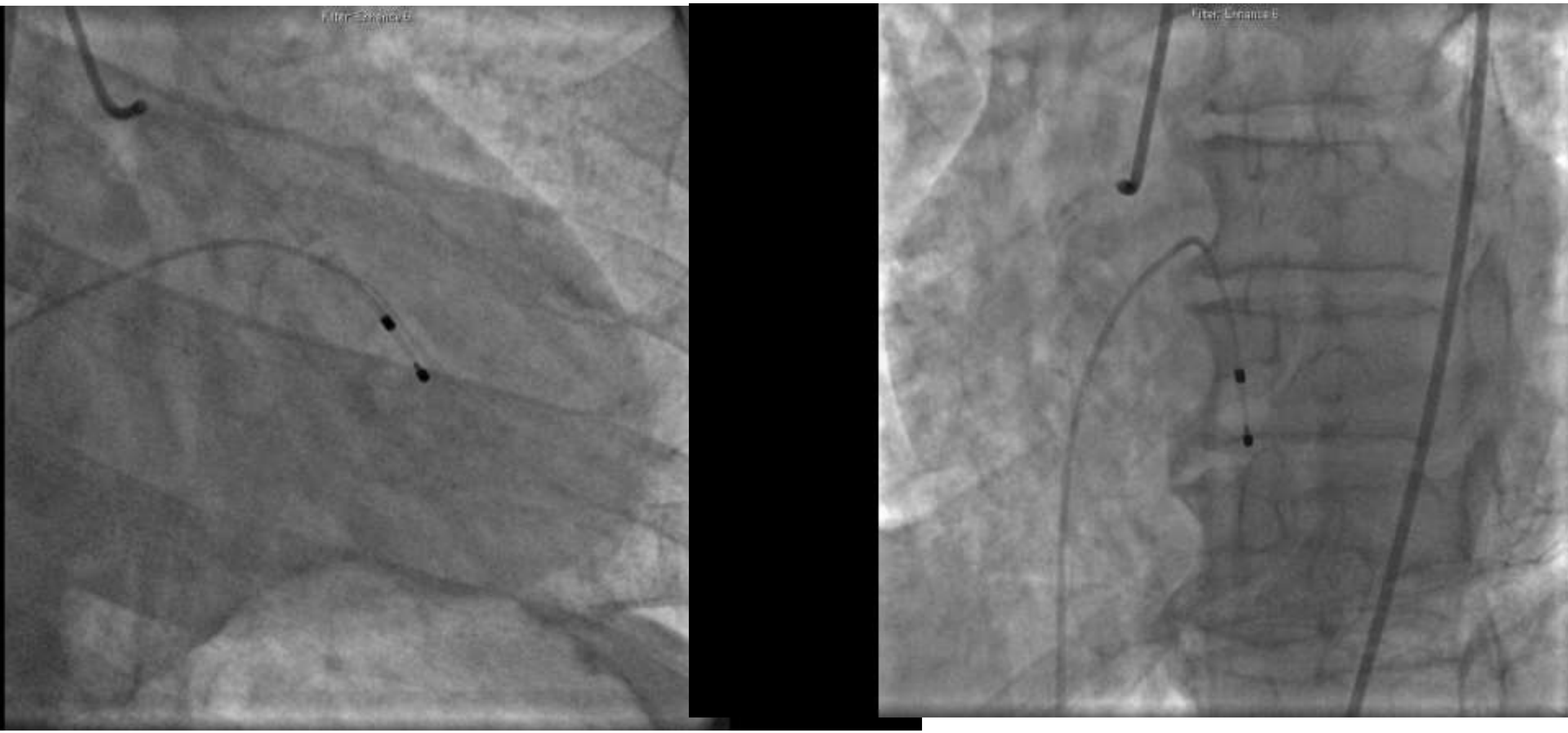
Left Main PCI in Acute Myocardial Infarction

David Geffen School of Medicine | UCLA Health

Michael S. Lee, MD FACC, FSCAI
Associate Professor

ULMCA PCI in Myocardial Infarction



Acute left main occlusion occurs in 0.8% of STEMI

ULMCA PCI in Myocardial Infarction

68 y.o. male with chest pain, ST-elevation in V1-V6, shock on inotropes

ULMCA PCI in Myocardial Infarction

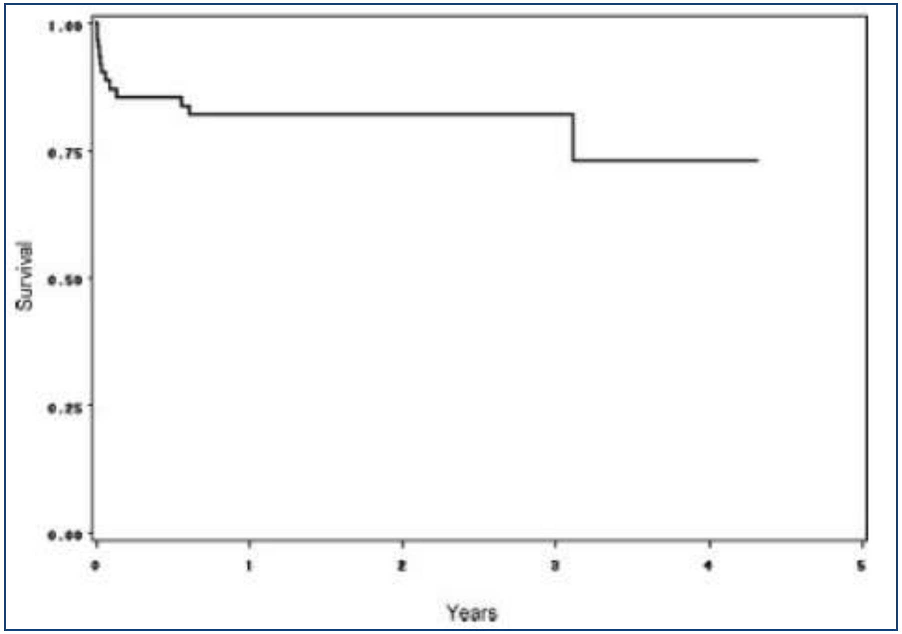
Multicenter International Registry of Unprotected Left Main Coronary Artery Percutaneous Coronary Intervention With Drug-Eluting Stents in Patients With Myocardial Infarction

Michael S. Lee,[1*] MD, Dario Sillano,[2] MD, Azeem Latib,[3] MD, Alaide Chieffo,[3] MD, Giuseppe Biondi Zoccai,[2] MD, Ravi Bhatia,[1] Imad Sheiban,[2] MD, Antonio Colombo,[3] MD, and Jonathan Tobis,[1] MD

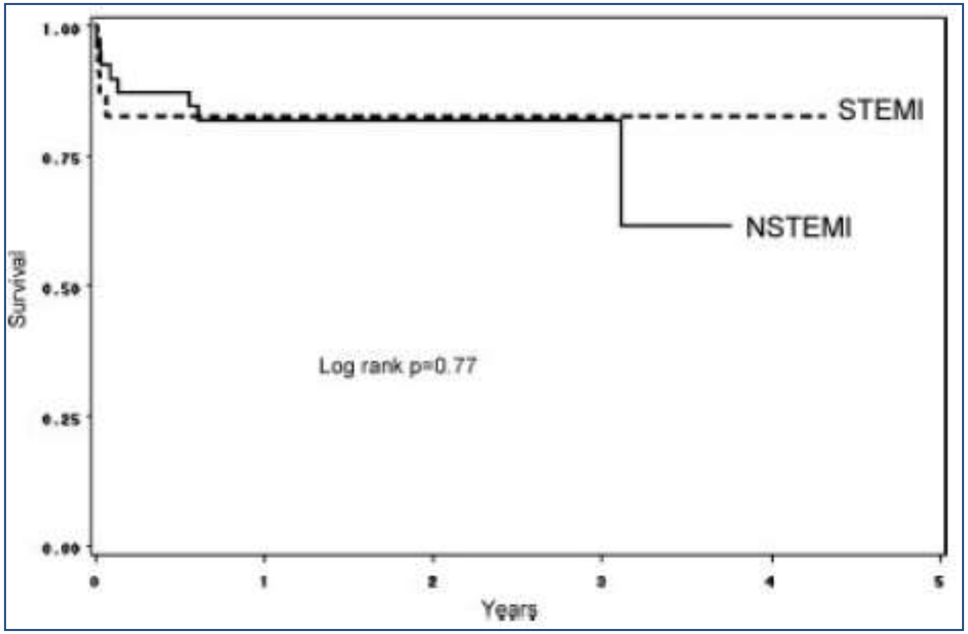
Background: Patients who present with myocardial infarction (MI) and unprotected left main coronary artery (ULMCA) disease represent an extremely high-risk subset of patients. ULMCA percutaneous coronary intervention (PCI) with drug-eluting stents (DES) in MI patients has not been extensively studied. Methods: In this retrospective multicenter international registry, we evaluated the clinical outcomes of 62 consecutive patients with MI who underwent ULMCA PCI with DES (23 ST-elevation MI [STEMI] and 39 non-ST-elevation MI [NSTEMI]) from 2002 to 2006. Results: The mean age was 70 ± 12 years. Cardiogenic shock was present in 24%. The mean EuroSCORE was 10 ± 8. Angiographic success was achieved in all patients. Overall in-hospital major adverse cardiac event (MACE) rate was 10%, mortality was 8%, all due to cardiac deaths from cardiogenic shock, and one patient suffered a periprocedural MI. At 586 ± 431 days, 18 patients (29%) experienced MACE, 12 patients (19%) died (the mortality rate was 47% in patients with cardiogenic shock), and target vessel revascularization was performed in four patients, all of whom had distal bifurcation involvement (two patients underwent repeat PCI and two patients underwent bypass surgery). There was no additional MI. Two patients had probable stent thrombosis and one had possible stent thrombosis. Diabetes [hazard ratio (HR) 4.22, 95% confidence interval (CI) (1.07–17.36), $P = 0.04$), left ventricular ejection fraction [HR 0.94, 95% CI (0.90–0.98), $P = 0.005$), and intubation [HR 7.00, 95% CI (1.62–30.21), $P = 0.009$) were significantly associated with increased mortality. Conclusions: Patients with MI and ULMCA disease represent a very high-risk subgroup of patients who are critically ill. PCI with DES appears to be technically feasible, associated with acceptable long-term outcomes, and a reasonable alternative to surgical revascularization for MI patients with ULMCA disease. Randomized trials are needed to determine the ideal revascularization strategy for these patients.

ULMCA PCI in Myocardial Infarction

Overall Survival



STEMI vs. NSTEMI

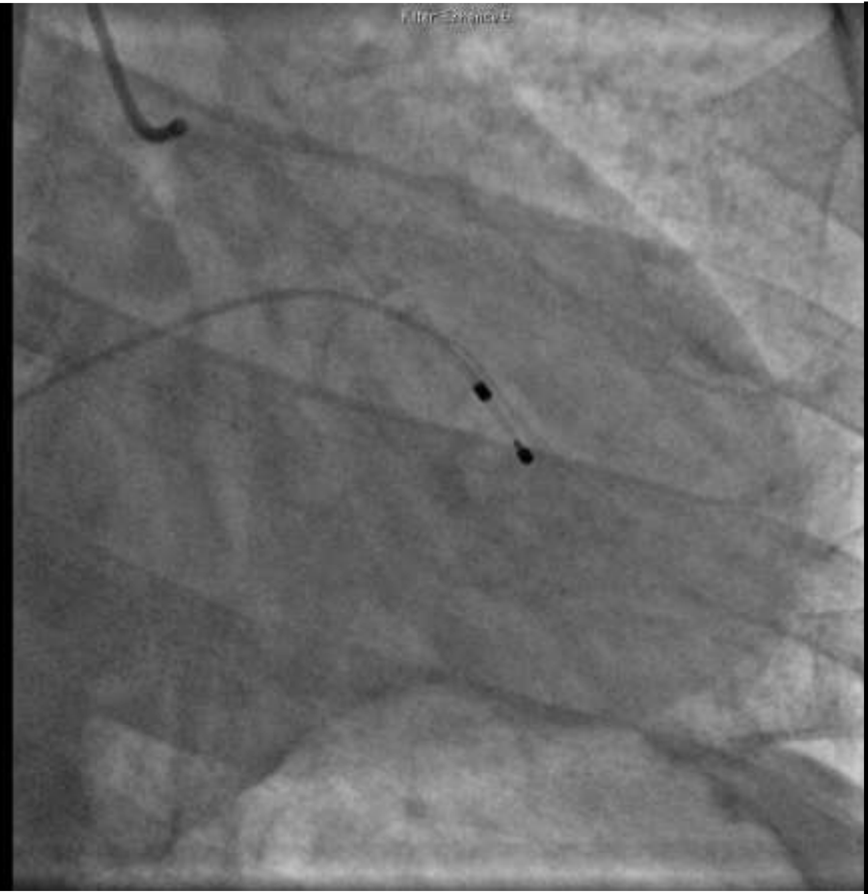


N=62
Cardiogenic shock 24%
All in-hospital deaths from cardiogenic shock

ULMCA PCI in Myocardial Infarction

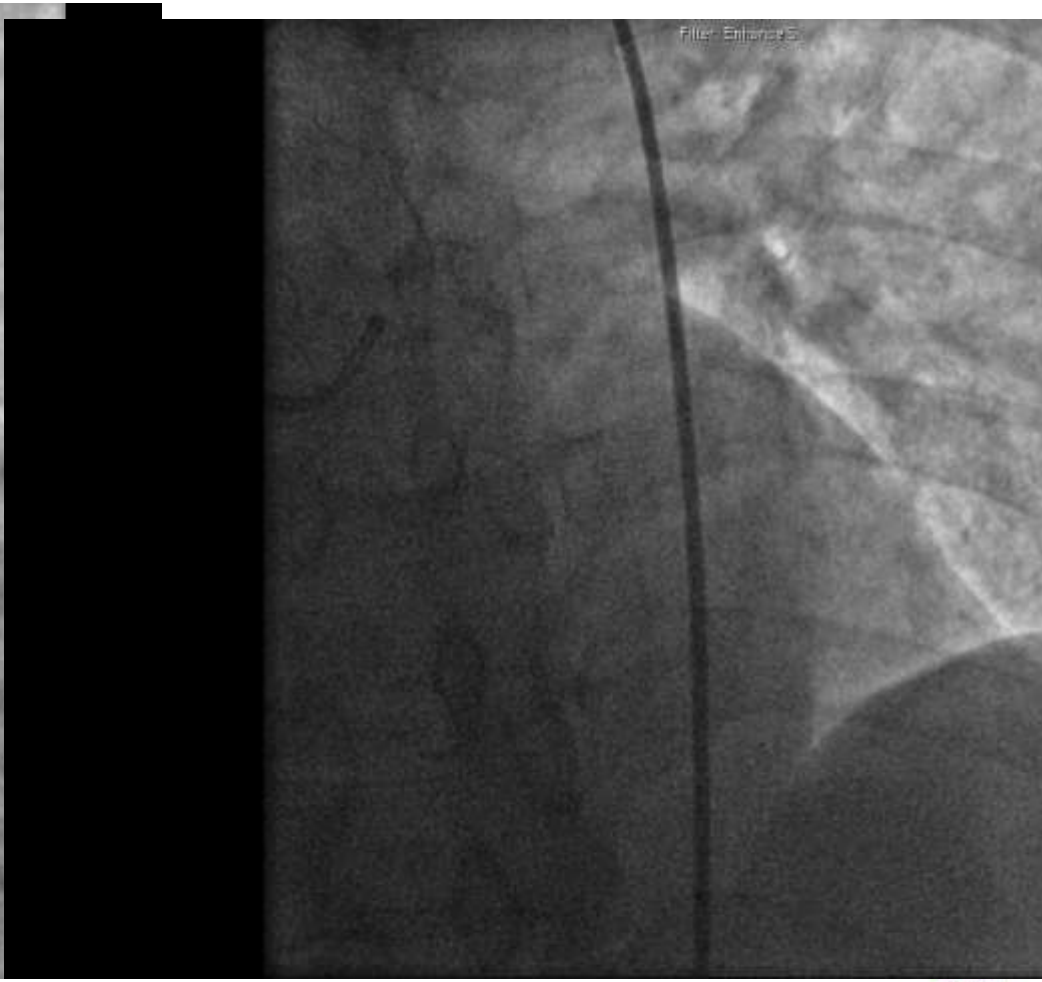
Minimum 1 hour

ULMCA PCI in Myocardial Infarction



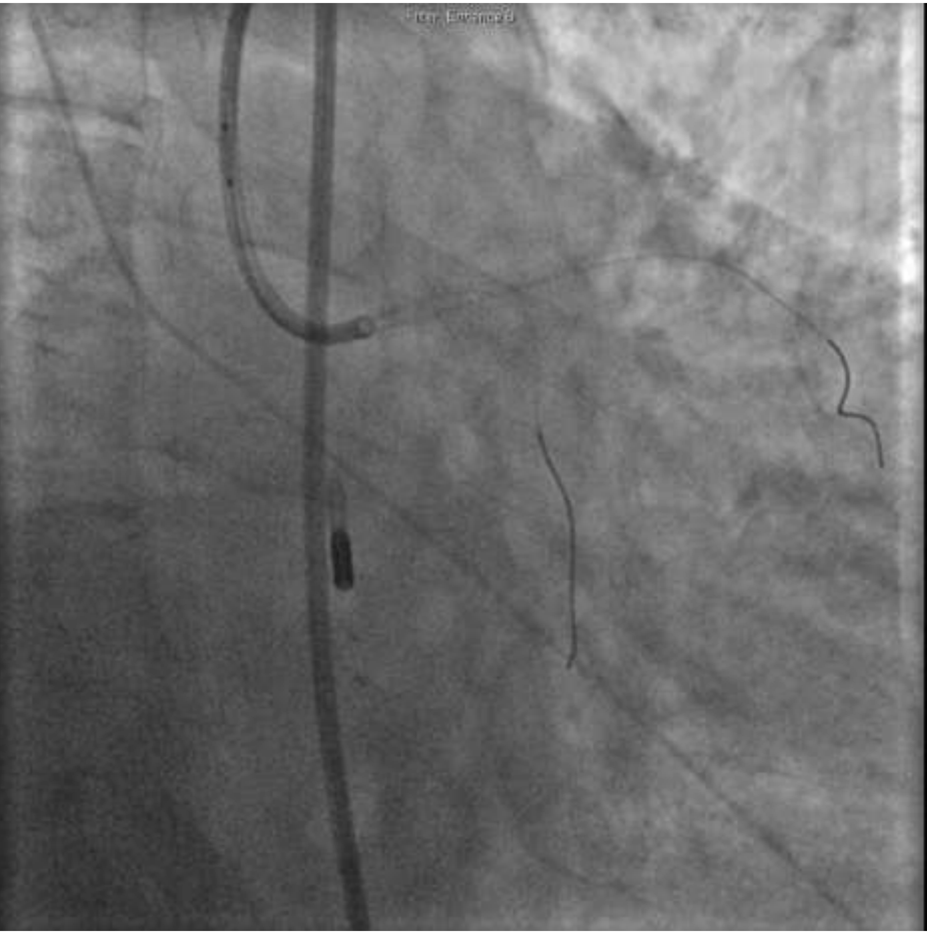
5 minutes!

Complex Coronary Anatomy
Double Bifurcation

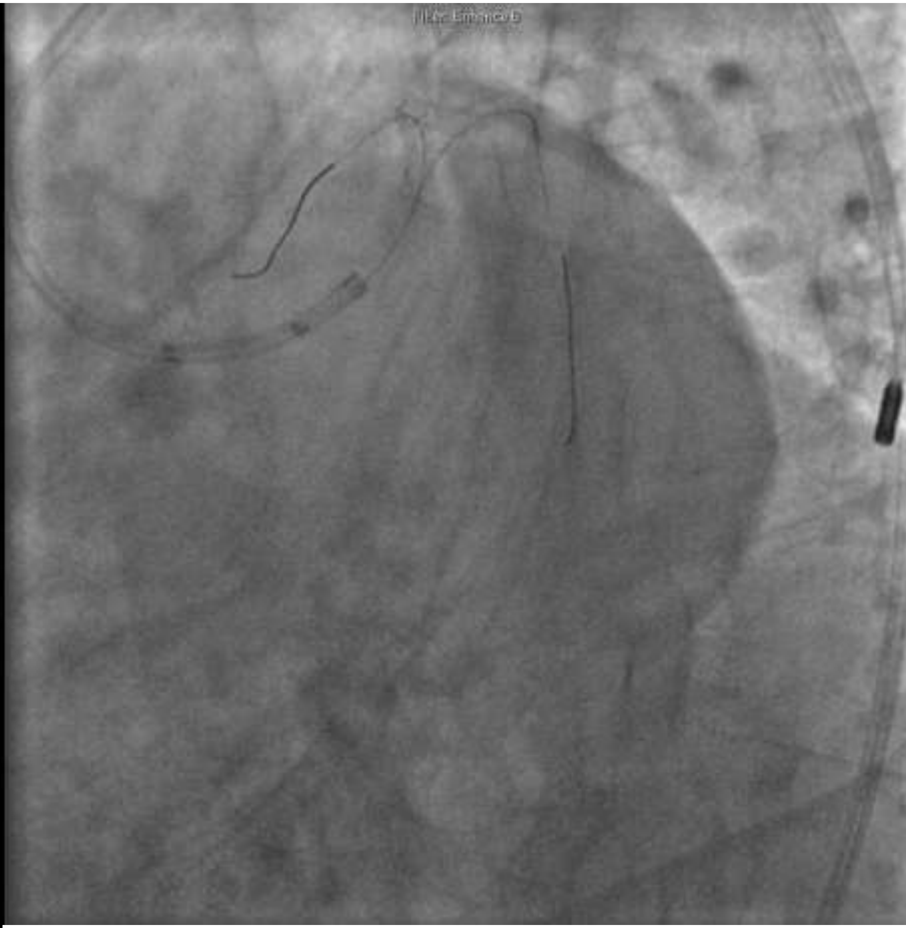


72 y.o. male with chest pain, ST elevation in AVR, and shock on inotropes

ULMCA PCI in Myocardial Infarction



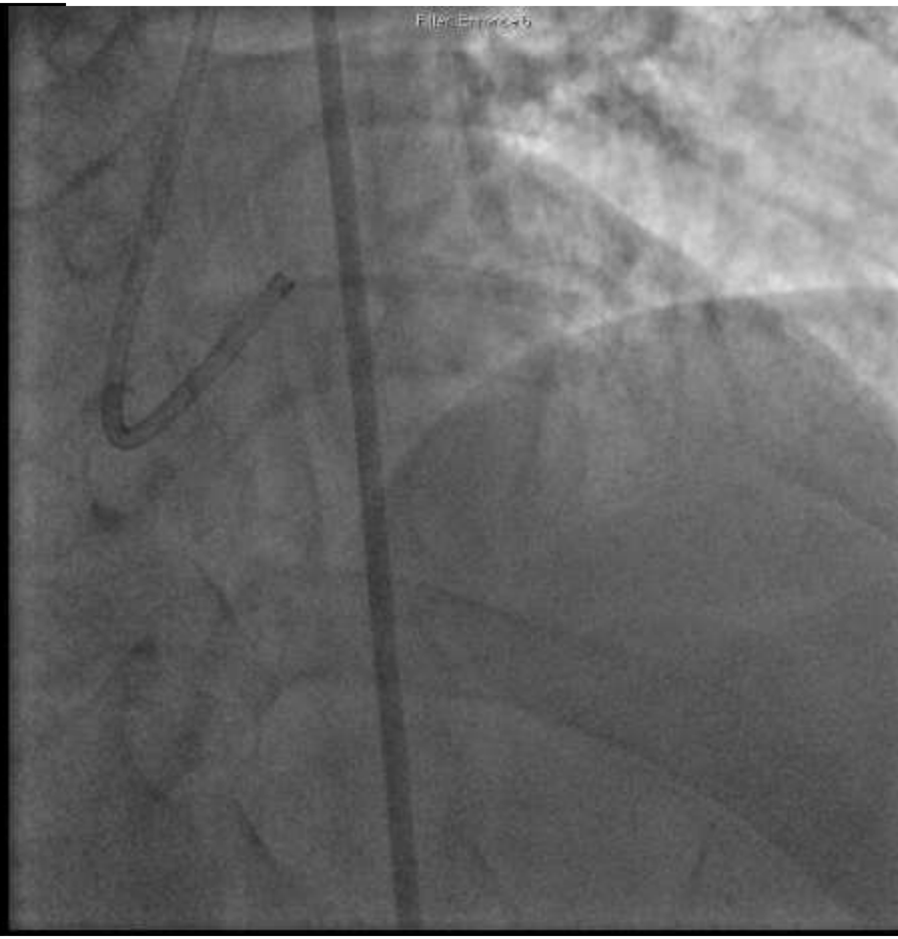
LM stent across LCX



LAD stent across D1

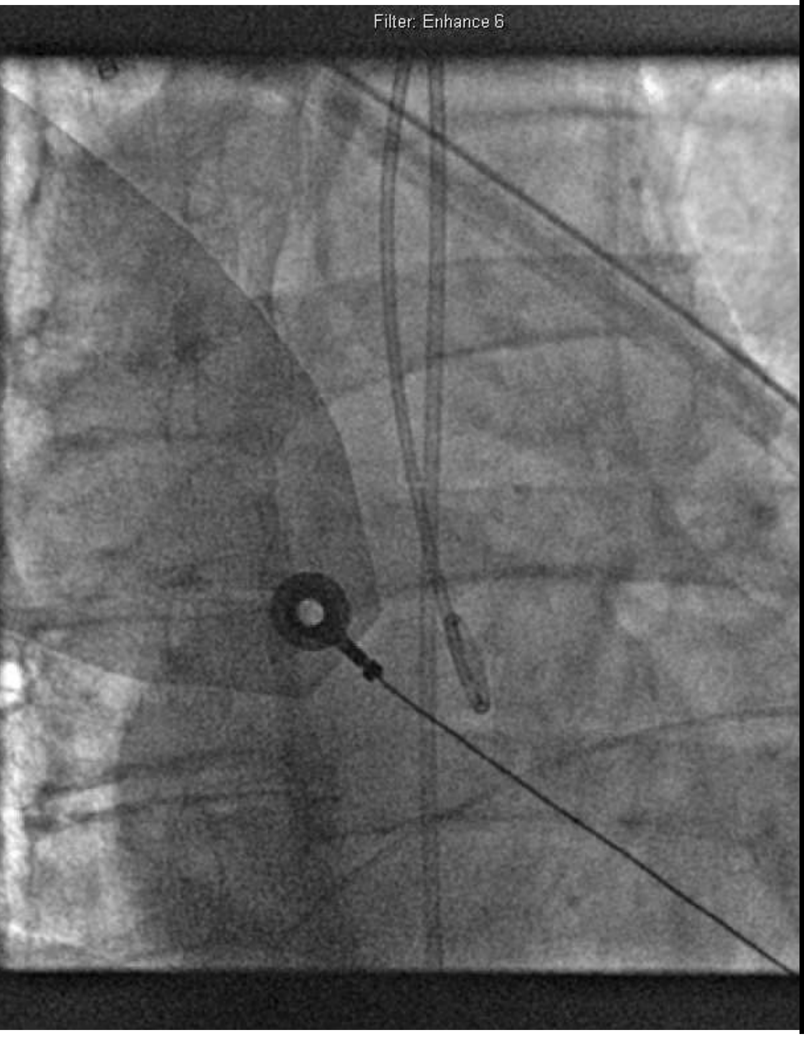
ULMCA PCI in Myocardial Infarction

Provisional ballooning of LCX



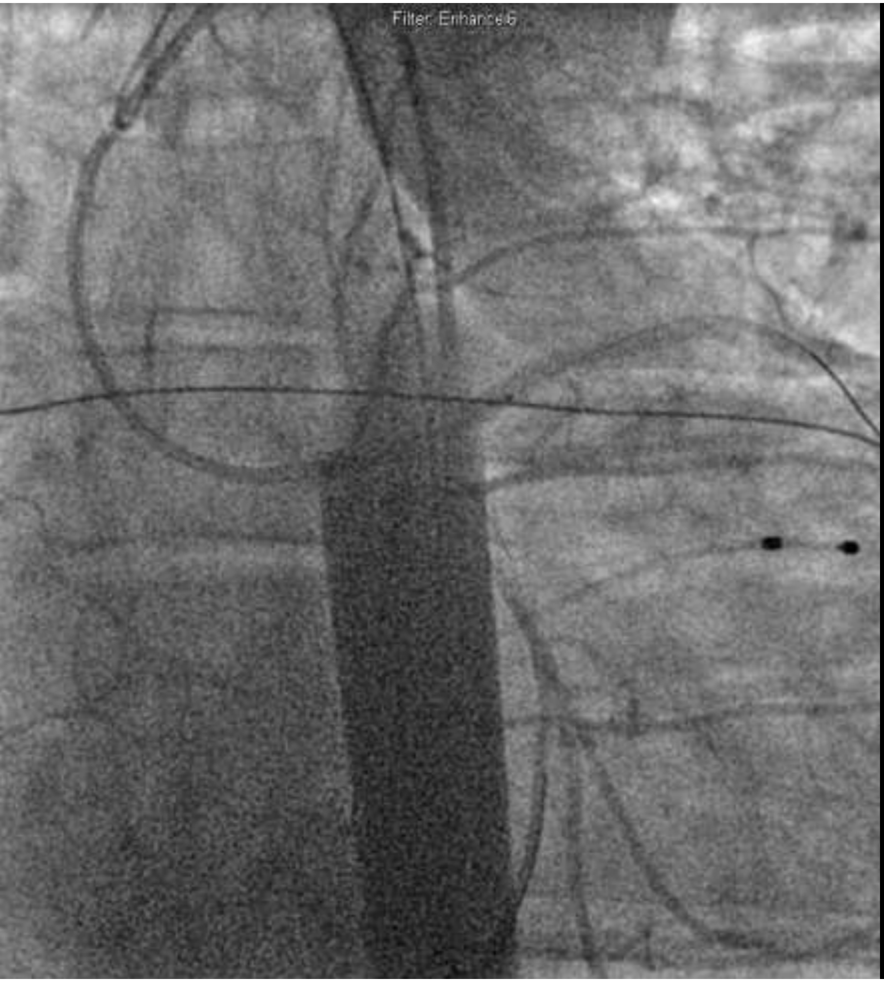
TAP of LAD/D1

ULMCA PCI in Myocardial Infarction



49 y.o. male with inferior ST-elevation and cardiac arrest in ED

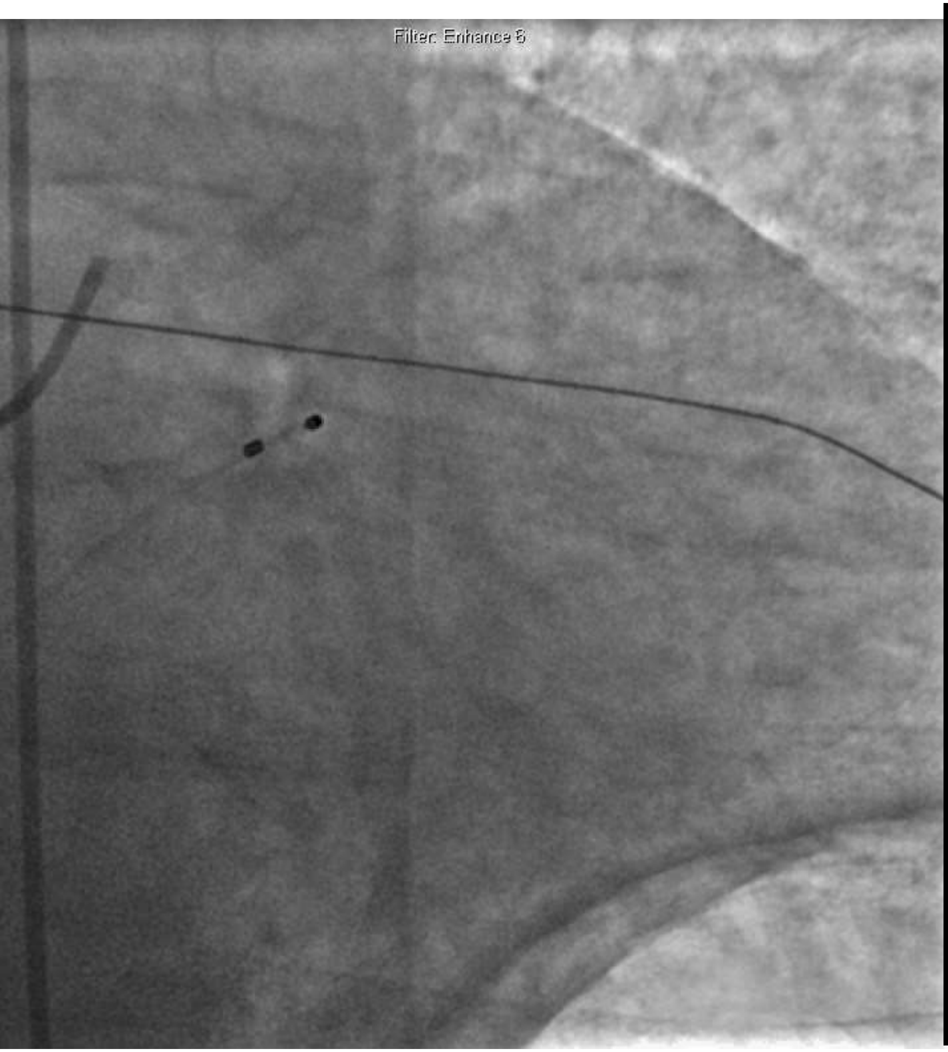
ULMCA PCI in Myocardial Infarction



LM stent across LCX
ECMO inserted

Compromise of LCX

ULMCA PCI in Myocardial Infarction



Final angiography

EKG shows VF

ULMCA PCI in Myocardial Infarction

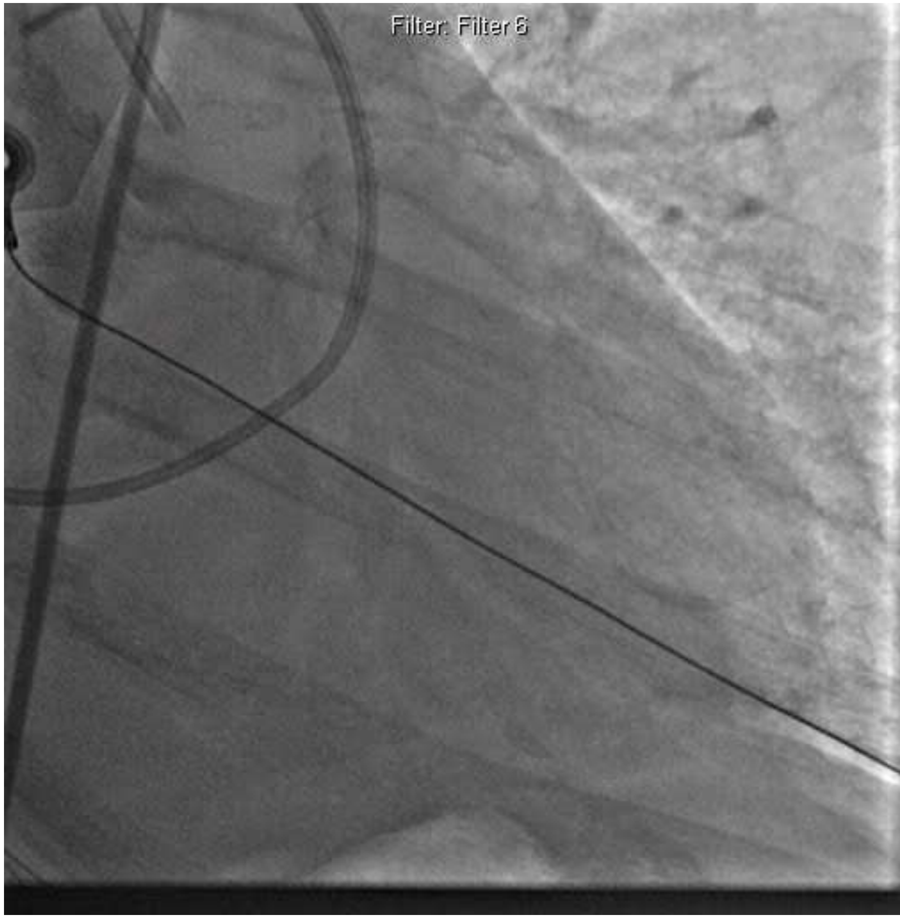
STATE-OF-THE-ART PAPER

Unprotected Left Main Coronary Disease and ST-Segment Elevation Myocardial Infarction

"Absent a randomized trial, it is our belief that physicians and guidelines committees should recognize emergent PCI as the preferred reperfusion modality for selected patients with MI and LMCA occlusion."

pared with CABG with acceptable short- and long-term outcomes, and is associated with a lower risk of stroke. PCI of the ULMCA should be considered as a viable alternative to CABG for selected patients with MI, including those with ULMCA occlusion and less than Thrombolysis In Myocardial Infarction flow grade 3, cardiogenic shock, persistent ventricular arrhythmias, and significant comorbidities. The higher risk of target vessel revascularization associated with ULMCA PCI compared with CABG is an acceptable tradeoff given the primary need for rapid reperfusion to enhance survival. (J Am Coll Cardiol Intv 2010;3:791–5) © 2010 by the American College of Cardiology Foundation

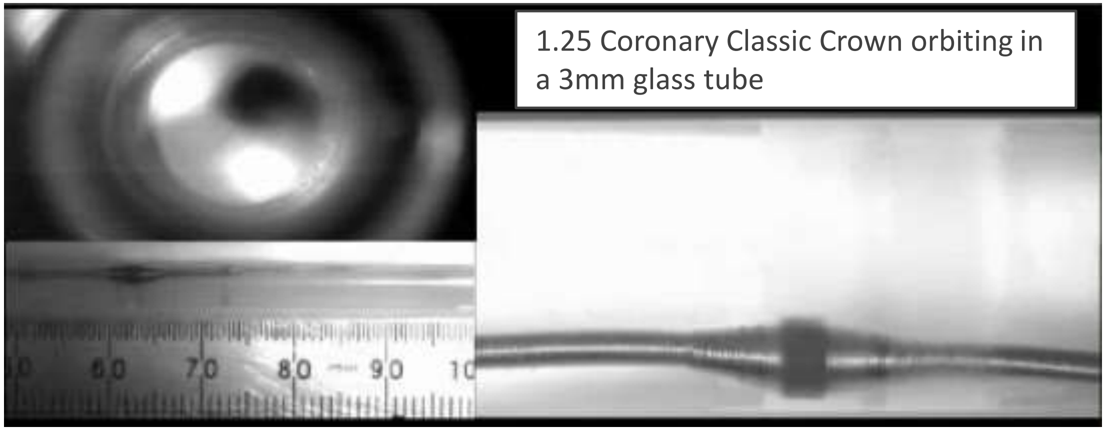
Calcified ULMCA In Patient with MI and Cardiogenic Shock



48 y.o. male with DM who presents with MI, cardiac arrest, cardiogenic shock, on ECMO

Orbital Atherectomy

Mechanism of Action



Differential Sanding:

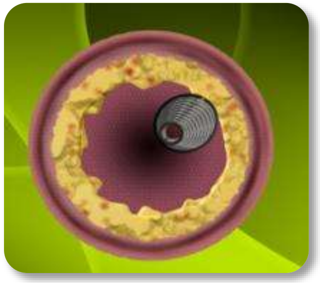
- 30 micron diamond coating
- Bi-directional sanding, eccentric mounted crown
- Healthy elastic tissue flexes away minimizing damage to the vessel

Centrifugal Force:

- 360° crown contact designed to create a smooth, concentric lumen
- Allows constant blood flow and particulate flushing during orbit
- Increasing speed increases radius of orbit
- Ability to treat multiple vessel diameters with one crown
- Treat large vessels through small sheaths

Before OAS

Crown will only sand the hard components of plaque



After OAS

Soft components (plaque/tissue) flex away from crown

David Geffen School of Medicine | UCLA Health

Outcomes After Orbital Atherectomy of Severely Calcified Left Main Lesions: Analysis of the ORBIT II Study

Michael S. Lee, MD[1]; Evan Shlofmitz, DO[2]; Richard Shlofmitz, MD[3]; Sheila Sahni, MD[1]; Brad Martinsen, PhD[4]; Jeffrey Chambers, MD[5]

ABSTRACT: **Objectives.** The ORBIT II trial reported excellent outcomes in patients with severely calcified coronary lesions treated with orbital atherectomy. Severe calcification of the left main (LM) artery represents a complex coronary lesion subset. This study evaluated the safety and efficacy of coronary orbital atherectomy to prepare severely calcified protected LM artery lesions for stent placement. **Methods.** The ORBIT II trial was a prospective, multicenter clinical trial that enrolled 443 patients with severely calcified coronary lesions in the United States. The major adverse cardiac event (MACE) rate through 2 years post procedure, defined by cardiac death, myocardial infarction (CK-MB >3x upper limit of normal with or without a new pathologic Q-wave) and target-vessel revascularization, was compared in the LM and non-left main (NLM) groups. **Results.** Among the 443 patients, a total of 10 underwent orbital atherectomy of protected LM artery lesions. At 2 years, there was no significant difference in the 2-year MACE rate in the LM and NLM groups (30.0% vs 19.1%, respectively; P=.36). Cardiac death was low in both groups (0% vs 4.4%, respectively; P=.99). Myocardial infarction occurred within 30 days in both groups (10.0% vs 9.7%, respectively; P=.99). Severe dissection, perforation, persistent slow flow, and persistent no reflow did not occur in the LM group. Abrupt closure occurred in 1 patient in the LM group. **Conclusions.** Orbital atherectomy for patients with heavily calcified LM coronary artery lesions is safe and feasible. Further studies are needed to assess the safety and efficacy of orbital atherectomy in patients with severely calcified LM artery lesions.

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KEY WORDS: calcification, percutaneous coronary intervention, atherectomy, left main

Severe coronary calcification is a marker for advanced coronary artery disease. Intravascular ultrasound (IVUS) is a useful yet underutilized technology for diagnosing the presence of coronary calcification, as it is under-appreciated with angiography alone. In a study of 1155 native coronary vessel target lesions (n = 1117 patients), angiography detected coronary calcification in 38% whereas IVUS detected calcification in 73% of lesions.[1]

The presence of severe coronary calcification increases the complexity level of percutaneous coronary intervention (PCI), as it may impede the full dilation of the lesion, possibly leading to coronary dissection from high-pressure inflation due to an undilatable lesion as well as inability to deliver the stent to the lesion.[2-5] The incidence of death, myocardial infarction (MI), and target-lesion revascularization (TLR) is increased when PCI is performed in undilatable lesions due to severe coronary calcification.[6] Stent implantation in an undilatable lesion can lead to stent underexpansion, which predisposes to in-stent restenosis[7] and stent thrombosis.[8] Patients with severely calcified left main (LM) lesions are often evaluated for coronary artery bypass graft (CABG) surgery given the increased complexity of treating these lesions, but are often not a surgical candidate given the high associated risk. Clinical trials often exclude patients with severely calcified coronary lesions, due to the associated complexity.

The current PCI guideline states that plaque modification with rotational atherectomy is a class IIa recommendation for fibrotic or heavily calcified lesions that might not be crossed by a balloon catheter or adequately dilated before stent implantation.[9] Orbital atherectomy represents a newer technology to modify severely calcified plaque and help prepare a lesion prior to stent implantation. The ORBIT II study reported excellent short-term and intermediate-term outcomes with orbital atherectomy of severely calcified lesions.[10-12] The rate of TLR at 2 years was 6.2% in this complex lesion subset.

The gold standard for the treatment of LM disease is CABG. However, PCI is a reasonable option in selected patients.[9] Severe LM calcification increases the complexity of PCI. As the LM supplies the largest territory of myocardium, severely calcified LM lesions can be challenging to dilate, leading to prolonged balloon inflation, which causes myocardial ischemia and may ultimately result in hemodynamic and electrical instability. Orbital atherectomy allows for vessel preparation, enabling successful stent deployment when treating severely calcified lesions. We report the outcomes of orbital atherectomy for the treatment of severely calcified LM disease from the ORBIT II study.

Methods

Device description. The coronary orbital atherectomy device (Cardiovascular Systems, Inc) used in the ORBIT II

Percutaneous Coronary Intervention in Severely Calcified Unprotected Left Main Coronary Artery Disease: Initial Experience With Orbital Atherectomy

Michael S. Lee, MD[1]; Evan Shlofmitz, MD[2]; Barry Kaplan, MD[2]; Richard Shlofmitz, MD[3]

ABSTRACT: **Objective.** We report the clinical outcomes of patients who underwent percutaneous coronary intervention (PCI) with orbital atherectomy for severely calcified unprotected left main coronary artery (ULMCA) disease. **Background.** Although surgical revascularization is the gold standard for patients with ULMCA disease, not all patients are candidates for this. PCI is increasingly used to treat complex coronary artery disease, including ULMCA disease. The presence of severely calcified lesions increases the complexity of PCI. Orbital atherectomy can be used to facilitate stent delivery and expansion in severely calcified lesions. The clinical outcomes of patients treated with orbital atherectomy for severely calcified ULMCA disease have not been reported. **Methods.** From May 2014 to July 2015, a total of 14 patients who underwent PCI with orbital atherectomy for ULMCA disease were retrospectively evaluated. The primary endpoint was major cardiac and cerebrovascular event (cardiac death, myocardial infarction, stroke, and target-lesion revascularization) at 30 days. **Results.** The mean age was 78.2 ± 5.8 years. The mean ejection fraction was 41.8 ± 19.8%. Distal bifurcation disease was present in 9 of 14 patients. Procedural success was achieved in all 14 patients. The 30-day major adverse cardiac and cerebrovascular event rate was 0%. One patient had coronary dissection that was successfully treated with stenting. No patient had perforation, slow flow, or thrombosis. **Conclusions.** Orbital atherectomy in patients with severely calcified ULMCA disease is feasible, even in high-risk patients who were considered poor surgical candidates. Randomized trials are needed to determine the role of orbital atherectomy in ULMCA disease.

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KEY WORDS: atherectomy, calcified lesions, ULMCA

Drug-eluting stents, which significantly reduce the rate of repeat revascularization, have led to expanded use of percutaneous coronary intervention (PCI) in patients with complex coronary anatomy. Although the gold standard for the treatment of unprotected left main coronary artery (ULMCA) disease is coronary artery bypass graft (CABG) surgery, PCI is a safe and effective treatment option when patients are carefully selected.[1] In particular, patients who are most likely to benefit are patients with low-to-intermediate SYNTAX scores.[2] The presence of heavy calcification increases the SYNTAX score. Severely calcified coronary artery lesions are associated with poor short-term and medium-term prognosis.[3] Severe coronary calcification increases the complexity of PCI by decreasing vessel elasticity, and therefore, may prohibit the delivery of the stent to the lesion as well as optimal stent expansion and apposition, increasing the risk of death, myocardial infarction, stent thrombosis, and in-stent restenosis.[4]

Rotational atherectomy modifies severely calcified plaque, facilitating optimal stent expansion and apposition as well as improving procedural success.[5] The American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions PCI guideline provides a class IIa recommendation for rotational atherectomy for fibrotic or heavily calcified lesions that might not be crossed by a balloon catheter or adequately dilated before stent implantation.[1] The data on the clinical benefit of rotational atherectomy of the ULMCA are limited by small studies with short-term follow-up.[6,7]

Orbital atherectomy (Cardiovascular Systems, Inc) was approved by the United States Food and Drug Administration on October 21, 2013 for the treatment of severe coronary artery calcification given the excellent results at 30 days of the ORBIT II trial.[8] The 1-year and 2-year data also reported excellent outcomes.[9,10] However, the safety and efficacy of orbital atherectomy for the treatment of severely calcified ULMCA disease are unknown, as these trials did not include patients with ULMCA. We report the first clinical outcomes in patients with severely calcified ULMCA disease treated with orbital atherectomy.

Methods

Study population. Between May 2014 and July 2015, the data on 13 patients with severely calcified ULMCA disease who underwent PCI with orbital atherectomy were retrospectively analyzed. The patients included 14 patients who were treated from three centers (UCLA Medical Center, Los Angeles, California [2 patients], St. Francis Hospital, Roslyn, New York [4 patients], and North Shore University Hospital, Manhasset, New York [8 patients]). During the same period of this study, 7 patients underwent rotational atherectomy for calcified ULMCA disease (UCLA Medical Center [3 patients],

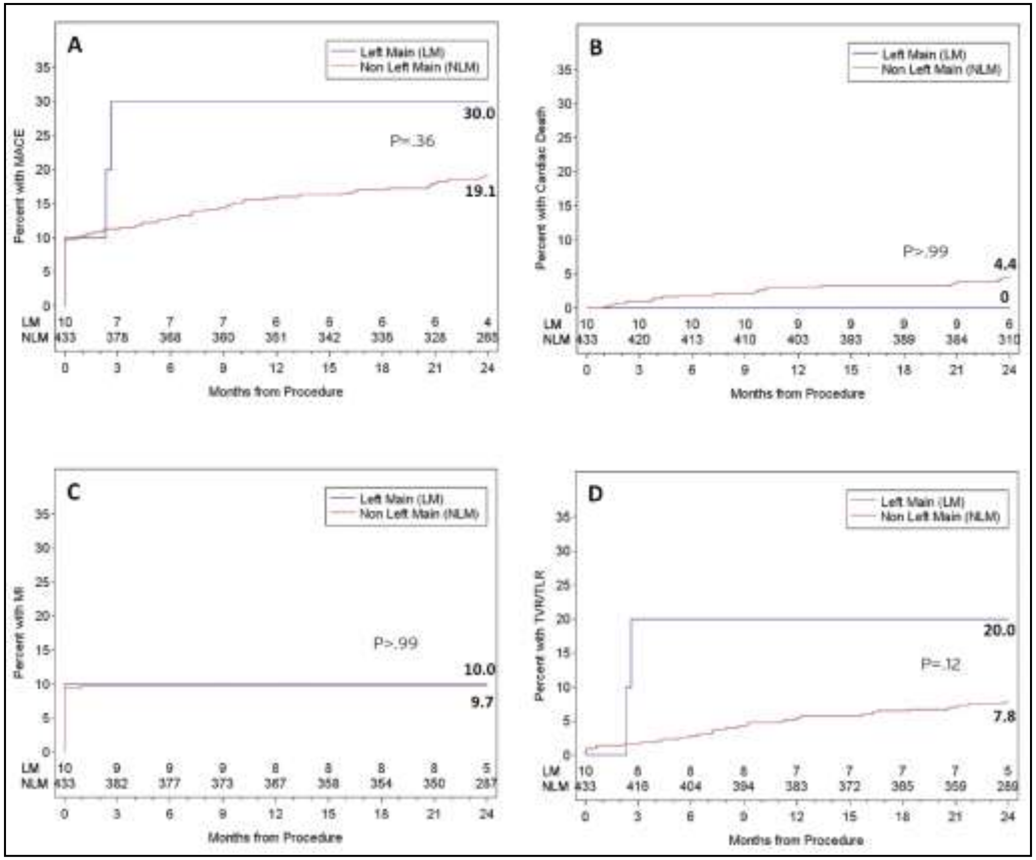
ORBIT II Trial

Left Main Subset

Table 6. Clinical outcomes.

	Left Main	Non-Left Main	*P*-Value
30-day MACE	10.0%	10.4%	>.99
Cardiac death	0.0%	0.2%	>.99
Myocardial infarction	10.0%	9.7%	>.99
Target-vessel revascularization	0.0%	1.4%	>.99
Severe angiographic complications	1/10 (10.0%)	31/433 (7.2%)	.53
Severe dissection (type C-F)	0/10 (0.0%)	15/433 (3.5%)	>.99
Perforation	0/10 (0.0%)	8/433 (1.8%)	>.99
Persistent slow flow	0/10 (0.0%)	4/433 (0.9%)	>.99
Persistent no reflow	0/10 (0.0%)	0/433 (0.0%)	>.99
Abrupt closure	1/10 (10.0%)	7/433 (1.6%)	.17

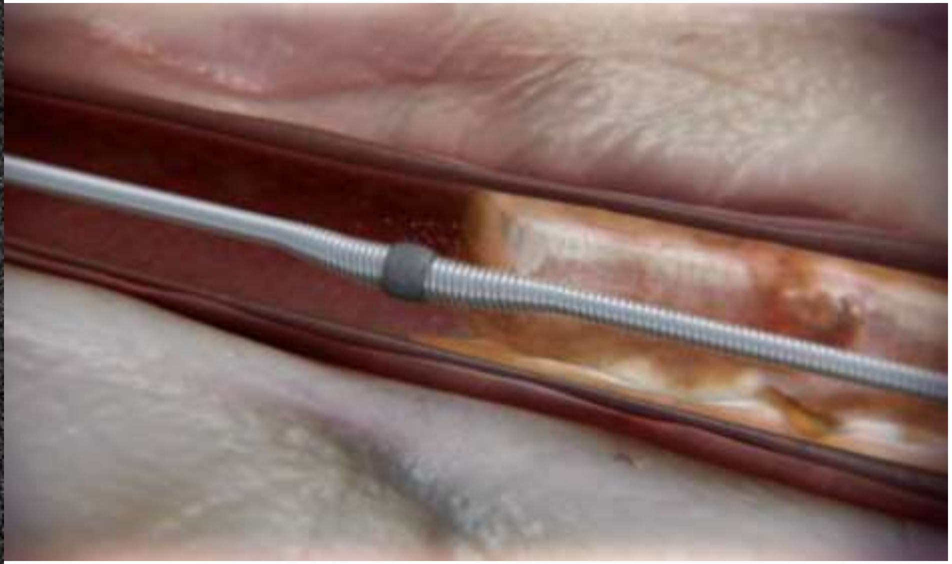
Data given as number (%). MACE = major adverse cardiac events.



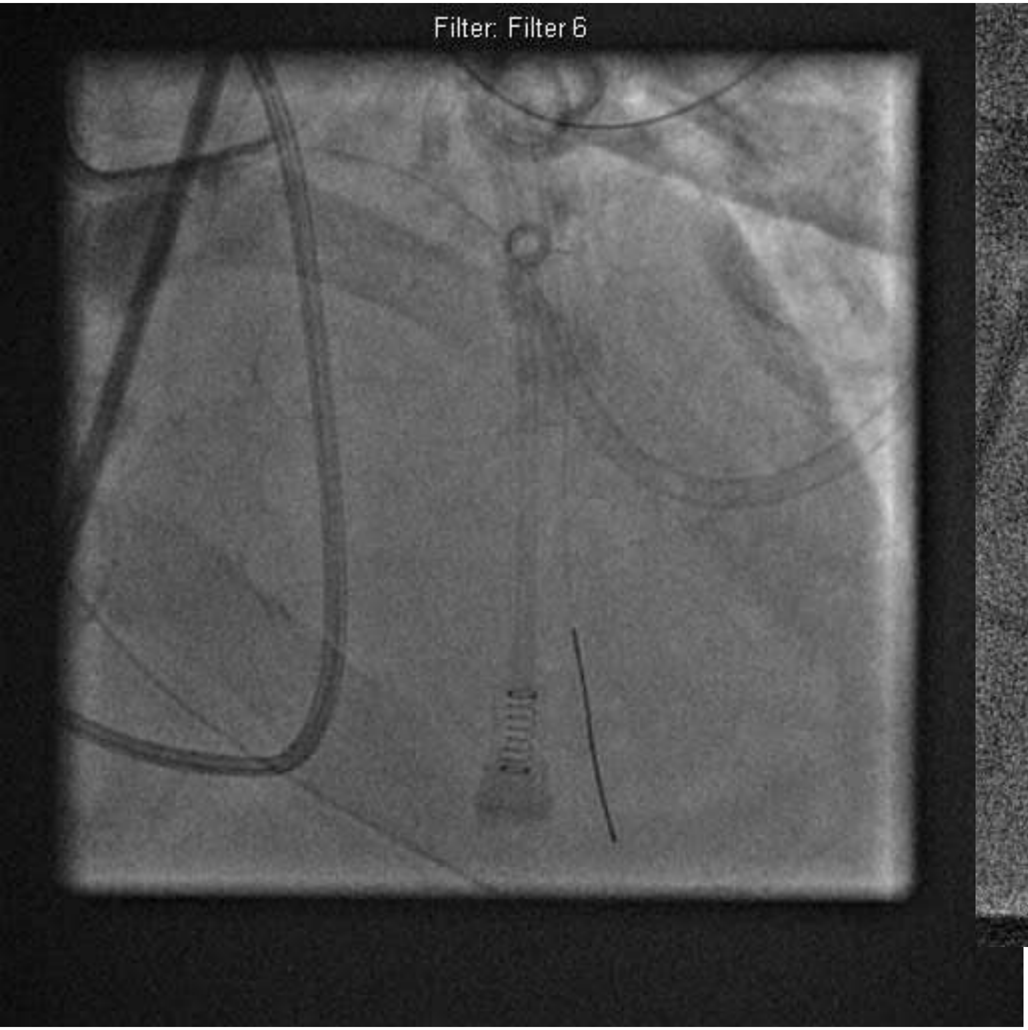
Lee MS, et al. J Invasiv Cardiol 2016

Orbital Atherectomy

Differential Sanding and Centrifugal Force

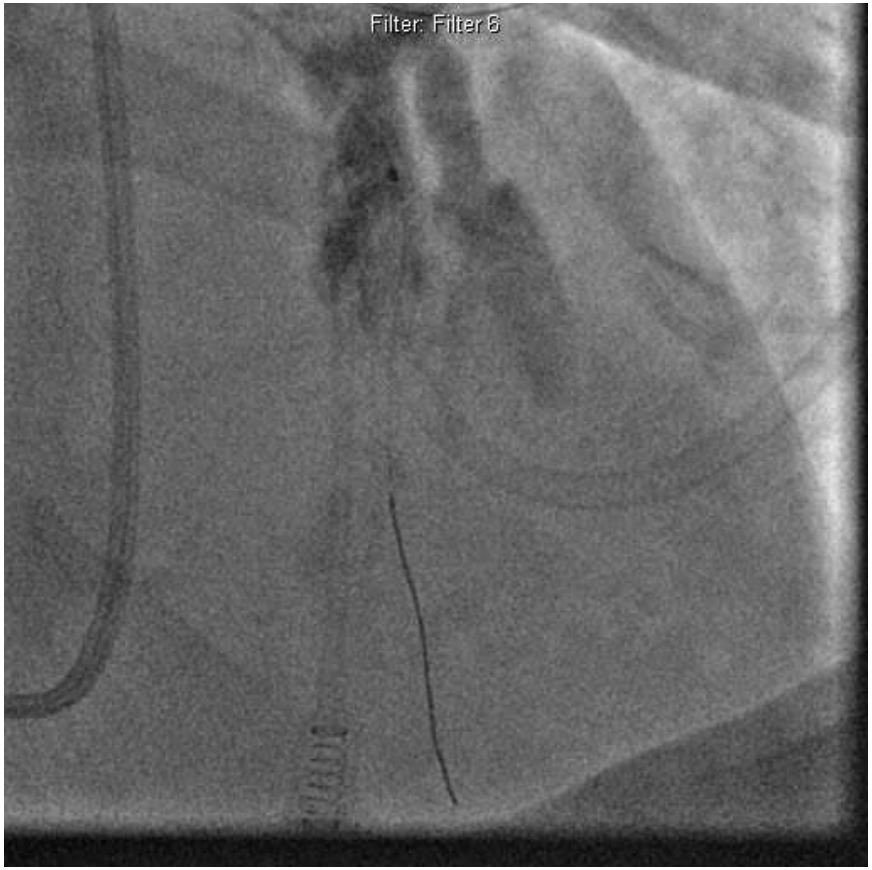


Unique MOA treats 360˚ of the vessel.The diamond coated crown sands away calcium and allows healthy elastic tissue to flex away minimizing injury to the vessel.



After orbital atherectomy

2.75 x 38 mm EES



Grade 3 perforation

Persistent perforation

LM stenting in LAO cranial

Final angiography after covered stent

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PRACTICE GUIDELINE

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions

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2.2. Revascularization to Improve Survival: Recommendations

Left Main CAD Revascularization

CLASS I

1. CABG to improve survival is recommended for patients with significant (≥50% diameter stenosis) left main coronary artery stenosis (24–30). *(Level of Evidence: B)*

CLASS IIa

1. PCI to improve survival is reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) unprotected left main CAD with: 1) anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of good long-term outcome (e.g., a low SYNTAX score [≤22], ostial or trunk left main CAD); and 2) clinical characteristics that predict a significantly increased risk of adverse surgical outcomes (e.g., STS-predicted risk of operative mortality ≥5%) (13,17,19,23,31–48). *(Level of Evidence: B)*
2. PCI to improve survival is reasonable in patients with UA/NSTEMI when an unprotected left main coronary artery is the culprit lesion and the patient is not a candidate for CABG (13,36–39,44,45,47–49). *(Level of Evidence: B)*
3. PCI to improve survival is reasonable in patients with acute STEMI when an unprotected left main coronary artery is the culprit lesion, distal coronary flow is less than TIMI (Thrombolysis In Myocardial Infarction) grade 3, and PCI can be performed more rapidly and safely than CABG (33,50,51). *(Level of Evidence: C)*

Thank You!