Percutaneous ventricular cardiac assist device in cardiogenic shock

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Background

- Mortality in patients with cardiogenic shock remains about 50% despite early PCI
- Mechanical support devices might improve prognosis
- Problems: costs, experience needed, evidence
Support devices in cardiogenic shock

- Which patient?
- When?
- Which device?

Pros and cons of mechanical support devices

- Pro: hemodynamic improvement, initial stabilization
- Con: invasive nature of the devices, complications, costs, lack of outcome data
### Randomized Trials in Cardiogenic Shock

<table>
<thead>
<tr>
<th>Trial</th>
<th>Follow-up</th>
<th>n/N</th>
<th>n/N</th>
<th>Relative Risk</th>
<th>95% CI</th>
<th>Relative Risk</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revascularization (PCI/CABG)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>SHOCK</td>
<td>1 year</td>
<td>81/152</td>
<td>100/150</td>
<td>0.72</td>
<td>(0.54;0.95)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SMASH</td>
<td>30 days</td>
<td>22/32</td>
<td>18/23</td>
<td>0.87</td>
<td>(0.66;1.29)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>103/184</td>
<td>118/173</td>
<td>0.82</td>
<td>(0.69;0.97)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Currently Available Percutaneous Devices

- IABP
- Impella
- ECLS (ECMO)
- Tandem Heart
- iVAC 2L

Thiele et al. Eur Heart J 2015;36:1223-1230
IABP for cardiogenic shock

History:

1962  Animal studies
       Moulopoulos et al, Am Heart J 1962;63:669-675

1968  First in man experience in shock
       Kantrowitz et al, JAMA 1968;203:135-140

1973  Positive hemodynamic effects in shock,
       No mortality benefit
       Scheidt et al, NEJM 1973;288:979-984

> 40 years > 1 Mill. Patients, low complication rate
       Benchmark Registry
       Ferguson et al, JACC 2001;38:1456-1462

IABP – Mode of action

Improvement of coronary perfusion
After load reduction
Reduction of \( O_2 \)-consumption ↓
**Primary Study Endpoint (30-Day Mortality)**

- **Control**: 41.3%
- **IABP**: 39.7%

P = 0.92; log-rank test
Relative risk 0.96; 95% CI 0.79-1.17; P = 0.69; Chi²-Test

**Mortality 12-Month Follow-up**

- **Control**: 48.7%
- **IABP**: 49.2%

P = 0.94; log-rank test
Relative risk 1.02; 95% CI 0.88-1.19

**No. at risk**

- **IABP**: 301 181 171 165 161 159 154 152 149 147 146 144 136 45 21
- **Control**: 299 174 166 165 159 154 152 147 147 146 144 140 55 29

Thiele, Zeymer et al. NEJM 2012;367:1287-1296

Thiele, Zeymer et al. Lancet 2013;382:1638-1645
ESC Revascularization Guidelines 2014

IABP in cardiogenic shock

Class IC → IIb B → III


IABP + Other Devices Use in the US

Cath PCI US Registry: 76474 patients with PCI and cardiogenic shock

No mechanical support
IABP
Mechanical support

Currently Available Percutaneous Devices

LVAD vs IABP?

- Improved LV-Preload
- Hemodynamic Support

- Bleedings ↑
- More invasive ↑
- Higher costs
- Implantation procedure
Currently Available Percutaneous Devices

Technical Parameters

| Catheter size (F) | 11 (expandable) | 9 | 12 | 1 | 17–19 venous
| Corrugate size (F) | 17 | 21 venous
| Flow (L/min) | 21–19 arterial
| Pump speed (rpm) | Max 5.7 | Max 7500
| Pulse rate | Max 3.3 | Max 33 000
| Insertion/Placement | Percutaneous (femoral artery + vein for left atrium) | Peripheral surgical (femoral artery) | Percutaneous (femoral artery) | Percutaneous (femoral artery + vein)
| LV unloading | + | ++ | ++ | + | –
| Anticoagulation | + | ++ | ++ | + | –
| Recommended duration of use | 21 days | 14 days | 10 days | 10 days | 7 days
| CE-certification | + | ++ | ++ | + | –
| FDA | – | ++ | ++ | + | –
| Relative costs | ++ | ++ | ++ | + | –

LVAD or IABP?

Hemodynamics

LVAD or IABP?

Cardiac Index

LVAD MW ± SD | IABP MW ± SD | Mean difference | P (Heterogeneity) = 0.22
Thiele et al | 2.3±0.6 | 1.8±0.4 | 0.55 (0.23–0.87)
Burkhoff et al | 2.2±0.6 | 1.8±0.7 | 0.16 (-0.14–0.46)
Seyfarth et al | 2.2±0.6 | 1.8±0.7 | 0.36 (-0.11–0.88)
Pooled | 2.2±0.6 | 1.8±0.7 | 0.35 (0.09–0.61)

LVAD MW ± SD | IABP MW ± SD | Mean arterial pressure mean difference | P (Heterogeneity) = 0.10
Thiele et al | 76±10 | 70±16 | 5.5 (-2.9–13.9)
Burkhoff et al | 91±16 | 72±12 | 18.6 (9.4–27.9)
Seyfarth et al | 87±16 | 71±12 | 16.0 (0.5–31.5)
Pooled | 87±16 | 71±12 | 12.8 (3.6–22.0)

LVAD MW ± SD | IABP MW ± SD | Mean difference | P (Heterogeneity) = 0.01
Thiele et al | 16±4 | 22±7 | -8.4 (-11.0–5.8)
Burkhoff et al | 19±5 | 20±6 | -1.0 (-5.2–3.2)
Seyfarth et al | 19±5 | 20±6 | -5.3 (-9.4–1.2)
Pooled | 19±5 | 20±6 |
LVAD oder IABP - Mortality

Individual patient-based meta-analysis

Thiele et al. Eur Heart J 2010;31:1828–1835

LVAD oder IABP?

Complications

IMPELLA VERSUS IABP –
The randomized IMPRESS trial

Henriques et al, J Am Coll Cardiol 2017; 69: 280-287

Currently Available Percutaneous Devices
**ECMO - Evidence**

Historical control without ECMO; 1993 – 2002 versus ECMO; 2002 – 2009 retrospective analysis

![ECMO Survival Graph](image)

Log-rank $p=0.003$

With ECMO

No ECMO

<table>
<thead>
<tr>
<th>Follow-up (Days)</th>
<th>At risk ECMO (n=46)</th>
<th>No ECMO (n=25)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>32</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>31</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>28</td>
<td></td>
</tr>
</tbody>
</table>

Sheu et al. Crit Care Med 2010;38:1810-1817

**Problems with ventricular assist devices in cardiogenic shock**

![Ventricular Assist Devices](image)

Zeymer and Thiele J Am Coll Cardiol 2017; 69: 288-90
Summary
• Routine IABP in cardiogenic shock not useful
• Maybe used in patients with mechanical complications (VSD, mitral insufficiency)
• IMPELLA provides hemodynamic support, survival benefit needs to be shown
• ECMO useful in patients after CPR to be able to perform PCI

Conclusion
• Which patient:
  - Young patient hemodynamic unstable after successful revascularization
• When:
  - after PCI, only in patients with ongoing CPR before revascularization
• Which device:
  - IABP only for mechanical complications. Impella low output after PCI, ECMO: CPR, pulmonary problems