Usefulness of Everolimus-Eluting Coronary Stent Implantation in Patients on Maintenance Hemodialysis

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The outcomes of second-generation drug-eluting stent (DES) are unknown in patients on maintenance hemodialysis (HD) although HD has been reported as a strong predictor of adverse outcome after the first-generation DES implantation. The OUCH-PRO Study is a prospective multicenter single-arm registry design to study clinical and angiographic outcomes after everolimus-eluting stent (EES). Patients who underwent maintenance HD were prospectively enrolled at the time of elective coronary intervention using EES. Quantitative coronary angiography was performed in an independent core laboratory. The primary end point was the occurrence of target vessel failure (TVF) defined as cardiac death, myocardial infarction (MI), and target vessel revascularization at 1 year. A total of 123 patients were enrolled and 161 EES were implanted. The TVF rate at 1 year was 18% (4% cardiac death, 0% MI, 17% target vessel revascularization). No stent thrombosis was documented. Other clinical events at 1 year were 3% noncardiac death, 3% stroke, and 9% non−target-vessel revascularization. Late lumen loss in stent was 0.37 ± 0.63 mm at 8 months. In conclusion, EES had a high TVF rate and great late lumen loss in patients on HD compared with previous huge EES data in non-HD patients. **(Am J Cardiol 2015;116:872−876)**

Cardiovascular disease is a major cause of mortality in patients on hemodialysis (HD).[1−3] Bypass surgery has superior long-term outcome to percutaneous coronary intervention (PCI) using bare metal stents (BMS) in dialysis patients.[4] Although drug-eluting stents (DES) are associated with lower event rates than BMS, outcomes of the first-generation DES are reported to be disappointing in dialysis patients.[5] Big registry studies of sirolimus-eluting stent (SES) have shown that dialysis was the strongest predictor of adverse outcome.[6,7] SES for patients on dialysis showed that the target vessel failure (TVF) rate at 1 year was as high as 25%,[8] despite the TVF at 1 year was <10% in nondialysis patients.[6] The second-generation DES has better long-term outcome than the first-generation DES.[9,10] It is necessary to evaluate the second-generation DES, everolimus-eluting stent (EES), in the group of patients on HD.

Methods

The OUtCome in Hemodialysis with PROmus stent Study (OUCH-PRO) is a prospective multicenter registry study targeting the outcome of EES implantation in patients undergoing maintenance HD. Inclusion criteria were end-stage renal disease requiring HD, age ≥21 years, and elective percutaneous coronary intervention (PCI) with EES. Exclusion criteria were a history of survival after an episode of sudden death, cardiogenic shock, emergency PCI, ST-segment elevation myocardial infarction, intolerance to antiplatelet drugs, coronary stenting within 6 months, in-stent restenosis after DES implantation, myocardial infarction within 30 days, severe valvular heart disease, critical limb ischemia, patients waiting for renal transplantation, and total occlusion of the target vessel. All patients received information about the inclusion and exclusion criteria for the study and gave written informed consent.

All PCI procedures were carried out at the discretion of the operator and with the objective of achieving optimal results, although in elective situations, the use of EES (Promus or Xience) was mandatory. BMS could be used only to facilitate bailout in cases where EES caused edge dissection. Use of other DESs was prohibited; however, rotablator could be used when necessary. Use of intravascular ultrasound to confirm optimal stent expansion was encouraged.

Follow-up was started from the date of the PCI. Planned staged PCI procedures were not considered as adverse events. The "target lesion" was defined at the time of the initial PCI. Follow-up clinical data were collected at 1, 8, and 12 months, and follow-up coronary angiography was performed at 8 months. Maintenance HD was performed 3 times a week using a high-performance membrane.

In the presence of Thrombosis in Myocardial Infarction (TIMI) grade 3 flow, angiographic success was defined as the achievement of a minimum stenosis diameter reduction to <50%. Overall procedural success was defined as the

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See page 875 for disclosure information.

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Table 1
Patient characteristics

Patient number	123
Male gender	75%
Age (years)	67 ± 10
Height (cm)	161 ± 9
Weight (kg)	59 ± 11
Body mass index (kg/m^2)	22.7 ± 3.3
Hypertension	85%
Dyslipidemia	48%
Current smoking	37%
Peripheral artery disease	22%
Cerebrovascular disease	7%
Family history of CAD	7%
Diabetes mellitus	67%
Reason of renal failure	
Diabetic nephropathy	64%
Non-diabetic nephropathy	36%
Duration of hemodialysis (years)	5.9 ± 5.8
Diagnosis	
Stable angina	48%
CCS Class 1	32%
CCS Class 2	14%
CCS Class 3	2%
Unstable angina	14%
Asymptomatic ischemia	38%
Prior myocardial infarction	17%
Prior PCI	23%
Prior CABG	5%
Number of diseased vessels	
1	51%
2	33%
3	16%
Non-protected left main disease	4%
Ejection fraction	56 ± 11%
Ejection fraction < 50%	24%
Baseline Antiplatelet therapy	
Dual antiplatelet therapy	111 (90%)
Aspirin + Clopidogrel	100
Aspirin + Ticlopidine	8
Aspirin + Cilostazol	3
Triple antiplatelet therapy (aspirin + clopidogrel + cilostazol)	12 (10%)
Baseline medications	
Statin	33%
Angiotensin converting enzyme Inhibitor	7%
Angiotensin receptor blocker	51%
Beta blocker	28%
Insulin	24%
Sevelamer	11%
Baseline blood data	
Hemoglobin (g/dL)	10.9 ± 2.5
Calcium (mg/dL)	8.8 ± 0.8
Phosphate (mg/dL)	4.9 ± 3.1
BNP (pg/mL)	492 ± 751
hsCRP (mg/dL)	0.54 ± 1.23

BNP = B-type natriuretic peptide; CAD = coronary artery disease; hsCRP = High sensitive C-reactive protein.

Table 2
Lesion characteristics and coronary intervention procedures

Number of lesions	161
Target vessels	
LMCA	2%
LAD	45%
LCX	22%
RCA	31%
ACC / AHA classification	
A	1%
B1	6%
B2	51%
C	42%
TIMI flow	
TIMI 0	6%
TIMI 1	2%
TIMI 2	10%
TIMI 3	82%
Lesion type	
Discrete	24%
Tubular	37%
Diffuse	39%
Angiographic calcification	
None/mild	33%
Moderate	32%
Severe	35%
Lesion tortuosity	
None/mild	84%
Moderate	13%
Severe	3%
Eccentric lesion	68%
Thrombus	1%
Dissection	1%
Haziness	12%
Ulceration	4%
Aneurysm	1%
Irregular lesion surface	49%
Lesion bending >45 degree	19%
Ostial lesion	22%
De novo lesion	94%
In stent restenosis	3%
Vein grafts	1%
Intravascular ultrasound guided	71%
Chronic total occlusion	6%
Bifurcation	41%
Rotational atherectomy	14%

LAD = left anterior descending; LCX = left circumflex; LMCA = left main coronary artery; RCA = right coronary artery; TIMI = thromobolysis in myocardial infarction.

presence of angiographic success plus absence of a major complication and procedural failure as either lack of angiographic success or occurrence of a major complication.

All the angiographic data were transmitted to the independent core laboratory (Japan Cardiocore, Tokyo, Japan) and assessed by experts blinded to patient data. Quantitative coronary angiography (QCA) was carried out in an independent core laboratory using CAAS 5.4 (Pie Medical Imaging, Maastricht, The Netherlands).

The primary end point of the study was occurrence of TVF, defined as cardiac death, MI in the target vessel, and the requirement for TVR within the first year after PCI. MACE was defined as death, MI, repeat PCI, or coronary artery bypass graft (CABG) surgery. Deaths were classified as cardiac or noncardiac. Sudden death due to an unknown cause was classified as a cardiac death. Repeat PCI was categorized as target lesion, target vessel, or nontarget vessel revascularization according to whether the index lesion or artery was involved. Stent thrombosis was categorized as definite, probable, or possible according to the Academic Research Consortium definition.[11]