IntraAortic Balloon Pump (IABP): Indication For and Beyond Cardiogenic Shock

Dr Aaron Wong
Senior Consultant
National Heart Centre
Singapore
Introduction

- IABP - one of the most effective and frequently used mechanical circulatory support
- It relies on the twin concept of diastolic augmentation and afterload reduction to facilitate the functioning of an ischemic and failing myocardium
- The concept was proposed by Moulopoulos et al in 1962, first clinical report of human use in 1968 by Kantrowitz
- Although experience technological evolution, the design and function has not changed substantially during the past 40 years
What is IAPB?

- Intravascular catheter mounted counterpulsation device with a balloon volume of 30 to 40 ml using helium gas
- A central lumen allows passage of the balloon catheter over a guidewire and monitoring of central aortic blood pressure
- Attached to a small bed-side console and triggered to the pts ECG, arterial pressure curve or pacing spikes
- New technology using fibre-optic in IABP catheter with in vivo auto-calibration to detect flow in proximal aorta and thus tracking the LV ejection and time the counterpulsation more accuracy even in pts with rapid or irregular heart rate
IAPB in the 70s and now
IABP Kit Contents

- Introducer needle
- Guide wire
- Vessel dilators
- Sheath
- IABP (34 or 40cc)
- Gas tubing
- 60-mL syringe
- Three-way stopcock
- Arterial pressure tubing (not in kit)
The IAB should be selected according to the following chart (chart located on every box)

Clinical Reference Sizing Chart

- **50 cc** Approx. Height – Over 6' (183 cm)
- **40 cc** Approx. Height – From 5'4" - 6' (163 cm - 183 cm)
- **34 cc** Approx. Height – From 5'-5'4" (152 cm - 163 cm)
- **25 cc** Approx. Height – Less than 5' (152 cm)
IABP in Action
How does IABP work?

- Position on the descending thoracic aorta distal to left subclavian artery
- Set to inflate at the dicrotic notch (diastolic) therefore displacing a volume of blood to proximal aorta causes a rise in aortic root pressure which augments coronary blood flow and myocardial O2 supply
- It rapid deflation during the iso-volumetric phase of LV contraction creates a vacuum reducing the after load and myocardial O2 consumption
Three goals achieved by IABP:

1. An improvement in myocardial oxygen delivery via an increased in coronary perfusion pressure
2. A reduction in cardiac work by a decrease in systolic blood pressure (afterload)
3. An improvement in forward blood flow in patients with impaired cardiac contractile function
### Effect of IABP on Hemodynamic Parameters

<table>
<thead>
<tr>
<th>Hemodynamic Parameter</th>
<th>Effect</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic systolic pressure</td>
<td>Decrease</td>
<td>20</td>
</tr>
<tr>
<td>Aortic diastolic pressure</td>
<td>Increase</td>
<td>30</td>
</tr>
<tr>
<td>Mean aortic pressure</td>
<td>Increase</td>
<td></td>
</tr>
<tr>
<td>Left ventricular afterload</td>
<td>Decrease</td>
<td></td>
</tr>
<tr>
<td>Mean PCWP</td>
<td>Decrease</td>
<td>20</td>
</tr>
<tr>
<td>Cardiac output</td>
<td>Increase</td>
<td>20</td>
</tr>
<tr>
<td>LVEF</td>
<td>Increase</td>
<td></td>
</tr>
<tr>
<td>Heart Rate</td>
<td>Decrease</td>
<td>20</td>
</tr>
<tr>
<td>Diastolic pressure-time index (DPTI)</td>
<td>Increase</td>
<td></td>
</tr>
<tr>
<td>Tension-time index (TTI)</td>
<td>Decrease</td>
<td></td>
</tr>
<tr>
<td>Endocardial viability ratio (DPTI/TTI)</td>
<td>Increase</td>
<td></td>
</tr>
</tbody>
</table>
Timing of IABP Counterpulsation

- Timing of balloon counterpulsation to the mechanical events of the cardiac cycle is crucial to derive optimal haemodynamic benefits
- Maximize diastolic augmentation: inflate balloon at end-systole immediately after closure of aortic valve

**FIGURE 31-1** Timing of balloon inflation is adjusted to obliterate the dicrotic notch (n) on radial artery pressure curve.
Timing of IABP Counterpulsation

- Maximize afterload reduction: besting timing of balloon deflation less well defined but have to be before LV ejection
- However, peak systolic pressure is directly related to ventricular wall stress and related to myocardial consumption
Contraindications of IABP use

Absolute Contraindications
- Occlusion or severe stenosis of distal aorta
- Aortic aneurysm
- Aortic dissection
- Severe aortic regurgitation

Relative Contraindications
- Severe peripheral vascular disease
- Aortic or iliofemoral bypass grafts
- Contraindication to intravenous anticoagulation
- Moderate aortic regurgitation
- Sustained tachyarrhythmias (with ventricular rate >160 beats/min)
Practical issues for IABP use

- Access: femoral, axillary or brachial artery
- Femoral artery with best palpable pulsation
- Previous 11Fr via cutdown but now 8Fr percutaneously using guidewire thus minimizes vascular complications
- IABP positioning: fluoroscopy and daily chest X-ray
- Assist ratio: usually 1:1 augmentation but 1:2 if HR>120 or for weaning
- IABP timing adjustment: Use 1:2 assist ratio
- Need for anticoagulation not conclusive but preferred if no contraindication, use >24 hr or lesser assist ratio
- Gradual weaning: either reduction in assist ratio or balloon volume
Complications

- Benchmark Registry (n=17000) major complications (limb ischaemia, severe bleeding, balloon leak and device-relate death) occurred in 2.6% and 0.5% device related death
- Vascular complication occur in 6 to 25% of cases which includes limb ischaemia, arterial trauma and bleeding
- Others: mal-position of balloon catheter, balloon rupture (0.5 to 6%), gas embolism, catheter fracture, balloon entrapment (0.3 to 0.5%), infections
- The presence of PVD (claudication, bruit or absent pulses) is the most consistent and reproducible predictor of complications
Indications for the IABP

1. Complicated acute myocardial infarction
2. Cardiogenic shock
3. Refractory unstable angina
4. Severe CAD with hemodynamic compromise
5. Mechanical complications of AMI
6. Support of high risk coronary intervention
7. Stabilization of left main disease
8. Induction and weaning of cardiopulmonary bypass
9. Bridge to cardiac transplantation
10. Refractory arrhythmias
11. Surgery for high risk cardiovascular patients
Benchmark Registry: IABP in clinical Practice

- First large computerize data base for pts receiving IABP (N=22,663)
- June 96-August 2000
- 203 Hospitals (90%US)
- 16909 patient case records
- Verified by external audit

Ferguson et al. J Am Coll Cardiol 2001; 38:1456
# Benchmark Registry: Indication

<table>
<thead>
<tr>
<th>Indication</th>
<th>Total Population (n = 16,909)</th>
<th>Diagnostic Catheterization Only (n = 1,576)</th>
<th>Catheterization and PCI Only (n = 3,882)</th>
<th>Surgery CABG (n = 9,179)</th>
<th>Surgery Non-CABG (n = 1,086)</th>
<th>No Intervention or Revascularization Noted (n = 1,186)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Support and stabilization (%)</td>
<td>20.6</td>
<td>21.4</td>
<td>54.4</td>
<td>9.7</td>
<td>5.0</td>
<td>7.8</td>
</tr>
<tr>
<td>Cardiogenic shock (%)</td>
<td>18.8</td>
<td>33.1</td>
<td>23.7</td>
<td>12.3</td>
<td>23.8</td>
<td>29.4</td>
</tr>
<tr>
<td>Weaning from cardiopulmonary bypass (%)</td>
<td>16.1</td>
<td>0.4</td>
<td>0.1</td>
<td>24.9</td>
<td>31.4</td>
<td>7.1</td>
</tr>
<tr>
<td>Preop: high risk CABG (%)</td>
<td>13.0</td>
<td>4.6</td>
<td>0.2</td>
<td>22.1</td>
<td>6.4</td>
<td>1.9</td>
</tr>
<tr>
<td>Refractory unstable angina (%)</td>
<td>12.3</td>
<td>15.3</td>
<td>8.3</td>
<td>15.8</td>
<td>2.2</td>
<td>3.0</td>
</tr>
<tr>
<td>Refractory ventricular failure (%)</td>
<td>6.5</td>
<td>9.1</td>
<td>2.5</td>
<td>5.9</td>
<td>15.7</td>
<td>12.7</td>
</tr>
<tr>
<td>Mechanical complication due to AMI (%)</td>
<td>5.5</td>
<td>9.8</td>
<td>7.0</td>
<td>4.2</td>
<td>5.2</td>
<td>5.1</td>
</tr>
<tr>
<td>Ischemia related to intractable VA (%)</td>
<td>1.7</td>
<td>1.6</td>
<td>1.5</td>
<td>1.9</td>
<td>1.7</td>
<td>1.6</td>
</tr>
<tr>
<td>Cardiac support for high risk general surgery patients (%)</td>
<td>0.9</td>
<td>2.1</td>
<td>0.2</td>
<td>0.5</td>
<td>4.3</td>
<td>1.1</td>
</tr>
<tr>
<td>Other (%)</td>
<td>0.8</td>
<td>0.7</td>
<td>0.2</td>
<td>0.8</td>
<td>2.5</td>
<td>2.0</td>
</tr>
<tr>
<td>Intraoperative pulsatile flow (%)</td>
<td>0.4</td>
<td>0.1</td>
<td>0.1</td>
<td>0.7</td>
<td>0.5</td>
<td>0.2</td>
</tr>
<tr>
<td>Missing indication (%)</td>
<td>3.3</td>
<td>1.8</td>
<td>1.9</td>
<td>1.2</td>
<td>1.5</td>
<td>28.1</td>
</tr>
</tbody>
</table>

AMI = acute myocardial infarction; CABG = coronary artery bypass graft; PCI = percutaneous coronary intervention; VA = ventricular arrhythmias.

Ferguson et al. J Am Coll Cardiol 2001; 38:1456
### Benchmark Registry: Complications

<table>
<thead>
<tr>
<th></th>
<th>Total Population (n = 16,909)</th>
<th>Diagnostic Catheterization Only (n = 1,576)</th>
<th>Catheterization and PCI Only (n = 3,882)</th>
<th>Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CABG (n = 9,179)</td>
</tr>
<tr>
<td>In-hospital mortality (%)</td>
<td>21.2</td>
<td>32.2</td>
<td>18.4</td>
<td>16.8</td>
</tr>
<tr>
<td>Mortality—balloon in place (%)</td>
<td>11.6</td>
<td>17.6</td>
<td>10.1</td>
<td>9.2</td>
</tr>
<tr>
<td>IABP-related mortality* (%)</td>
<td>0.05</td>
<td>0.1</td>
<td>0.1</td>
<td>0.0</td>
</tr>
<tr>
<td>Amputation†</td>
<td>0.1</td>
<td>0.0</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>Major limb ischemia‡ (%)</td>
<td>0.9</td>
<td>0.6</td>
<td>0.5</td>
<td>1.2</td>
</tr>
<tr>
<td>Any limb ischemia (%)</td>
<td>2.9</td>
<td>3.2</td>
<td>1.9</td>
<td>3.5</td>
</tr>
<tr>
<td>Severe access site bleeding (%)</td>
<td>0.8</td>
<td>0.8</td>
<td>1.2</td>
<td>0.7</td>
</tr>
<tr>
<td>Any access site bleeding (%)</td>
<td>2.4</td>
<td>2.7</td>
<td>4.4</td>
<td>1.7</td>
</tr>
<tr>
<td>Balloon leak (%)</td>
<td>1.0</td>
<td>0.9</td>
<td>0.8</td>
<td>1.1</td>
</tr>
<tr>
<td>Composite outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major IABP complication§ (%)</td>
<td>2.8</td>
<td>2.8</td>
<td>2.2</td>
<td>3.0</td>
</tr>
<tr>
<td>Any IABP complication‖ (%)</td>
<td>7.0</td>
<td>7.6</td>
<td>7.5</td>
<td>7.1</td>
</tr>
<tr>
<td>Any unsuccessful IABP¶ (%)</td>
<td>2.3</td>
<td>2.5</td>
<td>1.7</td>
<td>2.5</td>
</tr>
</tbody>
</table>

*Death as direct consequence of IABP therapy. †All major limb ischemia. ‡Loss of pulse or sensation, abnormal limb temperature or pallor, requiring surgical intervention. §Balloon leak, severe bleeding, major limb ischemia or death as a direct consequence of IABP therapy. ‖Any access site bleeding, any limb ischemia, balloon leak, poor inflation, poor augmentation, insertion difficulty or death as direct result of IABP therapy. ¶Balloon leak, poor inflation, poor augmentation or insertion difficulty.

CABG = coronary artery bypass graft; IABP = intra-aortic balloon pump; PCI = percutaneous coronary intervention.

Ferguson et al. J Am Coll Cardiol 2001; 38:1456
Benchmark Registry: Risk Factor for Major Complications

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Estimated Odds Ratio (Presence/Absence)</th>
<th>95% Confidence Limits</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PVD</td>
<td>1.968</td>
<td>1.557, 2.487</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Female</td>
<td>1.737</td>
<td>1.414, 2.134</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>BSA &lt;1.65 m²</td>
<td>1.453</td>
<td>1.095, 1.926</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Age ≥75 yrs</td>
<td>1.289</td>
<td>1.048, 1.585</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>

BSA = body surface area; IABP = intra-aortic balloon pump; PVD = peripheral vascular disease.

Ferguson et al. J Am Coll Cardiol 2001; 38:1456
High Risk PCI

- Hemodynamic support and increase coronary perfusion provided by IABP may be of benefit for high risk pts (low EF, multi-vessel disease, left main stenosis and hemodynamic instability) undergoing PCI
- There is also supporting data for use of IABP before emergency CABG after coronary angiography (Alcan 1983)
- IABP in pts with failed PCI underwent eCABG had lower post-op MI (20% vs. 33%) (Murphy 1984)
- Briguori et al (2003) compared elective pre-procedural placement vs. standby IABP in 133 pts underwent high risk PCI
- In pts with low EF, MACE (AMI, shock, stroke, eCABG, or death) was 0% vs. 17% (p=0.001), respectively
Balloon-Pump Assisted Coronary Intervention Study (BCIS-1)

- First randomized controlled trial to assess the efficacy and safety of elective IABP use in patients undergoing high-risk PCI

Objectives:
To compare the efficacy and safety of elective Intra-Aortic Balloon Pump (IABP) insertion prior to high-risk PCI vs. conventional treatment (with no planned IABP use)

Structure:
- Prospective, open, randomized trial
- 17 UK centres
- n=300 (150 in each arm)

Sample Size = 274 pts (predicted MACCE 5% vs. 15%, β=80%, α= 5%)

Perera et al. JAMA. 2010;304(8):867-874
Balloon-Pump Assisted Coronary Intervention Study (BCIS-1)

LVEF ≤ 30%
- Jeopardy Score ≥ 8

Randomize

Elective IABP Insertion

No Planned IABP

PCI

Remove IABP 4-24 hrs after PCI

Hospital Follow-up
To discharge or 28 days

6 month follow-up
Balloon-Pump Assisted Coronary Intervention Study (BCIS-1)

Primary Outcome Measure

Major Adverse Cardiovascular or Cerebral Events (MACCE) at hospital discharge or 28 days (whichever is sooner), including

- All-Cause Death
- Acute MI
- Further revascularization by PCI or CABG
- CVA
Balloon-Pump Assisted Coronary Intervention Study (BCIS-1)

- Inclusion Criteria
  - Impaired LV function \((\text{EF} \leq 30\%)\)
  - Extensive Myocardium at Risk
    - BCIS-1 Jeopardy Score \(\geq 8\)
    - or...Target vessel supplying occluded vessel which supplies >40% of myocardium
Balloon-Pump Assisted Coronary Intervention Study (BCIS-1)

- Jeopardy Score

6 Major Coronary Segments

2 points for each lesion + 2 for each territory distal to lesion

Negative points for functioning grafts

Allows LM and Graft Classification
Balloon-Pump Assisted Coronary Intervention Study (BCIS-1)

- **Inclusion Characteristic**

<table>
<thead>
<tr>
<th></th>
<th>IABP (N=151)</th>
<th>No Planned (N=150)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean E.F. (SD)</strong></td>
<td>23.6 (5.2)</td>
<td>23.6 (5.2)</td>
</tr>
<tr>
<td><strong>BCIS-1 Jeopardy Score</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Mean (SD)</em></td>
<td>10.38 (1.71)</td>
<td>10.32 (1.72)</td>
</tr>
<tr>
<td>8</td>
<td>40 (26.5%)</td>
<td>42 (28%)</td>
</tr>
<tr>
<td>10</td>
<td>39 (25.8%)</td>
<td>39 (26%)</td>
</tr>
<tr>
<td>12</td>
<td>71 (47%)</td>
<td>68 (45.3%)</td>
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</table>
Balloon-Pump Assisted Coronary Intervention Study (BCIS-1)

- Procedure details

<table>
<thead>
<tr>
<th></th>
<th>IABP</th>
<th>No Planned</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Elective</strong></td>
<td>70 (46%)</td>
<td>65 (43%)</td>
</tr>
<tr>
<td><strong>Urgent/ Emergency</strong></td>
<td>81 (53%)</td>
<td>85 (57%)</td>
</tr>
<tr>
<td>Lesions attempted</td>
<td>323</td>
<td>305</td>
</tr>
<tr>
<td>Lesions successfully revasc</td>
<td>94.7%</td>
<td>94.1%</td>
</tr>
<tr>
<td>Mean lesions per patient</td>
<td>2.15</td>
<td>2.05</td>
</tr>
<tr>
<td>Mean stents per patient</td>
<td>2.56</td>
<td>2.31</td>
</tr>
<tr>
<td>GP2b3a use</td>
<td>39.3%</td>
<td>43.3%</td>
</tr>
</tbody>
</table>
Balloon-Pump Assisted Coronary Intervention Study (BCIS-1)

- **Trial Outcomes**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Elective IABP (n = 151)</th>
<th>No Planned IABP (n = 150)</th>
<th>OR (95% CI)a</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary end point</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>MACCEb</td>
<td>23 (15.2)</td>
<td>24 (16.0)</td>
<td>0.94 (0.51-1.76)</td>
<td>.85</td>
</tr>
<tr>
<td>MI</td>
<td>19 (12.6)</td>
<td>20 (13.3)</td>
<td>0.93 (0.48-1.83)</td>
<td>.85</td>
</tr>
<tr>
<td>Death</td>
<td>3 (2.0)</td>
<td>1 (0.7)</td>
<td>3.02 (0.31-29.37)</td>
<td>.34</td>
</tr>
<tr>
<td>CVA</td>
<td>2 (1.3)</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Further revascularization</td>
<td>1 (0.7)</td>
<td>4 (2.7)</td>
<td>0.24 (0.03-2.20)</td>
<td>.21</td>
</tr>
<tr>
<td>Secondary end points</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6-mo mortality</td>
<td>7 (4.6)</td>
<td>11 (7.4)c</td>
<td>0.61 (0.24-1.62)</td>
<td>.32</td>
</tr>
<tr>
<td>Bleeding</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>29 (19.2)</td>
<td>17 (11.3)</td>
<td>1.86 (0.93-3.79)</td>
<td>.06</td>
</tr>
<tr>
<td>Major</td>
<td>5 (3.3)</td>
<td>6 (4.0)</td>
<td>0.83 (0.20-3.36)</td>
<td>.77</td>
</tr>
<tr>
<td>Minor</td>
<td>24 (15.9)</td>
<td>11 (7.3)</td>
<td>2.39 (1.07-5.61)</td>
<td>.02</td>
</tr>
<tr>
<td>Procedural complications</td>
<td>2 (1.3)</td>
<td>16 (10.7)</td>
<td>0.11 (0.01-0.49)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Access-site complications</td>
<td>5 (3.3)</td>
<td>0</td>
<td></td>
<td>.06d</td>
</tr>
</tbody>
</table>
Balloon-Pump Assisted Coronary Intervention Study (BCIS-1)

- The study did not demonstrate a difference in MACCE at hospital discharge and therefore does not support routine elective IABP insertion before high-risk PCI.
- However, 12% of patients who underwent PCI without elective IABP insertion required rescue IABP support, which highlights the importance of adopting a standby IABP strategy when undertaking high-risk PCI.
- Reasons for neutral trials:
  - Advance in PCI techniques (e.g. stents)
  - Limitation of Jeopardy Score (no lesion characteristic, viability)
  - Not powered enough to detect smaller differences (<10%)
- Decision for IABP in high risk PCI still remains a judgment call.
Balloon-Pump Assisted Coronary Intervention Study (BCIS-1)

- Cumulative mortality curve at 6 month
Acute coronary syndromes

Unstable angina/NSTEMI

- Very few data, mainly confined to small observational retrospective studies
- Gold et al (1973) reported 9 of 11 pts with refractory angina had symptomatic improvement after IABP placement
- Fuchs et al (1983) reported 7 pts with >90% proximal LAD disease and unstable angina had improved symptoms and coronary flow (based on coronary Doppler) with the use of IABP prior PCI
- Despite small sample sizes, these support the use of IABP in pts with refractory symptoms until destination therapy
- ACC/AHA give this a Class IIa indication, before or after coronary angiography
Acute coronary syndromes

STEMI

- IABP has been tested as an adjunct and support device in the setting of thrombolytic therapy, primary PCI and rescue PCI
- Benefits resulted from multiple factors: increased recovery of ischemic myocardium, decrease arterial reo-cclusion, enhanced lysis of thrombus, higher flow within the coronary artery
- Ohman et al (1994) found less recurrent ischemia, fewer repeat ePCI, lesser rate of IRA re-occlusion (8 vs. 25%, p<0.03) and lower overall MACE (13 vs. 24%, p<0.4) at 5 days in pts (n=182) randomized to IABP
Acute coronary syndromes

- **PAMI-2 Trial (1995)** classified into high and low risk cohorts
  - High risk: >70, LVEF <45%, presence of TVD, suboptimal PCI result, vein graft occlusion, and occurrence of dysrhythmia
  - High risk cohort were randomized to PCI with either IABP or standard care
  - The use of IABP was associated with fewer ischemic events, repeat interventions, reinfarctions, and less decompensated heart failure
  - No benefit of IABP was observed in low risk cohort who received PCI

- **Van’t Hof et al (1999)** found no difference after randomized post primary PCI pts (n=284) into IABP or standard care but there was 25% crossover rate to treatment arm

- **Brodie et al (1999)** with a registry of 1490 pts with AMI treated with primary PCI showed that the use of IABP before PCI was an independent predictor of lower peri-procedural complications
Acute coronary syndromes

- Although only a few randomized studies, these consistently indicates IABP in the setting of STEMI is associated with a decrease incidence of ischemic events without excessive vascular or hemorrhagic complications.
- The current ACC/AHA guidelines state a Class I indication for IABP in STEMI associated with the following sequelae:
  - Recurrent postinfarction angina
  - Reinfarction
  - Mechanical complications of AMI (ventricular septal rupture, acute MR)
## Cardiogenic Shock in AMI - Causes

<table>
<thead>
<tr>
<th>Causes</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-MI LV failure</td>
<td>85%</td>
</tr>
<tr>
<td>STEMIs</td>
<td>≈70%</td>
</tr>
<tr>
<td>NSTEMIs</td>
<td>≈15%</td>
</tr>
<tr>
<td>RV MI</td>
<td>3% - 4%</td>
</tr>
<tr>
<td>Severe MR</td>
<td>7% - 8%</td>
</tr>
<tr>
<td>Post-MI-VSD</td>
<td>3% - 4%</td>
</tr>
<tr>
<td>Free wall rupture/</td>
<td>2% - 3%</td>
</tr>
<tr>
<td>tamponade</td>
<td></td>
</tr>
</tbody>
</table>

*Shock Trial Registry*
Cardiogenic Shock – Causes

- Myopathic
  - AMI
  - Dilated cardiomyopathy
  - Myocardial depression in septic shock
- Mechanical
  - Mitral regurgitation
  - Ventricular septal defect
  - Ventricular aneurysm
  - Left ventricular tract obstruction (aortic stenosis, hypertrophic cardiomyopathy)
- Arrhythmic
- Extra-cardiac Obstructive
  - Pericardial tamponade
  - Pulmonary embolism
  - Severe pulmonary hypertension
Cardiogenic Shock

- CS occurs in 5 to 10% of pts with STEMI and is associated with high mortality
- 30-day mortality for pts with CS in the GUSTO-1 treated with thrombolytic therapy was 58%
- In the interventional era, the mortality rate of CS still remains 50 to 80%
- In the pre-thombolytic era, IABP did not show benefit in pts with CS in 2 randomized trials (*O’Rouke 1981 and Flaherty 1985*)
- Since the advent of thrombolysis, several observational studies supported potential benefit
- In a subgroup analysis in 200 pts with CS in the Duke Cardiovascular Databank by *Bengston et al (1992)*, lower mortality was noted when IABP was used in conjunction with PCI vs. IABP alone
Cardiogenic Shock

- In **GUSTO-1 (1995)**, 7% (2,972) of pts had CS and IABP was used in 734 pts with a trend towards decreased mortality at 30 days (47% vs. 60%, p=0.06)
- **International Shock Registry (Hochman 1995)** enrolled 251 pts with CS and found unadjusted mortality to be lower in the 173 pts treated with IABP (57% vs. 72%, p=0.039)
- **SHOCK Trial Registry (Sanborn 2000)** looked at 856 pts with LV heart failure and CS, found pts did better with revascularization and IABP when compared with medical management alone (47% vs. 77%, p<0.0001)
- In **NRMI-2 Registry (Chen 2003)** with n=23,138, 31% of CS was treated with IABP and a substantial mortality benefit (49% vs. 67%) was seen when IABP was used in conjunction with reperfusion therapy, especially thrombolysis
- There was lower overall mortality in pts underwent primary PCI but not influenced by the use of IABP (45% vs. 47%)
Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock (SHOCK) Trial

- N=302 with CS were randomized to received initial emergent revascularization (ERV) vs. initial medical stabilization (IMS)
- IABP was placed in 86% of pts

(Hochman et al 1999)

<table>
<thead>
<tr>
<th>OUTCOME AND SUBGROUP</th>
<th>REvascularization</th>
<th>MEDical Therapy</th>
<th>DIFFERENCE BETWEEN GROUPS (95% CI)</th>
<th>RELATIVE RISK (95% CI)</th>
<th>P VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>percent (number in subgroup)</td>
<td>percent</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-day mortality</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>46.7 (152)</td>
<td>56.0 (150)</td>
<td>-9.3 (-20.5 to 1.9)</td>
<td>0.83 (0.67 to 1.04)</td>
<td>0.11</td>
</tr>
<tr>
<td>Age &lt;75 yr</td>
<td>41.4 (128)</td>
<td>56.8 (118)</td>
<td>-15.4 (-27.8 to -3.0)</td>
<td>0.73 (0.56 to 0.95)</td>
<td>0.01†</td>
</tr>
<tr>
<td>Age ≥75 yr</td>
<td>75.0 (24)</td>
<td>53.1 (32)</td>
<td>+21.9 (-2.6 to 46.4)</td>
<td>1.41 (0.95 to 2.11)</td>
<td></td>
</tr>
<tr>
<td>6-mo mortality‡</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>50.3 (151)</td>
<td>63.1 (149)</td>
<td>-12.8 (-23.2 to -0.9)</td>
<td>0.80 (0.65 to 0.98)</td>
<td>0.027†</td>
</tr>
<tr>
<td>Age &lt;75 yr</td>
<td>44.9 (127)</td>
<td>65.0 (117)</td>
<td>-20.1 (-31.6 to -7.1)</td>
<td>0.70 (0.56 to 0.89)</td>
<td>0.003†</td>
</tr>
<tr>
<td>Age ≥75 yr</td>
<td>79.2 (24)</td>
<td>56.3 (32)</td>
<td>+22.9 (0.7 to 46.6)</td>
<td>1.41 (0.97 to 2.03)</td>
<td></td>
</tr>
</tbody>
</table>
Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock (SHOCK) Trial
Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock (SHOCK) Trial

All Patients

Proportion Alive

Log-Rank $P = .03$

Early Revascularization

Initial Medical Stabilization

Years Since Randomization

No. at Risk

ERV 152
IMS 150

56 42 33 18 3
38 29 18 9 2
Cardiogenic Shock

- Although there is no randomized study, ACC/AHA guidelines give a Class 1 recommendation for AMI patients presented with CS who are not responsive to medical therapy, especially STEMI
- IABP also indicated in other causes of CS, although with less clear data:
  - Critical aortic stenosis
  - Severe decompensated MR
  - Progressive right and/or left heart failure despite medical therapy (bridge to other treatment)

- However, a recent meta-analysis has challenged this recommendation, which showed that only STEMI pts treated with thrombolysis not PCI benefit from IABP, not even in setting of CS
- The results were contradicting to many experience interventional cardiologist as many will be reluctant not to insert an IABP in patient with STEMI complicated by CS
- The validity of this meta-analysis is still controversial as the study populations included were heterogeneous with respect to patient characteristics, treatment strategies, timing of IABP, primary endpoints etc
- A randomized study is needed to verify the findings but unlikely due to ethical issue and conviction of benefit of IABP by many cardiologists

Intra-aortic balloon counterpulsation (IABP) in ST-segment elevation myocardial infarction (STEMI) with cardiogenic shock is strongly recommended (class IB) in the current guidelines. We performed meta-analyses to evaluate the evidence for IABP in STEMI with and without cardiogenic shock.

Medical literature databases were scrutinized to identify randomized trials comparing IABP with no IABP in STEMI. In absence of randomized trials, cohort studies of IABP in STEMI with cardiogenic shock were identified. Two separate meta-analyses were performed respectively. The first meta-analysis included seven randomized trials (n = 1009) of STEMI. IABP showed neither a 30-day survival benefit nor improved left ventricular ejection fraction, while being associated with significantly higher stroke and bleeding rates. The second meta-analysis included nine cohorts of STEMI patients with cardiogenic shock (n = 10529). In patients treated with thrombolysis, IABP was associated with an 18% [95% confidence interval (CI), 16–20%; *P* < 0.0001] decrease in 30 day mortality, albeit with significantly higher revascularization rates compared to patients without support. Contrariwise, in patients treated with primary percutaneous coronary intervention, IABP was associated with a 6% (95% CI, 3–10%; *P* < 0.0008) increase in 30 day mortality.

The pooled randomized data do not support IABP in patients with high-risk STEMI. The meta-analysis of cohort studies in the setting of STEMI complicated by cardiogenic shock supported IABP therapy adjunctive to thrombolysis. In contrast, the observational data did not support IABP therapy adjunctive to primary PCI. All available observational data concerning IABP therapy in the setting of cardiogenic shock is importantly hampered by bias and confounding. There is insufficient evidence endorsing the current guideline recommendation for the use of IABP therapy in the setting of STEMI complicated by cardiogenic shock. Our meta-analyses challenge the current guideline recommendations.
A systematic review and meta-analysis of intra-aortic balloon pump therapy in ST-elevation myocardial infarction: should we change the guidelines?  


---

**A**

<table>
<thead>
<tr>
<th>Trial</th>
<th>IABP</th>
<th>no IABP</th>
<th>30-day mortality risk difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>No reperfusion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>O’Rourke</td>
<td>n/N = 8/14</td>
<td>n/N = 10/16</td>
<td>0.01 (–0.26 to 0.23)</td>
</tr>
<tr>
<td>Flaherty</td>
<td>n/N = 4/10</td>
<td>n/N = 3/10</td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>n/N = 12/24</td>
<td>n/N = 13/26</td>
<td></td>
</tr>
<tr>
<td>Thrombolysis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kono</td>
<td>n/N = 0/23</td>
<td>n/N = 0/22</td>
<td></td>
</tr>
<tr>
<td>TACTICS</td>
<td>n/N = 10/30</td>
<td>n/N = 12/27</td>
<td>–0.06 (–0.21 to 0.08)</td>
</tr>
<tr>
<td>Overall</td>
<td>n/N = 10/53</td>
<td>n/N = 12/49</td>
<td></td>
</tr>
</tbody>
</table>

**B**

<table>
<thead>
<tr>
<th>Trial</th>
<th>IABP</th>
<th>no IABP</th>
<th>LVEF difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>No reperfusion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flaherty</td>
<td>n = 8</td>
<td>Mean (SD) = 36 (17)</td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>n = 191</td>
<td>Mean (SD) = 194</td>
<td>–0.10 (–2.24 to 2.04)</td>
</tr>
<tr>
<td>Primary PCI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PAMI-II</td>
<td>n = 107</td>
<td>Mean (SD) = 50 (9)</td>
<td></td>
</tr>
<tr>
<td>van’t Hof</td>
<td>n = 84</td>
<td>Mean (SD) = 40 (9)</td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>n = 199</td>
<td>Mean (SD) = 202</td>
<td>–0.09 (–2.21 to 2.03)</td>
</tr>
<tr>
<td>Overall</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Meta-analysis of randomized clinical trials of IABP therapy in STEMI

Meta-analysis of randomized clinical trials of IABP therapy in STEMI

Meta-analysis of cohort studies of IABP therapy in STEMI complicated by cardiogenic shock.
Cardiac Surgery

- IABP was used in the beginning by the cardiac surgeon when there were difficulties weaning pts off cardiopulmonary bypass following CABG.
- Recommended with unstable left main disease after coronary angiography.
- Prophylactic IABP placement prior to CABG in pts with high risk features: critical anatomy (including left main disease), severe LV dysfunction and unstable angina.
- Although no mortality benefit, high risk pts randomized to pre-op IABP had significant higher post-op CO, shorter intubation times, and shorter hospital stays (Christenson et al 1999).
- Suzuki et al (2004) found that high-risk pts (n=32) underwent off-pump CABG with pre-op IABP (higher LM disease and emergent surgeries) had similar outcomes compared to low- to moderate-risk cohort without pre-op IABP.
Transplantation and Arrhythmia

- In patient with severe end stage cardiomyopathy, IABP can be used as a bridging modality for cardiac transplant and reduce the need for LVAD.
- But due to limitation of duration of use, IABP is used more as a bridging to other LVAD, which are more successful bridge to transplant.
- However, IABP can still used following transplant rejection for hemodynamic support.

- Some malignant ventricular arrhythmias can be associated with uncorrected ischemic substrate.
- Anecdotal reports have described cessation of VT/VF after IABP insertion.
- ACC/AHA guidelines given a Class IIa recommendation for refractory malignant dysrhythmias due to ischemia.
## ACC/AHA Practice Guidelines: Indications for IABP Therapy

<table>
<thead>
<tr>
<th>Clinical Scenario</th>
<th>ACC/AHA Recommendation</th>
<th>Level of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe or refractory unstable angina</td>
<td>Class IIa</td>
<td>C</td>
</tr>
<tr>
<td>High risk AMI (re ischemia/infarction/mechanical complications)</td>
<td>Class I</td>
<td>C</td>
</tr>
<tr>
<td>Refractory decompensated heart failure</td>
<td>Class IIb</td>
<td>C</td>
</tr>
<tr>
<td>Cardiogenic shock</td>
<td>Class I</td>
<td>B</td>
</tr>
<tr>
<td>Refractory polymorphic ventricular tachycardia</td>
<td>Class IIa</td>
<td>B</td>
</tr>
</tbody>
</table>
Indications for the IABP

1. Complicated acute myocardial infarction
2. Cardiogenic shock
3. Refractory unstable angina
4. Severe CAD with hemodynamic compromise
5. Mechanical complications of AMI
6. Support of high risk coronary intervention
7. Stabilization of left main disease
8. Induction and weaning of cardiopulmonary bypass
9. Bridge to cardiac transplantation
10. Refractory arrhythmias
11. Surgery for high risk cardiovascular patients
Conclusions

- IABP was first used to help cardiac surgeon to wean off CPB and now has emerged as an effective and widely used mechanical circulatory assist device
- It is based on the dual physiologic concept of diastolic augmentation and systolic afterload reduction and best in salvaging the function of a ischemic and falling left ventricle
- The development of percutaneous approach and refinements of the device has enhance the speed and the ease of insertion, as well as lowering the vascular complications of the device
- Although data for IABP may be conflicting due to lack of randomized studies, with improved risk benefit ratio, IABP should probably be used more often in certain clinical situations to enhance patient outcomes
Thank You!
SHOCK Registry

- N=856 patients with cardiogenic shock in acute MI
- 36 participating centres
- Treatment:
  - No thrombolysis / no IABP 33%
  - IABP only 33%
  - Thrombolysis only 15%
  - Thrombolysis and IABP 19%
- TT vs. no TT (54% VS. 64%, p=0.005)
- IABP vs. no IABP (50% vs. 72%, p<0.001)

Sanborn et al. J Am Coll Cardiol 2000; 36:1123