DEBATE: Impella vs IABP
For High-Risk PCI

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For High-Risk PCI

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What is a debate?

- Contention in argument; strife, dissention, quarrelling, controversy
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My plan...

- Tell you about Impella
- Top 5 reasons why Dr Low doesn’t like Impella.
What is an Impella
Impella

- Nonpulsatile axial flow
- Three versions
  - 12F – Impella 2.5 (2.5 L/min)
  - 14F – Impella CP (3-4 L/min)
  - 21F – Impella 5.0 (5L/min)
- Benefits
  - Does not require timing/trigger
  - Stable during transient arrhythmias
- Negatives
  - Ventricular arrhythmias not well tolerated ??
  - Larger bore than IABP
Impella

- **Hemodynamic effects**
  - Unload LV – Increasing forward flow
  - Reduced myocardial oxygen demand
  - Improved MAP
  - Reduced PCWP

- **Contraindications?**
  - Mechanical AV
  - LV thrombus
  - ? AS and AI (? Relative contraindications)
  - PAD
  - Systemic anticoagulation intolerance
Impella

- Complications:
  - Vascular Injury
  - Hemolysis
    - 5-10% in first 24h. Reposition.
  - Thrombocytopenia
Dr Low’s Top 5 Reasons NOT to use Impella

- “It’s no better than IABP for high risk PCI”
- “It costs too much”
- “It takes too long to put in”
- “Too many vascular problems with Impella.”
  - “IABP never causes vascular problems”
- “Impella is for the weak.”
REASON 1:

“It’s no better than IABP for High Risk PCI”
Elective Intra-aortic Balloon Counterpulsation During High-Risk Percutaneous Coronary Intervention
A Randomized Controlled Trial

No planned IABP
Elective IABP

Cumulative Mortality, %

Follow-up, mo

Log-rank P = .33

No. at risk

<table>
<thead>
<tr>
<th>No planned IABP</th>
<th>150</th>
<th>147</th>
<th>144</th>
<th>141</th>
<th>140</th>
<th>140</th>
<th>0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elective IABP</td>
<td>151</td>
<td>146</td>
<td>146</td>
<td>146</td>
<td>145</td>
<td>144</td>
<td>0</td>
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Long-Term Mortality Data From the Balloon Pump–Assisted Coronary Intervention Study (BCIS-1)
A Randomized, Controlled Trial of Elective Balloon Counterpulsation During High-Risk Percutaneous Coronary Intervention

Cumulative Mortality Estimates by Treatment Assignment

Number at risk:
- No planned IABP: 150
- Planned IABP: 161

Time (years):
- 0
- 1
- 2
- 3
- 4
- 5

Cumulative Mortality (%):
- 0
- 10
- 20
- 30
- 40
- 50
- 60

p = 0.039
PROTECT II Study Flow

Assessed for Eligibility
N=1082

Randomized Intent-to-Treat
N=447

Per Protocol population= Patients that met all inclusion and exclusion criteria.
Per Protocol population was pre-specified and patients were identified prospectively prior to the statistical analysis.

Intent-To-Treat (ITT) population (N=447)

IABP
N= 223
90day F/U, N=220

IMPELLA
N= 224
90day F/U, N=222

Not Eligible: N=635
47.8% Met Exclusion criteria
30% Patient refusal, MD decision
13% Unknown
9.2% Referred for CABG

Randomized Intent-to-Treat N=447

IABP
30day N= 211
90day F/U, N=210

IMPELLA
30day N= 215
90day F/U, N=213

Not Eligible: N=635
47.8% Met Exclusion criteria
30% Patient refusal, MD decision
13% Unknown
9.2% Referred for CABG

Per Protocol (PP) population (N=426)

IABP
N= 211
90day F/U, N=210

IMPELLA
N= 215
90day F/U, N=213
PROTECT II Outcome** (PP)

MACCE = Death/Stroke or TIA/MI/Repeat Revascularization

**Using x8ULN for biomarkers or Q-wave for Peri-procedural MI (Stone et al Circulation 2001;104:642-647) and 2xULN for Spontaneous MI (Universal MI definition)

p=0.037
↓ 38% MACCE

N=213
N=210

p=0.038
↓ 29% MACCE

N=210
N=213

p=0.595

N=215
N=211

In-hospital MACCE

Post-Discharge MACCE

Total 90 days MACCE
PROTECT II MACCE**
Per Protocol Population, N=426

Death, Stroke, MI, Repeat revasc.

Log rank test, p=0.04

**Using x8ULN threshold for biomarkers or Q-wave for Peri-procedural MI (Stone et al Circulation 2001;104:642-647) and 2xULN threshold for biomarkers for Spontaneous MI (Universal MI definition)
REASON 1:

“IT’S NO BETTER THAN IABP FOR HIGH RISK PCI”

PROTECT II. IMPELLA > IABP
REASON 2:

“IT COSTS TOO MUCH”
Protect II Economic Study
Hospital Charges Per Patient at 90 Days

All Patients
$19k Savings*

Survivors Only
$22k Savings*

Device Cost
$19k Difference

IABP | Impella
---|---
164,929 | 145,679
↓12% Reduction

IABP | Impella
---|---
156,023 | 133,958
↓16% Reduction

IABP | Impella
---|---
800 | 20,000

Impella Savings Driven by:
- 47% Reduction in repeat revascularization at 90 days
- 67% Lower charges per readmission vs. IABP

* All Per Protocol patients with Billing claim forms and data extrapolation N=249, Device expense added back in.
** Additional patients may be added in the future to the economic report
***Analysis reported by Presscott Associates, Ltd
REASON 2:

"IT COSTS TOO MUCH": SHORT TERM YES
LONG TERM, MAYBE NOT
REASON 3:

“It takes too long to put in”
LEARNING CURVE

Awareness

Unconscious

Incompetence

Competence

Conscious

Competence

1

2

3

4

B

A
REASON 3:

“IT TAKES TOO LONG TO PUT IN”

WE JUST NEED TO PRACTICE MORE!!!
REASON 4:

“TOO MANY VASCULAR PROBLEMS WITH IMPELLA.”
“IABP NEVER CAUSES VASCULAR PROBLEMS”
70 yo with inferior STEMI
70 yo with inferior STEMI
On HD 3, RNs call noting blood in the gas line
Attending and fellow at bedside immediately
The IABP is retracted and just before the entire system is retracted, resistance is appreciated
Additional force applied in retracting IABP
Despite 30 minutes of manual pressure, continued bleeding from access site.

The patient is transferred urgently to the cath lab.
70 yo with inferior STEMI
REASON 4:

“TOO MANY VASCULAR PROBLEMS WITH IMPELLA.”
“IABP NEVER CAUSES VASCULAR PROBLEMS”

BOTH CAN CAUSE VASCULAR PROBLEMS. METICULOUS TECHNIQUE AND ASSESSMENT OF PAD PRIOR TO INSERTION OF ANY DEVICE.
REASON 5:

“IMPELLA IS FOR THE WEAK”
Impella is NOT for every patient

- **Patient Factors**
  - Age
  - EF
  - Renal Function
  - PAD

- **Anatomic Factors**
  - UPLM
  - Single remaining vessel
  - Calcification

- **Operator Experience/Competence**
Assessing PCI Risk

Anatomy Complexity vs. Patient Complexity

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Assessing PCI Risk

Anatomy Complexity

Patient Complexity

High Risk Anatomy
Low Risk Patient
High Risk Anatomy
High Risk Patient

Low Risk Anatomy
High Risk Patient
Assessing PCI Risk

Anatomy Complexity vs Patient Complexity

- High Risk Anatomy
- Low Risk Patient
- Low Risk Anatomy
- High Risk Patient

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Assessing PCI Risk

Anatomy Complexity vs Patient Complexity

- High Risk Anatomy
- Low Risk Anatomy
- High Risk Patient
- Low Risk Patient
85 yo, angina, HTN, MVD, hybernating myocardium
85 yo, angina, HTN, MVD, hybernating myocardium
Assessing PCI Risk

Patient Complexity

Anatomy Complexity

High Risk Anatomy
Low Risk Patient

High Risk Anatomy
High Risk Patient

Low Risk Anatomy
High Risk Patient

Low Risk Anatomy
High Risk Patient
85 yo, angina, HTN, MVD, hybernating myocardium
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75 yo, Class III angina, on max med therapy.
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- SBP 80
- HR 70
- SpO2 100%
- mRA 10
- PA 50/25
- mWP 23
Assessing PCI Risk

Anatomy Complexity

Patient Complexity

High Risk Anatomy
Low Risk Patient

High Risk Anatomy
High Risk Patient

Low Risk Anatomy
High Risk Patient
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REASON 5: "IMPELLA IS FOR THE WEAK"

IMPELLA IS NOT FOR EVERY PATIENT AND NOT FOR EVERY CASE.
MUST ASSESS MD COMFORT/EXPERIENCE, PATIENT AND ANATOMIC COMPLEXITY
What is a debate?

- Contention in argument; strife, dissention, quarrelling, controversy
University of California Davis Medical Center

THANK YOU