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Drug-Eluting Stenting of Unprotected Left Main Coronary Artery Stenosis in Patients With Orthotopic Heart Transplantation: Initial Clinical Experience

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Objectives: To assess the safety and efficacy of percutaneous coronary intervention (PCI) with drug-eluting stents (DES) in orthotopic heart transplantation (OHT) patients with unprotected left main coronary artery (ULMCA) disease. Background: Accelerated transplant coronary artery disease occurs in 50% of patients at 5 years and is the major cause of death following OHT. The optimal treatment for ULMCA disease in OHT patients is unknown. Methods: From April 2003 to December 2006, five OHT patients with ULMCA disease underwent PCI with DES at the University of California, Los Angeles, Medical Center. Results: Technical success was achieved in all five patients. At a median follow-up of 518 days (range 124–990 days), all five patients were alive and free from death, myocardial infarction, and target vessel revascularization. No binary restenosis was present in four patients who underwent surveillance angiography. One patient underwent repeat OHT for progressive left ventricular dysfunction. Conclusions: In OHT patients, ULMCA PCI with DES is feasible with an excellent technical success rate and is a reasonably palliative treatment option for this difficult patient population. © 2008 Wiley-Liss, Inc.

Key words: drug-eluting stents; left main coronary artery; orthotopic heart transplantation

INTRODUCTION

Transplant coronary artery disease (TCAD) is the major cause of late death in orthotopic heart transplantation (OHT) patients [1–4]. The prevalence of TCAD is 10% per year, with 50% of OHT patients having angiographic evidence of TCAD 5 years after transplantation [5]. The prevalence is higher based on the detection of abnormal intimal hyperplasia with intravascular ultrasound [6].

Currently, there is no medical treatment to reverse TCAD. Possible alternatives include percutaneous coronary intervention (PCI), coronary artery bypass surgery, and repeat OHT. PCI has been performed on OHT patients with excellent angiographic results and is the preferred revascularization strategy in patients with TCAD because of the technical problems and increased mortality associated with coronary artery bypass surgery [7–24]. However, neither PCI nor bypass surgery is effective when the transplant vasculopathy involves diffuse areas or affects the distal vessels. Repeat OHT is associated with high perioperative mortality and poor long-term survival in addition to the shortage of organs.

According to the current American College of Cardiology/American Heart Association guidelines, the standard of care for the treatment of unprotected left main coronary artery (ULMCA) stenosis is coronary artery bypass surgery [25]. However, in non-OHT patients, data suggest that ULMCA PCI with sirolimus-eluting stents (Cypher, Cordis, Johnson and Johnson, Miami, FL) and paclitaxel-eluting stents (Taxus, Boston Scientific, Natick, MA) may be safe and effective in decreasing in-stent restenosis when compared with bare-metal stents [26–28]. Compared with bypass surgery, PCI with drug-eluting stents (DES) in nonrandomized observational studies has also been shown to provide similar clinical outcomes in patients with ULMCA disease [29,30]. Although there are anecdotal reports of ULMCA PCI with bare-metal stents in OHT patients, there is a paucity of data on ULMCA PCI

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with DES in these patients [30–35]. We present our experience on PCI with DES in OHT patients with ULMCA disease.

METHODS

Study Patients

The study population consisted of the first five consecutive OHT patients with ULMCA disease treated with PCI with either sirolimus-eluting stents or paclitaxel-eluting stents from April 2003 to December 2006. The University of California, Los Angeles, Medical Center Institutional Review Board approved the use of the database review for this study. Inclusion criteria were OHT patients with angiographic evidence of $\geq$50% diameter stenosis of the ULMCA that were treated with PCI with DES.

Percutaneous Coronary Intervention

Description of the technique for PCI of the ULMCA has been previously reported [36]. The use of intraaortic balloon counterpulsation, intravascular ultrasound (Boston Scientific Corp.), and choice of anticoagulation regimen and DES was left to the discretion of the operator. All patients received aspirin 325 mg/day indefinitely. Clopidogrel was continued for a minimum of 6 months, but was recommended indefinitely after a loading dose of 300 mg. Cardiac enzymes (creatine kinase and CK-MB) were routinely drawn post-PCI.

Definitions

Technical success was defined as thrombosis in myocardial infarction grade 3 flow and a final diameter stenosis $<$30% without the need for emergency bypass surgery. Major adverse cardiac events (MACE) were defined as the occurrence of death, myocardial infarction, or target vessel revascularization. Death was defined as any postprocedure death. A myocardial infarction was defined as ischemic symptoms associated with creatine kinase and CK-MB elevation greater than three times the upper limit of the normal value. Target lesion revascularization was defined as a repeat revascularization to treat a luminal stenosis within the stent or within 5-mm segments distal and proximal to the stent, including the ostium of the left anterior descending artery and/or left circumflex artery. Binary restenosis was defined as the presence of $>$50% stenosis on follow-up angiography.

Follow-Up

Patient data were retrospectively collected on a dedicated database. Surveillance angiography was performed at 3–6 months or earlier if there was clinical evidence of ischemia to detect early restenosis. Quantitative coronary angiography was performed [36]. Follow-up data were obtained from clinic visits.

RESULTS

The baseline clinical and procedural characteristics for the five OHT patients who underwent ULMCA PCI with DES are presented in Table I. Technical success was achieved in all five patients. The mean length of stay was 3 $\pm$ 2 days (range 1–7 days). At a mean follow-up of 518 days (range 124–990 days), all patients were alive and free from MACE. Patient 1 was a 43-year-old male who underwent PCI of the mid-ULMCA with a 3.5 $\times$ 13 mm sirolimus-eluting stent for unstable angina. Repeat angiography performed at 360 days revealed no significant in-stent restenosis. The patient was free from MACE at 448 days follow-up.

Patient 2 was a 75-year-old male who underwent PCI of the ostial ULMCA with a 3.5 $\times$ 8 mm sirolimus-eluting stent for unstable angina. Repeat angiography performed at 96, 368, and 892 days revealed no significant in-stent restenosis. The patient was free from MACE at 892 days follow-up.

Patient 3 was a 64-year-old male who had sudden cardiac death during a stress test. After successful cardiopulmonary resuscitation, the patient was started on intravenous epinephrine and an intraaortic balloon pump was inserted for cardiogenic shock. He then underwent emergent PCI of an ostial ULMCA with a 3.0 $\times$ 16 mm paclitaxel-eluting stent. Repeat angiography performed at 107 days revealed no significant restenosis. The patient was free from MACE at 124 days follow-up.

Patient 4 was a 23-year-old male who underwent PCI of the distal bifurcation of the ULMCA with two 3.0 $\times$ 18 mm sirolimus-eluting stents using the simultaneous kissing stenting technique for severe asymptomatic TCAD. Repeat angiography performed at 91 days demonstrated no significant in-stent restenosis. The patient was free from MACE at 124 days follow-up.

Patient 5 was a 61-year-old female who underwent PCI of the distal bifurcation of the ULMCA with 3.5 $\times$ 18 mm^2 and 3.0 $\times$ 13 mm sirolimus-eluting stents using the simultaneous kissing stent technique for severe TCAD. She subsequently underwent repeat OHT at 153 because of progressive left ventricular dysfunction. Her postoperative course was complicated by respiratory failure, mediastinal hematoma requiring reexploration, and renal failure requiring hemodialysis. The patient was alive at 755 days follow-up.

TABLE I. Baseline Clinical and Procedural Characteristics and Clinical Follow-up

Patient	Age (years)	Sex	Diabetes	CRI	EF (%)	Time from OHT to PCI (years)	Clinical indication
1	43	Male	No	No	55	16	Unstable angina
2	75	Male	Yes	Yes	50	14	Unstable angina
3	64	Male	No	No	60	14	Sudden cardiac death
4	23	Male	No	No	40	5	Surveillance angiography
5	61	Female	No	No	40	10	Surveillance angiography

	Stent	Size (mm)	Location	Postdilatation	IABP	IVUS
1	Cypher	3.5 × 13	Mid body	Yes	No	Yes
2	Cypher	3.5 × 8	Ostial	No	Yes	Yes
3	Taxus	3.0 × 16	Ostial	No	Yes	No
4	Cypher	3.0 × 18, 3.0 × 18	Distal bifurcation	No	Yes	Yes
5	Cypher	3.5 × 18, 3.0 × 13	Distal bifurcation	No	Yes	No

	Length of stay (days)	Length of follow-up (days)	Repeat angiography
1	1	577	Yes
2	1	990	Yes
3	7	143	Yes
4	3	124	Yes
5	2	755	No[a]

	Baseline MLD (mm)	Final MLD (mm)	Follow-up MLD (mm)	MACE
1	1.69	3.80	2.20	No
2	1.22	3.52	2.98	No
3	0.72	2.96	2.62	No
4	0.75	4.04	4.02	No
5	1.42	3.61	–[a]	–[a]

CRI, chronic renal insufficiency; EF, ejection fraction; IABP, intraaortic balloon pump; ISR, in-stent restenosis; IVUS, intravascular ultrasound; MACE, major adverse cardiac events; MLD, minimal lumen diameter; OHT, orthotopic heart transplantation; PCI, percutaneous coronary intervention.
[a]Patient subsequently underwent repeat orthotopic heart transplantation.

DISCUSSION

In this single center experience, the main finding was that ULMCA PCI with DES in OHT patients was safe, associated with an excellent immediate success rate, and offers a less invasive treatment option for revascularization in this difficult patient population.

Medical therapy for ULMCA disease in non-OHT patients has been associated with a 3-year mortality rate of approximately 50% [37,38]. Aggressive medical therapy may be a reasonable treatment option for TCAD [11]. However, medical therapy for OHT patients with ULMCA disease is probably not an option, as the only clinical manifestation of ULCMA disease may be sudden death.

Asymptomatic angiographically significant ULMCA stenosis was present in one patient. The heart of OHT patients is denervated, and patients may not experience the classic symptoms of ischemia. Instead, the only clinical manifestations of TCAD may be congestive heart failure, ventricular arrhythmias, myocardial infarction, and sudden death [39]. Routine surveillance coronary angiography is performed in OHT patients, because noninvasive imaging modalities like exercise thallium scintigraphy, rest and stress exercise radionuclide cineangiography, and echocardiography have low sensitivity and predictive value to detect TCAD [40,41].

Technical success was achieved in all five patients. This is consistent with previous reports for ULMCA PCI with DES in non-OHT patients [26–29,42]. Our study consisted of high-risk patients. Furthermore, arteries in patients with TCAD are susceptible to intense spasm. Three of the five patients underwent PCI with hemodynamic support via an intraaortic balloon pump. Elective insertion of an intraaortic balloon pump may prevent intraprocedural events in elective ULMCA PCI, especially in high-risk patients [43].

The American College of Cardiology/American Heart Association/Society for Cardiovascular Angiography and Interventions 2005 Guideline Update for PCI state that ULMCA PCI is a class III indication [44]. The main limitations of ULMCA PCI are restenosis and stent thrombosis, which may both lead to sudden death. The restenosis rate after PCI for TCAD with bare-metal stents is higher compared with native coro-

TABLE II. Summary of Studies of Bare-Metal Stenting for Left Main Disease in Orthotopic Heart Transplant Patients

Study	Age/sex	Years post-OHT	Location	Follow-up angiography	Length of follow-up	Clinical follow
Weston et al. [33]	54/M	4	Body	Patent	3 years	No MACE
	69/M	10	Distal	Patent	18 months	No MACE
	43/F	3	Ostial	Patent	1 year	No MACE
de Gevigney et al. [34]	61/M	10	–[a]	In-stent restenosis	5 months	CABG
	52/F	2	–[a]	In-stent restenosis	5 months	Died during CABG
Chan et al, [35]	50/F	2	Distal	In-stent restenosis	1 year	No MACE
	59/M	8	Body	In-stent restenosis	3 months	Re-listed for OHT
	58/M	4	Ostial	In-stent restenosis	5 months	Cardiogenic shock; TVR

CABG, coronary artery bypass grafting; MACE, major adverse cardiac events; OHT, orthotopic heart transplantation; TVR, target vessel revascularization.
[a]Not reported.

naries. Intense lymphoproliferation in the intima, media, and adventitia is seen in patients with TCAD and may explain the high restenosis rates in these patients after PCI. The restenosis rate of 43% at a mean angiographic follow-up period of 139 ± 68 days was reported with PCI with bare-metal stents in TCAD [18]. A high restenosis rate may be reflective of the underlying inflammatory nature of TCAD. Two studies reported trends toward lower restenosis rates with DES compared with bare-metal stents in OHT patients [12,45]. In one report, two OHT patients who underwent ULMCA PCI with bare-metal stents for TCAD developed restenosis and underwent coronary artery bypass surgery [34] (Table II). One of the patients died subsequently. Typically, follow-up angiography is performed every year in OHT patients. However, earlier angiography, perhaps at 3 months, should be strongly considered to detect early restenosis in this critical location, especially when the distal bifurcation is involved, as this may possibly prevent sudden death. Scripps Clinic, which performed surveillance angiography at 3 and 9 months on left main stenting in patients without transplants, reported a 38% target lesion revascularization rate [42]. The majority of cases of restenosis occurred within 3 months of the PCI. The high-target lesion revascularization rate may be explained by the high prevalence of distal bifurcation involvement (94%). Distal ULMCA disease was identified as a major predictor of adverse clinical outcomes after PCI with DES [46]. In non-OHT patients who underwent ULCMA PCI with DES for distal bifurcation disease, the 6-month angiographic restenosis rate was higher when a two-stent technique ("kissing technique" or "crush technique") was compared with a one-stent technique (24% vs. 5%, $P = 0.02$) [47].

Patients with OHT represent a unique group with high mortality. When the diagnosis of TCAD is made, long-term prognosis is poor, and the 5-year life expectancy of the allograft is ~17%, but can vary depending on the presence of distal arteriopathy [1,2]. In addition to PCI, other treatment options for OHT patients with UMLCA disease include coronary artery bypass surgery and repeat OHT. In non-OHT patients, coronary artery bypass surgery has been shown to improve long-term survival [48,49]. Diffuse, predominantly distal disease (distal arteriopathy) is prevalent in OHT patients and therefore makes coronary artery bypass surgery technically difficult and a poor treatment option for these high-risk patients with CAD. Repeat sternotomy and the associated mediastinal scarring and the risk of infection in these immunocompromised patients may increase the risk of complications. The perioperative mortality rate is high (40–80%), and the long-term patency rates of bypass grafts are unknown [7,19–24]. Halle et al. [7] reported that distal arteriopathy was the most significant risk factor for mortality in patients who underwent coronary artery bypass surgery. Bypass surgery in patients with ULMCA disease is also associated with a higher incidence of stroke, pneumonia, and a longer length of stay compared with patients who undergo PCI [37]. In addition, 7% of patients required repeat operation for significant bleeding.

The ideal long-term treatment after PCI with DES for TCAD involving the ULMCA is unknown. Dual antiplatelet therapy with aspirin and a thienopyridine for at least 12 months is recommended [50]. Repeat OHT is an option although there is a shortage of donors. Furthermore, repeat OHT is associated with a shorter survival compared with the initial surgery [51,52]. Repeat OHT has a 1-year survival rate of 75%, and half the patients develop recurrent TCAD in the second graft [19,23].

Limitations

This study was a single-center, nonrandomized, retrospective analysis with a small sample size and short-term follow-up. The impact of DES in ULMCA PCI in OHT patients in prolonging cardiac allograft or patient survival is unknown. Follow-up angiography was not available in all patients.

Conclusions

In OHT patients with ULMCA disease, PCI with DES is technically feasible with excellent technical results and may serve as a bridge to repeat OHT. Although improvements in DES and pharmacotherapy may decrease the risk of restenosis and stent thrombosis, large, randomized trials with long-term follow-up are needed to determine the ideal treatment for this difficult patient population. However, because ULMCA disease in OHT patients is uncommon, such a clinical trial may not be practical.

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