VENT-AVOID

**CONDITION:** Chronic Obstructive Pulmonary Disease (COPD) with acute exacerbations requiring hospitalization

**PI:** Ramiro Saavedra Romero, MD

**CONTACT INFO:** Kelly Wilson, RN | kelly.wilson@allina.com | 612-863-6288

**DESCRIPTION:** A prospective, multi-center, randomized, controlled, pivotal trial to validate the safety and efficacy of the Hemolung Respiratory Assist System for COPD patients experiencing an acute exacerbation requiring ventilator support.

**CRITERIA LIST/QUALIFICATIONS:**

**Inclusion:**
- COPD patient experiencing acute exacerbation requiring:
  - Medical management or
  - Ventilatory support (intubation)

**Exclusion:**
- Hemodynamically unstable or exacerbation is due primarily to congestive heart failure

**SPONSOR:** ALung Technologies, Inc.
Expanding horizons: Complex high risk percutaneous coronary interventions

CV GRAND ROUNDS
MINNEAPOLIS HEART INSTITUTE

ARSLAN SHAUKAT
INTERVENTIONAL CARDIOLOGY FELLOW
FEBRUARY 19, 2018

Objectives

- Describe existing data regarding complex high-risk PCI
- Describe the role of mechanical circulatory support
- Demonstrate case examples from our institution
The journey so far

<table>
<thead>
<tr>
<th>Time</th>
<th>Person(s)</th>
<th>Landmark events</th>
</tr>
</thead>
<tbody>
<tr>
<td>1964</td>
<td>Dotter and Judkins</td>
<td>Conceptual description of coronary angioplasty using an implantable prosthesis</td>
</tr>
<tr>
<td>May 1977</td>
<td>Gruntzig and Myler</td>
<td>First coronary angioplasty during coronary artery bypass graft surgery</td>
</tr>
<tr>
<td>September</td>
<td>Andreas Gruntzig</td>
<td>First coronary angioplasty in an awake patient; a revolution in interventional cardiology</td>
</tr>
<tr>
<td>1977</td>
<td>Geoffrey Hartzler</td>
<td>First balloon angioplasty to treat AMI</td>
</tr>
<tr>
<td>1986</td>
<td>Sigwart and Puel</td>
<td>The first implantation of a stent in human coronary arteries; second revolution in interventional cardiology</td>
</tr>
<tr>
<td>1991</td>
<td>Cannon and Roubin</td>
<td>First coronary stenting to treat AMI</td>
</tr>
<tr>
<td>1994</td>
<td>Semys et al. and Fischman et al.</td>
<td>Publication of first two landmark (Benestent and STRESS) trials</td>
</tr>
<tr>
<td>1994</td>
<td>FDA</td>
<td>FDA-approved use of stents to treat acute and threatened vessel closure after failed balloon angioplasty</td>
</tr>
<tr>
<td>1999</td>
<td>Eduardo Sousa</td>
<td>The first drug (sirolimus) eluting stent implanted in human coronary artery; third revolution in interventional cardiology</td>
</tr>
<tr>
<td>2002–04</td>
<td>EME and FDA</td>
<td>Approvals of Cypher and Taxus stents in Europe and USA</td>
</tr>
<tr>
<td>2011</td>
<td>EME</td>
<td>Approval of Absorb BVS (bioresorbable vascular scaffold) in Europe; fourth revolution in interventional cardiology</td>
</tr>
</tbody>
</table>

FDA, Food and Drug Administration USA; EME, European Medicines Agency;

The man with a plan

EuroIntervention 2017;13:621-624
State of the art: 40 years of percutaneous cardiac intervention
The start

EuroIntervention 2017;13:621-624
State of the art: 40 years of percutaneous cardiac intervention

1977-2017

40 years of percutaneous coronary intervention: where next?

State of the art: 40 years of percutaneous cardiac intervention

40 Years of Percutaneous Coronary Intervention
A Historical Remark on the Development and Evolution of Guidewire Technology
Coronary artery disease

- 15.5 million adults in the US
- 635,000 will have new coronary event every year
- Despite GDMT – large proportion initially present with severe CAD
- Revascularization → Improved QoL and reduced adverse events


PCI in CAD

- Revascularization has declined
- Least likely group
  - high or inoperable surgical risk
  - multiple comorbidities
  - HF
- Early experiences with PCI: lower success and higher complications

Utilization of high-risk PCI

- Lack of technical expertise
- Perception of low procedural success
- Confusion about indications for PCI in this population
- Lack of data on benefits of revascularization
- Excluded from most clinical trials
- Public reporting of adverse events


Back to the future

- Evolution of PCI: unprecedented advances in the last 2 decades – interventional tools and techniques, better patient selection
- CABG better than PCI or GDMT in complex left main/multivessel disease and intermediate-high SYNTAX scores
- But:
  - Inoperable or high-risk (>5%) for surgery
  - Prior CABG
  - Patient choice

Defining high-risk PCI

- Diversity of criteria
- Lack of consensus
- Makes comparisons between studies and standardization difficult
- Factors not captured in standard risk calculators
- Definition: somewhat arbitrary

What is high-risk PCI?

- A universal definition is elusive
- Combination of factors increased risk of periprocedural, subacute, medium- and long-term risk of MACCE


High-risk PCI

- Which model of risk stratification to use?
- Lack of risk scores \(\rightarrow\) identify who might benefit
- Age? Frailty?
- >80 yrs had higher PCI related hospital mortality (17% vs. 4%), lower 3-year survival (52% vs. 89%)*
- Short- and long-term AEs higher in frail pts**

*Kvakkestad KM et al. Eur Heart J Acute Cardiovasc Care 2015

Complex Higher Risk (and indicated) Patients - CHIP

- Most likely to receive robust clinical benefit
- “Higher risk, higher reward”
- Greater complexity → greater risk
- Reduce risk → Mechanical Circulatory Support


Planning high-risk PCI

- Which MCS to use?
- Heart team!

Mechanical Circulatory Support (MCS) devices

Keys to a good MCS device

- Effective insertion with minimal surgical application
- Simplicity of initiation and maintenance
- Aiding the coronary and peripheral circulation for hours or days
- Significant support for the ischemic myocardium

MCS use

- Increase from 1.3% to 3.4% of all PCIs (from 2004-2012)
- Mortality in those decreased from 41.1% to 33.4%

Intra-aortic balloon pump

- Concept described in 1950s
- First clinical implant in 1967
- 48-year old female with cardiogenic shock
- Originally 15 French

Diastolic balloon pumping (with carbon dioxide) in the aorta—A mechanical assistance to the failing circulation

Spyridon D. Mouloupoulos, M.D., Stephen Topaz, B.S. Eng., Willem J. Kolff, M.D.
IABP

- CathPCI registry analysis: 10.5% of all high-risk PCIs
- Multivariate adjustment: in-hospital mortality and complications not different between hospitals with different frequency of use
- 2 large retrospective analyses (~18000 and ~26500) of the NIS database: conflicting results in terms of mortality benefit of MCS over IABP

Khera R et al. Am J Cardiol 2016;117:10-6

BCIS-1 trial

Elective Intra-aortic Balloon Counterpulsation During High-Risk Percutaneous Coronary Intervention
A Randomized Controlled Trial

Perera D et al. JAMA, August 25, 2010—Vol 304, No. 8
IABP for high-risk PCI

- BCIS-1 trial: prospective, open, multicenter RCT
- 301 patients with EF <30% and BCIS-1 Jeopardy score ≥ 8
- MACCE at 28 days: 15.2% elective IABP vs. 16.0% no planned IABP (p=0.85)
- Similar 6-month mortality and bleeding
- More minor bleeds with IABP

BCIS-1 trial

- Less peri-procedural hypotension in IABP arm (1.3% v.s 10.7%, p<0.001)
- Did NOT support prophylactic use of IABP
- Perhaps role of standby IABP (given less hypotension)
BCIS-1 trial: 5-year mortality data


Figure 1. Kaplan-Meier survival curves are shown for patients treated with elective intra-aortic balloon pump (IABP) therapy (solid line) and those who had percutaneous coronary intervention without planned IABP support (dashed line). At median follow-up of 51 months, there were 42 deaths in the elective IABP group and 58 deaths in the no planned IABP group (hazard ratio, 0.66; 95% confidence interval, 0.44–0.98; P=0.039).

BCIS-1 long-term data

- Etiology of death not known
- Mechanism of reduced mortality with IABP?
- Cause-and-effect associations difficult
- Not originally designed to assess all-cause mortality
- Future adequately powered long-term studies?

TandemHeart

- Left atrium-femoral artery
- Centrifugal continuous-flow pump
- Flow of ~ 5 l/min at 7500 rpm
- FDA approved for short-term (6 hrs) support for CS and HR-PCI

TandemHeart

- CS: improves hemodynamics
- High-profile (21Fr and 15-17 Fr): bleeding, CLI, vascular complications a major concern
- No survival advantage over IABP in MI and CS
- More difficult to insert and position
- No RCTs in high-risk PCI
- No robust data overall

TandemHeart

Percutaneous Left Ventricular Assist Device With TandemHeart for High-Risk Percutaneous Coronary Intervention: The Mayo Clinic Experience

Oluseun O. Alli, MD, Inder M. Singh, MD, David R. Holmes, Jr., MD, FACC, Juan N. Pulido, MD, Soon J. Park, MD, and Charanjit S. Rihal, MD, FACC

Catheterization and Cardiovascular Interventions 80:728–734 (2012)

TandemHeart

- 54 patients
- 30-day survival of 90%
- 6-month survival of 87%
- Major vascular complications 13%
Impella

- Miniature axial flow rotary pump
- LV unloading
- 5.0: surgical cutdown
- 2.5: FDA approved in 2008 (3/15 for HR-PCI)
- CP (up to 4 l/min): FDA approved in September 2012

Impella in high-risk PCI

- USpella registry: prospective registry of the 2.5 device
- Revascularization success 99%
- Improved LVEF, functional status by ≥ 1 in 51%
- Less ICDs, lower mortality and MACE compared to known HR-PCI data
- Survival of 96% at 1 month, 88% at 1 year (lower than expected STS-PROM)
- 1.7% major vascular complications

Impella in elective high-risk PCI

- UPLM or last vessel and EF ≤ 35%
- 3-vessel disease and EF ≤ 30%
- N = 448 (ITT), n= 427 (PP)
- 30-day MAE rate similar – 35% vs. 40% (p=0.227)(ITT population)
- 90-day MAE:
  - Strong trend favoring Impella – 40.6% vs. 49.3% (p=0.066) (ITT)
  - Significantly lower in Impella – 40% vs. 51% (p=0.023) (PP)

PROTECT II trial

- Subsequent analysis with less stringent definition of MI:
  - At 90 days, the rates of both MACE and MACCE were lower in the Impella group compared with the IABP group (37% vs 49%, p=0.014; 22% vs. 31%, p=0.034)
- Terminated early due to futility
- Did not meet primary end-point
- Hypothesis-generating
- Late benefit also seen in BCIS-1 trial – more stable HDs? More complete revasc?
- Further RCTs needed


Impella for High risk PCI

Percutaneous left ventricular assist device for high-risk percutaneous coronary interventions: Real-world versus clinical trial experience

Mauricio G. Cohen, MD, * Ray Matthews, MD, † Brij Maini, MD, ‡ Simon Dixon, MD, ‡ George Vetrovec, MD, ‡ David Wolosh, MD, ‡ Igor Palacios, MD, ‡ Jeffrey Pogum, MD, ‡ E. Magnus Ohman, MD, ‡ Theodore Schreiber, MD, ‡ and William W. O’Neill, MD ‡ Miam, Fl; Los Angeles, Ca; Harrisburg, Pa; Royal Oak, Mi; Richmond, Va; Grand Rapids, Mi; Boston, Mi; Durham, Nc and Detroit, Mi

Cohen MG et al. Am Heart J 2015;170:872-9
PROTECT II vs. real-world

Flow chart of the Impella Registry high-risk PCI data.

Impact of HR-PCI with Impella

Figure 3

<table>
<thead>
<tr>
<th>NYHA Class</th>
<th>USpella Registry</th>
<th>PROTECT II Impella arm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>28.9%</td>
<td>21.3%</td>
</tr>
<tr>
<td>Class II</td>
<td>42.2%</td>
<td>48.3%</td>
</tr>
<tr>
<td>Class III</td>
<td>33.6%</td>
<td>30.0%</td>
</tr>
<tr>
<td>Class IV</td>
<td>10.9%</td>
<td>16.0%</td>
</tr>
</tbody>
</table>

Baseline vs. Discharge

Improvement in NYHA class after Impella-supported PCI in the USpella Registry and the Impella arm of the PROTECT II trial.
PROTECT II vs real-world

Table III. Hospital outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>All HPPO patients (n = 637)</th>
<th>PROTECT II-like patients (n = 339)</th>
<th>PROTECT II Impella arms (n = 216)</th>
<th>p</th>
<th>p*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>2.82 (1.5-4.1)</td>
<td>2.65 (0.9-4.4)</td>
<td>4.61 (1.8-7.4)</td>
<td>.19</td>
<td>.27</td>
</tr>
<tr>
<td>MI</td>
<td>1.25 (0.4-2.1)</td>
<td>0.29 (0.0-0.9)</td>
<td>15.8 (10.4-20.1)</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Stroke/TIA</td>
<td>0.00</td>
<td>0.00</td>
<td>0.5 (0.0-1.4)</td>
<td>.09</td>
<td>.21</td>
</tr>
<tr>
<td>Repeat revascularization</td>
<td>0.78 (0.1-1.5)</td>
<td>0.29 (0.0-0.9)</td>
<td>2.3 (0.3-4.3)</td>
<td>.07</td>
<td>.02</td>
</tr>
<tr>
<td>Vascular complications</td>
<td>2.51 (1.3-3.7)</td>
<td>2.36 (0.7-4.0)</td>
<td>1.40 (0.3-5.0)</td>
<td>.33</td>
<td>.42</td>
</tr>
<tr>
<td>Requiring surgery</td>
<td>5.18 (3.5-6.9)</td>
<td>5.60 (3.1-8.1)</td>
<td>9.3 (5.4-13.1)</td>
<td>.03</td>
<td>.10</td>
</tr>
<tr>
<td>Not requiring surgery</td>
<td>10.99 (6.6-13.4)</td>
<td>9.14 (6.1-12.2)</td>
<td>12.8 (8.1-16.9)</td>
<td>.53</td>
<td>.21</td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>5.81 (4.0-7.4)</td>
<td>7.56 (5.1-10.8)</td>
<td>6.5 (3.2-9.8)</td>
<td>.71</td>
<td>.52</td>
</tr>
<tr>
<td>Acute kidney injury</td>
<td>0.16 (0.0-0.5)</td>
<td>0.00</td>
<td>0.9 (0.0-2.3)</td>
<td>.10</td>
<td>.08</td>
</tr>
<tr>
<td>Hemolysis</td>
<td>7.06 (5.1-9.1)</td>
<td>6.78 (4.1-9.5)</td>
<td>10.2 (6.2-14.3)</td>
<td>.14</td>
<td>.15</td>
</tr>
<tr>
<td>Transient hypotension during support</td>
<td>4.40 (2.8-6.0)</td>
<td>3.90 (3.4-8.4)</td>
<td>6.9 (3.6-10.3)</td>
<td>.14</td>
<td>.62</td>
</tr>
</tbody>
</table>

Briasoulis A et al. Am J Cardiol 2016;118:369e 375

Meta-analysis of Impella studies

- 12 studies (11 cohort and one RCT)
- 1346 patients
- 30-day mortality: 3.5%
- MI: 3.3%
- Major bleeding: 7.1%
- Vascular complications: 4.9%

Briasoulis A et al. Am J Cardiol 2016;118:369e 375
Heart mate PHP

- Axial-flow pump
- 14 Fr
- Sheath retracts → 24 Fr
- Flows > 4 LPM
- SHIELD I trial: Feasibility in HR-PCI (Europe and S America)
- SHIELD II trial: currently enrolling (60 US centers, HR-PCI, vs. Impella 2.5)

Coronary interventions in high risk patients using a novel percutaneous left ventricular support device (SHIELD II) Available at: https://clinicaltrials.gov/ct2/show/NCT02468778.

ECMO

- First approved in the 1950s for use during cardiac surgery
- VA-ECMO: Modified CPB
- Continuous, non-pulsatile CO
- Femoral artery-vein
- Provides COMPLETE cardiopulmonary support
- Increases LV afterload and wall stress
ECMO

- Collaboration: cardiologist, surgeon, cath lab staff, anesthesiologist, perfusionist
- Needs AC: heparin
- Contraindications: Severe AI, severe PAD, bleeding diathesis, recent stroke or head trauma, uncontrolled sepsis

ECMO

- Significantly reduces mortality in STEMI and CS compared to historical cohort
- Well-validated in that setting
- ECMO for elective high-risk PCI: single center observational studies and case reports
- Feasible and efficacious
- Vascular complications a concern
- No RCT or meta-analysis data available – guidelines on expert consensus

Craner R et al. 2017 JCVA
ECMO

Elective High-Risk Percutaneous Coronary Interventions Supported by Extracorporeal Life Support

Jindra Vainer, MD, Vincent van Ommen, MD, PhD, Jos Maessen, MD, PhD, Gijs Geskes, MD, Leon Lamerichs, RN, and Johannes Walienberger, MD, PhD

Am J Cardiol 2007;99:771-773

- 15 patients
- Procedural success 14
- All weaned in cath lab
- Transfusion 8 patients
- No vascular complications
- No in-hospital death or MI
- 3 cardiac deaths at mean f/up of 15 months
ECMO

Open Access

Percutaneous Cardiopulmonary Support-Supported Percutaneous Coronary Intervention: A Single Center Experience

Sung Soo Cho, MD, Chang-Myung Oh, MD, Ji Yong Jung, MD, Hee Tae Yu, MD, Woe Dae Bang, MD, Jung-Sun Kim, MD, Young-Guk Ko, MD, Donghoon Choi, MD, Myeong-Ki Hoong, MD, Won-Heum Shim, MD, Seung-Yun Cho, MD, and Yangsoo Jang, MD

Division of Cardiology, Yonsei Cardiovascular Center, Yonsei University College of Medicine, Seoul, Korea

Korean Circ J 2011;41:299-303

ECMO

- 19 patients
- 10 with elective HR-PCI
- Mean f/up 541 days
- Elective group: 1 in-hospital death
- 2 non-cardiac deaths (no cardiac deaths) during f/up
ECMO

Outcome of extracorporeal membrane oxygenation support for complex high-risk elective percutaneous coronary interventions: A single-center experience

Salvatore Davide Tomasello, MD, a, Marouane Boukhris, MD a, b, Vladimir Ganyukov, MD c, Alfredo R. Galassi, MD, FACC, FESC, FSCAI d, Dmitri Shukevich, MD e, Boris Haes, MD f, Nikita Kochergin, MD g, Roman Tarasov, MD c, Vadim Popov, MD c, Leonid Barbarash, MD c

Heart & Lung 44 (2015) 309-313

ECMO

• 12 patients
• High risk for CABG
• LM stenosis in 10
• Results:
• Complete revasc achieved in 5
• 1 hemorrhagic complication, 1 pt needed HD
• 6-months:
  o no death, MI or ST
  o 2 needed revasc
MCS in high-risk PCI

- Solid physiological basis
- Equivocal results and mixed messages
- Modest use
- Clinically: all MCS have potential use, but perhaps not for every patient
- Heart team to decide

Current guidelines

| Table 2: Current Guideline Recommendations for the Use of Percutaneous Circulatory Assist Devices During High-Risk PCI |
|---|---|---|---|---|
| **Guideline, Year (Ref.)** | IABP | Impella | TandemHeart | Extracorporeal Membrane Oxygenation |
| PCI, 2018 (48) | A hemodynamic support device is recommended for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacological therapy. | Class Ia, Level of Evidence: B | Elective insertion of an appropriate hemodynamic support device as an adjunct to PCI may be reasonable in carefully selected high-risk patients. | Class IIb, Level of Evidence: C |
| | High risk patients includes: | | | |
| | - Unprotected left main or last remaining conduit PCI. | | | |
| | - Cardiogenic shock. | | | |
| STEMI, 2013 (44) | IABP can be useful for patients in cardiogenic shock after STEMI who do not quickly stabilize with pharmacological therapy. | Class IIa, Level of Evidence: B | PCI of a vessel subtending a large territory on a background of severely depressed left ventricular function. | Class IIb, Level of Evidence: C |
| | Alternative left ventricular assist devices for circulatory support may be considered in patients with refractory cardiogenic shock. | | | |
| UA/NSTEMI, 2013 (50) | IABP is reasonable in UA/NSTEMI patients for continuing or frequently recurring ischemia despite intensive medical therapies, hemodynamic instability prior to percutaneous coronary intervention, and hemodynamic complications of MI. | Class IIa, Level of Evidence: C | No individual device recommendations. |
MCS in high-risk PCI

**Consensus Statement**

2015 SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care (Endorsed by the American Heart Association, the Cardiological Society of India, and Sociedad Latino Americana de Cardiologia Intervention; Affirmation of Value by the Canadian Association of Interventional Cardiology—Association Canadienne de Cardiologie d’intervention)

CHARANIT T. REBILLA, MD, FSCAI, FACC; SREHARI S. NAIDU, MD, FSCAI, FACC, FAHA; MICHAEL M. GORBERT, MD, FACC; \(^{1}\) WILSON Y. SIEITI, MD; JAMES A. BURKE, MD, PhD, FACC; \(^{1}\) NINMAN KAPUR, MD; MORRIS KERN, MD, FSCAI, FACC; \(^{1}\) KIRK N. GARRATT, MD, FSCAI, FACC; \(^{1}\) JAMES A. GOLDSTEIN, MD, FSCAI, FACC; \(^{1}\) VIVIAN DIMAS, MHI; \(^{1}\) AND THOMAS TU, MD; \(^{1}\) FROM THE SOCIETY FOR CARDIOVASCULAR ANGIOGRAPHY AND INTERVENTIONS (SCAI), HEART FAILURE SOCIETY OF AMERICA (HFSA), SOCIETY FOR THORACIC SURGEONS (STS), AMERICAN HEART ASSOCIATION (AHA), AND AMERICAN COLLEGE OF CARDIOLOGY (ACC)

Journal of Cardiac Failure Vol. 21 No. 6 2015

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### Table 1. Suggested Indications for Percutaneous MCS

<table>
<thead>
<tr>
<th>Indication</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complications of AMI</td>
<td>Ischemic mitral regurgitation is particularly well suited to these devices as the hemodynamic disturbance is usually acute and substantial. Acutely depressed LV function from large AMI can be deteriorating and when primary PCI is an increasing indication for temporary MCS use. Cardiogenic shock from MI can be treated with percutaneous right ventricular support.</td>
</tr>
<tr>
<td>Severe heart failure in the setting of nonischemic cardiomyopathy</td>
<td>Examples include severe exacerbations of chronic systolic left failure as well as acutely reversible cardiomyopathies such as fulminating myocarditis, stress cardiomyopathy, or peripartum cardiomyopathy. In patients presenting in INTERMACS profiles 1 or 2, MCS can be used as a bridge to destination LAVD placement or as a bridge to recovery if the ejection fraction rapidly improves.</td>
</tr>
<tr>
<td>Acute cardiac allograft failure</td>
<td>Primary allograft failure (adult or pediatric) may be due to acute cellular or antibody-mediated rejection, uncontrolled ischemic time, or in situ anaphylaxis.</td>
</tr>
<tr>
<td>Prophylactic use for high-risk PCI</td>
<td>Particularly in patients with severe LV dysfunction (EF &lt;20–30%) and complex coronary artery disease involving a large territory (two or three vessel disease) or severe right ventricular dysfunction or moderate to severe mitral regurgitation or severe mitral regurgitation.</td>
</tr>
<tr>
<td>Patients close to mean from cardiac/pulmonary bypass following heart surgery</td>
<td>Although selected patients may be transitioned to a percutaneous system for additional support, this is usually done.</td>
</tr>
<tr>
<td>Refractory arrhythmia</td>
<td>Patients can be treated with a percutaneous system that is somewhat independent of the cardiac rhythm. For severe, refractory, ventricular arrhythmia, ECMO may be required for biventricular failure.</td>
</tr>
<tr>
<td>Prophylactic use for high-risk PCI</td>
<td>Particularly in patients with severe LV dysfunction (EF &lt;20–30%) and complex coronary artery disease involving a large territory (two or three vessel disease) and severe right ventricular dysfunction or moderate to severe mitral regurgitation.</td>
</tr>
<tr>
<td>High-risk or complex ablation of ventricular tachycardia</td>
<td>Similar to high-risk PCI, complex VT ablation can be made feasible with percutaneous support. MCS use allows the patient to remain in VT longer during ablation mapping without as much concern about systemic hypotension.</td>
</tr>
<tr>
<td>High-risk percutaneous valve interventions</td>
<td>These evolving procedures may be added with the use of MCSs.</td>
</tr>
</tbody>
</table>
MCS for high-risk PCI

- Body of evidence continues to grow
- FDA approved
- Expert consensus document supportive


Is there benefit to high-risk PCI?

High-risk percutaneous coronary intervention is associated with reverse left ventricular remodeling and improved outcomes in patients with coronary artery disease and reduced ejection fraction

LV reverse remodeling after high-risk PCI

- Echo at 30 and 90 days
- Reverse remodeling:
  - Increase in EF $\geq 5\%$

Table II. Left ventricular reverse remodeling after high-risk PCI

<table>
<thead>
<tr>
<th></th>
<th>No reverse remodeling (EF increase $\leq 5%$, $n = 91$)</th>
<th>Reverse remodeling (EF increase $&gt;5%$, $n = 93$)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline, longest follow-up</td>
<td>P</td>
</tr>
<tr>
<td>EF (%)</td>
<td>29.2 ± 9.5, 27.8 ± 9.0</td>
<td>.302</td>
</tr>
<tr>
<td>ESV (mL)</td>
<td>143.2 ± 39.9, 145.2 ± 62.9</td>
<td>.809</td>
</tr>
<tr>
<td>LV severity score</td>
<td>1.29 ± 0.63, 1.12 ± 0.55</td>
<td>.822</td>
</tr>
</tbody>
</table>

Values are mean ± SD.
LV remodeling after high-risk PCI

Table V: Comparison of clinical event rates in patients with and without reverse remodeling

<table>
<thead>
<tr>
<th>Event</th>
<th>No reverse remodeling (n = 91)</th>
<th>Reverse remodeling (n = 93)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composite death/MI/stroke/TIA</td>
<td>22 (24.2%)</td>
<td>9 (9.7%)</td>
<td>.009</td>
</tr>
<tr>
<td>Death</td>
<td>4 (4.4%)</td>
<td>1 (1.1%)</td>
<td>1.16</td>
</tr>
<tr>
<td>MI</td>
<td>18 (19.9%)</td>
<td>9 (9.7%)</td>
<td>.053</td>
</tr>
<tr>
<td>Periprocedural MI</td>
<td>8 (8.8%)</td>
<td>7 (7.5%)</td>
<td>.754</td>
</tr>
<tr>
<td>Spontaneous MI</td>
<td>10 (11.0%)</td>
<td>2 (2.2%)</td>
<td>.015</td>
</tr>
<tr>
<td>Stroke/TIA</td>
<td>2 (2.2%)</td>
<td>0 (0.0%)</td>
<td>.151</td>
</tr>
<tr>
<td>Repeat revascularization</td>
<td>12 (13.2%)</td>
<td>9 (9.7%)</td>
<td>.454</td>
</tr>
</tbody>
</table>

Figure 4

Relationship between the magnitude of reverse remodeling and clinical events. Comparison of event rates after 30 days between patients with and without reverse remodeling categorized by the magnitude of absolute change in EF.

MCS use without severely depressed EF

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The Role of Mechanical Circulatory Support During Percutaneous Coronary Intervention in Patients Without Severely Depressed Left Ventricular Function

Khaldoon Alswad, MD*, Mir Babar Basir, DO*, Akshay Khandelwal, MD*, Theodore Schreiber, MD*, William Lombardi, MD*, and William O’Neill, MD*

Am J Cardiol 2017
MCS use without severely depressed EF

- Global cVAD registry
- High-risk PCI with Impella 2.5 or CP
- 661 with EF \( \leq 35\% \), 230 with EF > 35\%
Last week: Impella now FDA approved for HR-PCI regardless of EF (and CS other than MI or cardiac surgery)

### Conclusions:
- A sizable minority of contemporary HRPCI supported with Impella do not have severely depressed left ventricular function
- These patients have severe co-morbidities and complex angiographic features
- HR-PCI with elective MCS: feasible, safe, and achieved favorable outcomes
Our experience at MHI with ECMO-assisted high-risk PCI

Case 1

- 79 M, h/o smoking, fam hx of CAD, COPD
- Late presentation of anterior STEMI (troponin ~5)
- Echo with EF of 35-40% (anterior akinesis)
Case 1

- MRI: LAD territory non-viable
- CTS: not good surgical candidate
- Planned for HR-PCI with right axillary – right CFV ECMO (19 and 26 Fr)
Case 1

- ECMO decannulated surgically in cath lab
- No in-hospital MACE
- Doing well at 1-month f/up
Case 2

- 91 M
- H/o severe AS, normal EF. Evaluated for TAVR
- Sx: Near-syncope, dyspnea
- Excellent functional status
- Came for angiogram
Case 2

- Not considered a CABG candidate mainly due to age
- Brought for planned HR-PCI with ECMO
Case 2

- ECMO cannulae percutaneously removed, perclose used in cath lab
- No in-hospital MACE
- Doing well at 1-month follow-up
- Not interested in TAVR at this time

Case 3

- 72 M
- Hx of CABG in 1979 (SVG Y graft to LAD/OM and SVG-RPDA)
- SVG-RPDA known to be occluded
- Hx of ICMP, VT s/p ICD, EVAR, CVA, CKD III, pulmonary fibrosis
- EF 20-25%
- Chest pain, transient STE in V1, aVR, mild troponin elevation
Case 3

- CTS consult: not a good surgical candidate (prior CABG, severe pulm fibrosis)

- Decision to proceed with HR-PCI with ECMO (same procedure)
Case 3

- Hospital course: Surgical decannulation < 24 hours
- VT, ICD shocks x 3, PNA
- EF improved to 51% prior to d/c
- No MACE at 1 year
MHI data

<table>
<thead>
<tr>
<th>Variable</th>
<th>All patients n = 8</th>
<th>Total patients n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age – mean ± SD</td>
<td>71.3 ± 11.2</td>
<td></td>
</tr>
<tr>
<td>Male gender</td>
<td>8 (100)</td>
<td></td>
</tr>
<tr>
<td>BMI – mean ± SD</td>
<td>26 ± 2.9</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>5 (63)</td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>3 (38)</td>
<td></td>
</tr>
<tr>
<td>Current smoking</td>
<td>3 (38)</td>
<td></td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>3 (38)</td>
<td></td>
</tr>
<tr>
<td>ESRD on HD</td>
<td>1 (13)</td>
<td></td>
</tr>
<tr>
<td>Prior MI</td>
<td>3 (38)</td>
<td></td>
</tr>
<tr>
<td>Prior PCI</td>
<td>1 (13)</td>
<td></td>
</tr>
<tr>
<td>Prior CABG</td>
<td>2 (25)</td>
<td></td>
</tr>
<tr>
<td>Prior CTA</td>
<td>1 (13)</td>
<td></td>
</tr>
<tr>
<td>COPD</td>
<td>3 (38)</td>
<td></td>
</tr>
<tr>
<td>Peripheral arterial disease</td>
<td>3 (38)</td>
<td></td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>1 (13)</td>
<td></td>
</tr>
<tr>
<td>Heart failure</td>
<td>6 (75)</td>
<td></td>
</tr>
<tr>
<td>Severe valvular disease</td>
<td>1 (13)</td>
<td></td>
</tr>
<tr>
<td>Ejection fraction – mean ± SD</td>
<td>29.8 ±19.6</td>
<td></td>
</tr>
<tr>
<td>STS risk score for mortality – mean ± SD</td>
<td>5.4 ± 3.5</td>
<td></td>
</tr>
<tr>
<td>Indication for revascularization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stable angina</td>
<td>2 (25)</td>
<td></td>
</tr>
<tr>
<td>Unstable angina</td>
<td>1 (13)</td>
<td></td>
</tr>
<tr>
<td>NSTEMI</td>
<td>2 (25)</td>
<td></td>
</tr>
<tr>
<td>STEMI</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Cardiomyopathy/heart failure</td>
<td>5 (63)</td>
<td></td>
</tr>
</tbody>
</table>

1 hematoma (insignificant)
1 major vascular complication
Mean hospital stay: 7 ± 3.7 days
Decannulations: 5 surgical, 3 percutaneous
Successful weaning in all
No MACCE in-hospital and at 30 days
1-year f/up in 5 patients: no MACCE
Conclusions:
ECMO can be successfully used for hemodynamic support during high-risk PCI

Knowledge gaps
- Exact size of CHIP population?
- No trial comparing PCI and GDMT in this population
- High surgical risk patients: is PCI as good as CABG?
- No risk models to calculate differential risk of PCI vs. GDMT
- Futility?

Future directions

1. Standardized criteria to define high-risk PCI
   - ACC/AHA/SCAI guidelines
2. No longer about which device but which patient
3. Forming a multicenter registry tracking outcomes
4. Registries → prelim database → formalized prospective studies (even RCTs)
5. Registries: use to create an accurate risk model


One does not simply
End a presentation with a good slide!
Thank you!