Mechanical Support Devices in High-Risk and/or Complex PCI

Michael S. Lee, MD FACC, FSCAI
Associate Professor
Percutaneous LV Assist Devices

IABP

Impella

ECMO

PCI with IABP

**Advantages**
- Easy
- Inexpensive ($800)
- 7F and 8F

**Disadvantages**
- Increases cardiac output by 0.5 L/m
68 y.o. male with chest pain, ST-elevation in V1-V6, shock on inotropes
68 y.o. male with chest pain, ST-elevation in V1-V6, shock on inotropes
Balloon-pump assisted Coronary Intervention Study: BCIS-1

Kaplan Meier 6 month mortality

7.4% vs 4.6%, p = 0.32

Perera D et al. JAMA 2010;304:867.
IABP-Shock II Trial
Primary Study Endpoint: 30-day Mortality

P=0.92 by log-rank test
Relative risk 0.96; 95% CI 0.79-1.17; P=0.69 by Chi$^2$-Test

Thiele H et al. NEJM 2012;367:1287.
PCI with Impella

Advantages
• Augment cardiac output by 3.5 L/min
• Use up to 7 days
• Does not require stable cardiac rhythm or native cardiac output/blood pressure signal for optimal function
• Unloads left ventricle

Disadvantages
• Requires 14 F catheter
• Non-pulsatile flow
• $20,000
ULMCA PCI
With Impella

85 y.o. male with CKD, polio presents with NSTEMI
ULMCA PCI With Impella

Rotational atherectomy

Crush technique
ULMCA PCI
With Impella

Final angiography
PROTECT II Trial Design

Hemodynamic support during high-risk, non-emergent PCI, N=654
Unprotected LM or last patent conduit & EF≤35% or 3VD & EF≤30%

Assess myocardium at jeopardy and indicate all stenosis considered for stenting

Primary Endpoint = MAE at 30-days

3 Month Follow-up; MAE at 90-days

IABP + PCI

1:1

IMPELLA + PCI

O’Neill et al, Circulation. 2012;126:1717
PROTECT II MAE Outcome

Intent to Treat (N=447)

- 30 day MAE (IABP): 40.4%
- 30 day MAE (IMPELLA): 35.7%
- 90 day MAE (IABP): 49.5%
- 90 day MAE (IMPELLA): 41.4%

p=0.312

Per Protocol (N=426)

- 30 day MAE (IABP): 42.7%
- 30 day MAE (IMPELLA): 34.9%
- 90 day MAE (IABP): 51.4%
- 90 day MAE (IMPELLA): 40.8%

p=0.029

↓ 21% MAE

MAE = Major Adverse Event Rate

Per Protocol = Patients that met all incl./excl. criteria.
PCI with ECMO

**Advantages**
- Augment cardiac output by >4.5 L/min
- Use up to several weeks
- Does not require stable cardiac rhythm or native cardiac output/blood pressure signal for optimal function
- Does not require fluoroscopy

**Disadvantages**
- Requires 21F and 18F catheters
- Non-pulsatile flow
- Increases afterload
- $25,000
- Dedicated perfusionist at bedside
49 y.o. male with inferior ST-elevation and cardiac arrest in ED
ULMCA PCI With ECMO

LM stent across LCX
ECMO inserted

Compromise of LCX
ULMCA PCI
With ECMO

Final angiography

Ventricular fibrillation
48 y.o. male with DM who presents with MI, cardiac arrest, cardiogenic shock, on ECMO
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.
ULMCA PCI With ECMO

2.75 x 38 mm EES

Grade 3 perforation
ULMCA PCI With ECMO

LM stenting in LAO cranial

Final angiography after covered stent
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 inhospital 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 566 ± 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. © 2008 Wiley-Liss, Inc.
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
“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.”
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: (a) anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of good long-term outcome (e.g., low SYNTAX score ≤22), ostial or trunk left main CAD; and (b) 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)
LV Support during High-Risk PCI: LVEF + Lesion Complexity

- **LVEF 30-35%**
  - No IABP
  - RHC: CPO <0.6 or SvO2 <50%
  - Impella

- **LVEF <30%**
  - High Syntax score >32 or STS >5
  - Extensive revascularization
  - Impella

- **Cardiac arrest**
  - ECMO

**CPO** – Cardiac power output \(\left(\frac{\text{MAP} \times \text{CO}}{451}\right)\)

**SvO2** – Mixed venous oxygen saturation
Kareem Abdul Jabbar
All-time NBA scoring leader
John Wooden
10 time NCAA champion

Kareem Abdul Jabbar
All-time NBA scoring leader

“Failing to prepare is preparing to fail.”