published a two-year clinical follow-up with DES versus BMS in a real-world registry of ULMCA. This multicentre observational study showed promising results with two-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 ($P < 0.001$). Gao *et al.* (2008) showed that the cumulative MACE rate at 15 months was significantly decreased in the elective patients (n = 220) who received DES (9.5%) as compared with patients (n = 224) treated with BMS (16.5%, $P < 0.05$) derived from Chinese registry of unprotected LM stenting, despite the fact that more complex patients and lesions were included in the DES group. These data are consistent with our study.

Stents vs CABG long term outcomes. The first randomised trial (the LE MANS study) of 52 PCI (35% with DES) and 53 CABG patients showed that major adverse cardiac and cerebral event (MACCE) — free one-year survival was similar in both groups (71.2% PCI vs. 75.5% CABG, $P > 0.05$) where MACCE was defined as cardiac death, acute myocardial infarction, stroke, repeat intervention, in-stent thrombosis (Buszman *et al*., 2008). Data from the largest on-going prospective multicentre randomised SYNTAX trial (Serruys *et al*., 2009) of 705 patients with ULMCA showed that overall MACCE (death, myocardial infarction, stroke, repeat revascularisation) at one year follow-up in the PCI group was comparable with CABG (15.8% PES vs.13.6% CABG). PCI outcomes were excellent relative to CABG in LM isolated and LM plus one vessel disease, but were not statistically different. The PES cohort of our study showed comparable results with the SYNTAX 1 year MACCE data. Long-term data of the SYNTAX trial are awaited, while the LE MANS study showed similar MACCE-free survival during a 28.8 ± 9.9 month follow-up in both groups (53.9.2% PCI vs. 56.6% CABG, $P > 0.05$). Despite the intermediate SYNTAX score in the LE MANS study and our study (25.2% and 32.0%, respectively) MACCE-free survival was lower in our study — 75.7% of MACE in both BMS and DES patients at three-year follow up.

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

In conclusion, based on the results of our study, patients with unprotected left main disease treated with paclitaxel-eluting stents using cutting balloon plague pre-treatment and IVUS guidance have favourable late outcomes in comparison with bare metal stents.

The results of long-term follow-up demonstrates significant benefit for paclitaxel-eluting stents versus bare metal stents in terms of clinical results.

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AR PAKLITAKSELU PILDĪTA STENTA VAI PARASTA METĀLA STENTA IMPLANTĀCIJA NEPROTEKTĒTĀ KREISĀS KORONĀRĀS ARTĒRIJAS KOPĒJĀ STUMBRA BOJĀJUMĀ: ILGTERMIŅA KLĪNISKO REZULTĀTU RANDOMIZĒTS SALĪDZINĀJUMS

Lai optimizētu perkutānās koronārās intervences stratēģiju neprotektētiem kreisās koronārās artērijas kopējā stumbra bojājumiem, veicām randomizētu pētījumu: intravaskulārās ultraskaņās (IVUS) kontrolētu parasta metāla stentu (BMS) un ar paklitakselu pildītu stentu (PES) implantācijas salīdzinājumu, pēc aterosklerotiskās plāksnes sagatavošanas ar griezošo balonu. Pētījuma mērķis bija apsekot pacientus pēc sešiem mēnešiem un trim gadiem, vērtējot viņu klīnisko stāvokli. Vairāki nesen publicēti ziņojumi demonstrējuši labus īstermiņa un vidēja termiņa rezultātus pacientiem pēc stentu implantācijas kreisās koronārās artērijas kopējā stumbra bojājumos. Tomēr dati par parasta metāla stentu un ar paklitakselu pildītu stentu ilgtermiņa rezultātiem šai pacientu kohortai ir limitēti. Randomizējām Latvijas Kardioloģijas centra pacientus ar kreisās koronārās artērijas kopējā stumbra aterosklerotiskiem bojājumiem BMS (n = 50) vai PES (n = 53) stentu implantācijai. Visas koronārās intervences bija IVUS kontrolētas, visiem pacientiem pirms stenta implantācijas aterosklerotisko plāksni sagatavoja ar griezošo balonu. Visiem pacientiem nozīmēta sešu mēnešu un trīs gadu apsekošana. Primārais beigu punkts bija liels kardiāls nelabvēlīgs notikums, ko definēja kā nāvi, Q miokarda infarktu vai mērķa bojājuma atkārtotu intervenci. Vispārējie pacientu un procedūras parametri bija salīdzināmi abās grupās. Pēc sešiem mēnešiem lielos nelabvēlīgos kardiālos notikumus nebija piedzīvojuši 70% BMS un 87% PES grupas pacienti ($P < 0,05$). Trīs gados lielos nelabvēlīgos kardiālos notikumus bija piedzīvojuši 18 BMS pacienti (36,0%) un septiņi PES pacienti (13,2%) ($P < 0,05$). Mūsu pētījuma sešu mēnešu un trīs gadu apsekošanas rezultāti pierādījuši IVUS kontrolētu, ar paklitakselu pildītu stentu implantācijas pārākumu pār parasta metāla stentu implantāciju pacientiem ar kreisās koronārās artērijas kopējā stumbra bojājumiem, pirms stenta implantācijas bojājumu sagatavojot ar griezošo balonu.