HKCC Annual Scientific Congress 2023

# Mechanical Circulatory Support for CHIP, Which and When?

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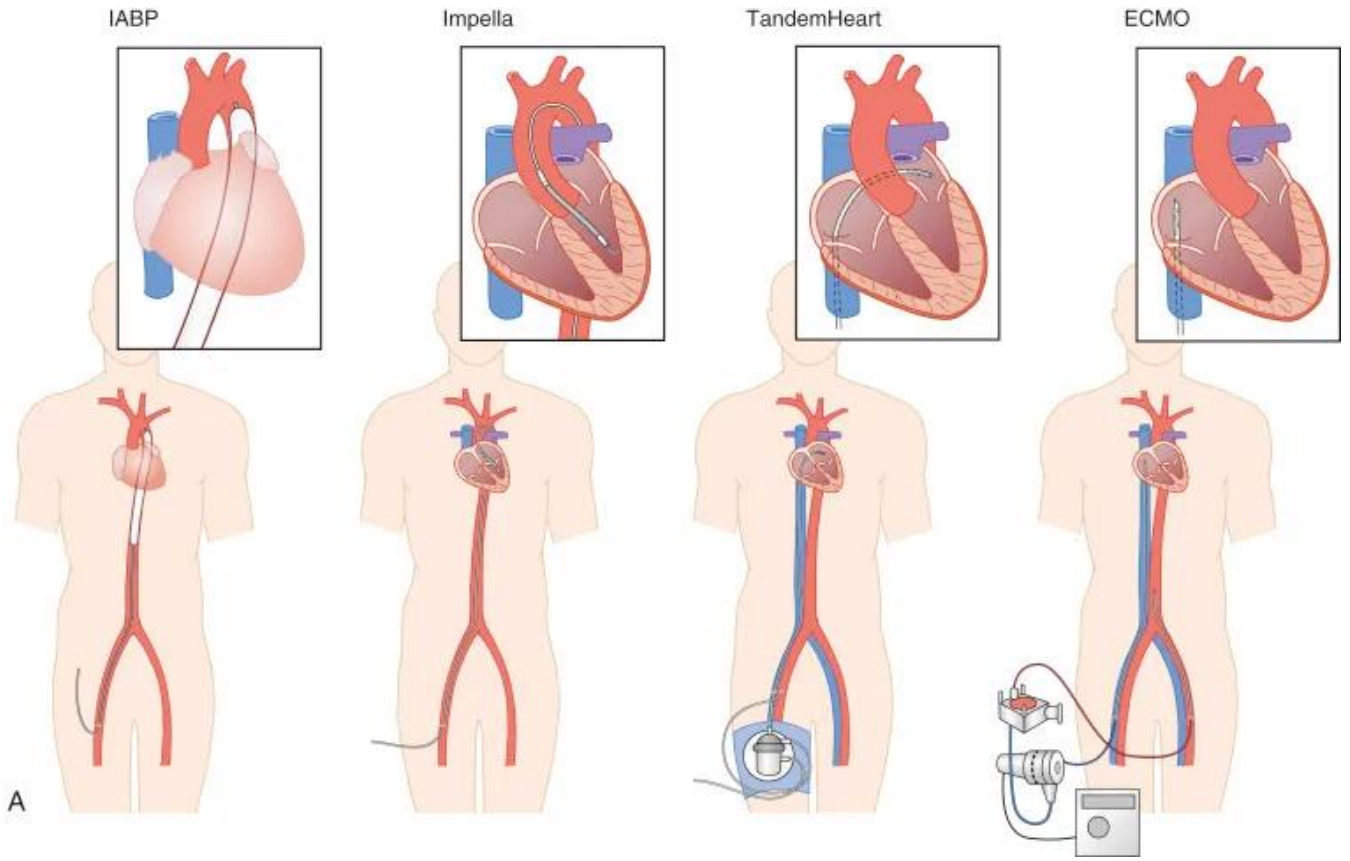
# Complex High risk Indicated Procedure

- Complex
  - Complex anatomy, likely need sophisticated stenting technique and use of high risk devices
- High risk patients
  - Likely with poor LVEF with high chance of hemodynamic compromise during procedure
  - Poor premorbid status with poor tolerance to impair blood flow during procedure
- Indicated
  - Risk of not doing procedure is even higher

# Which MCS to use?

- IABP
- Impella
- LVAD
  - Tandem Heart
- VA ECMO



# Which MCS to use?

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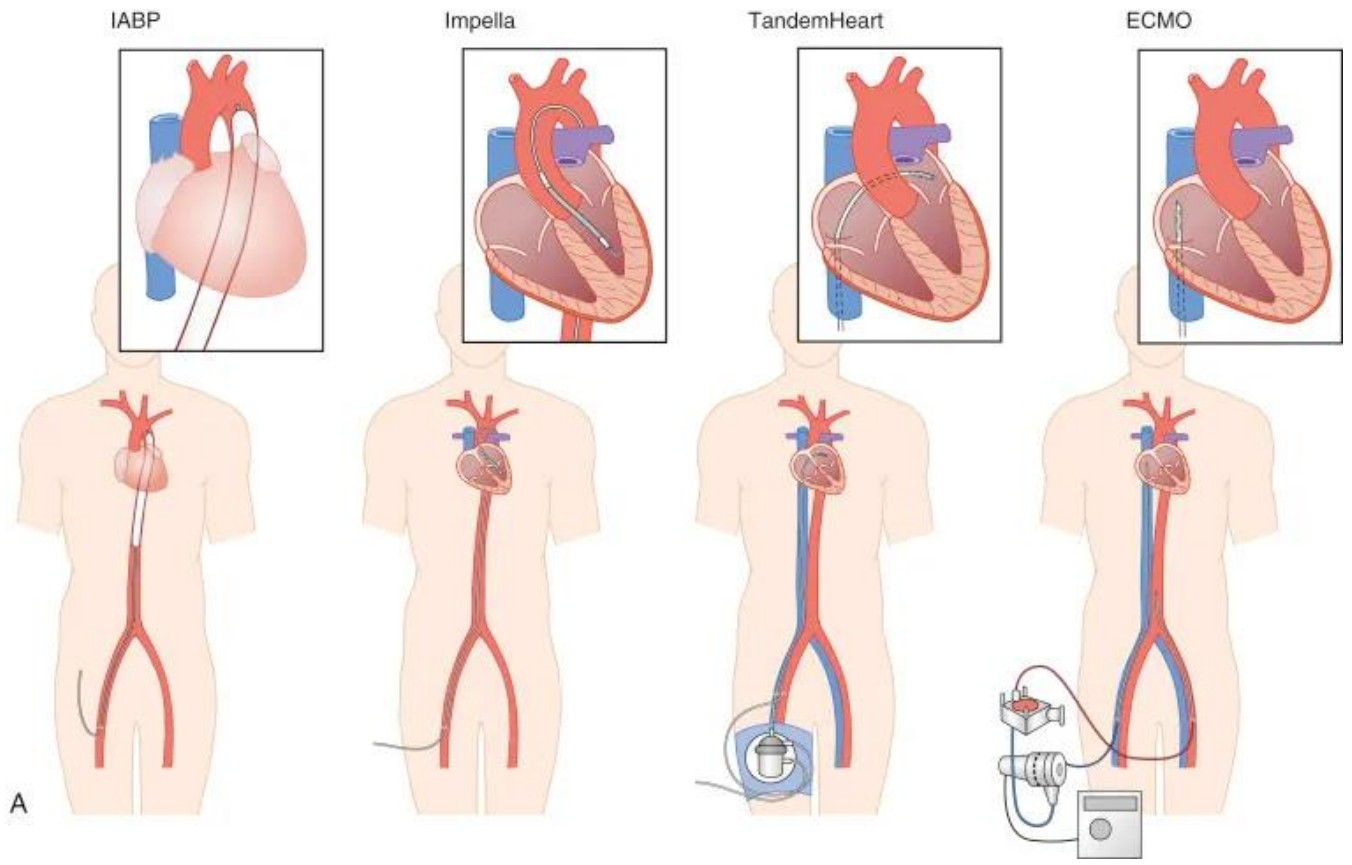
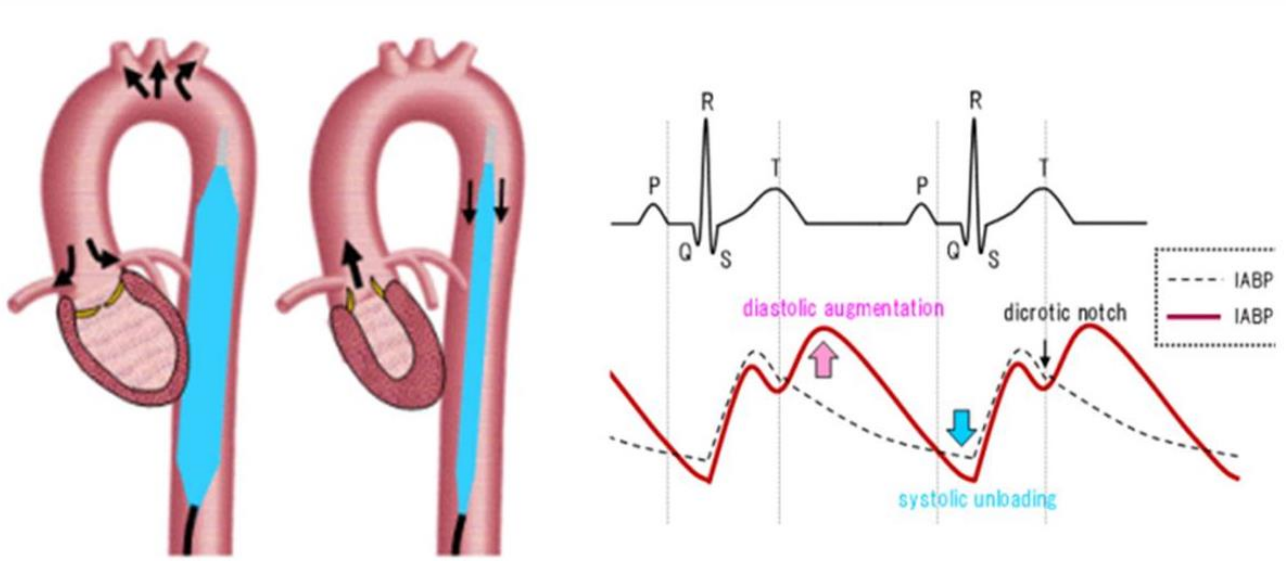


# When to use MCS?

- Upfront use
  - Anticipated hemodynamic collapse, setup MCS before procedure
- Ad-hoc use
  - Perform procedure and setup MCS when needed

# Intra-aortic Balloon Pump (IABP)

- Insert percutaneously
  - Femoral artery
  - Axillary artery
- Usually can be set up within 10 minutes
- Modest support
  - Less than 500ml per minute



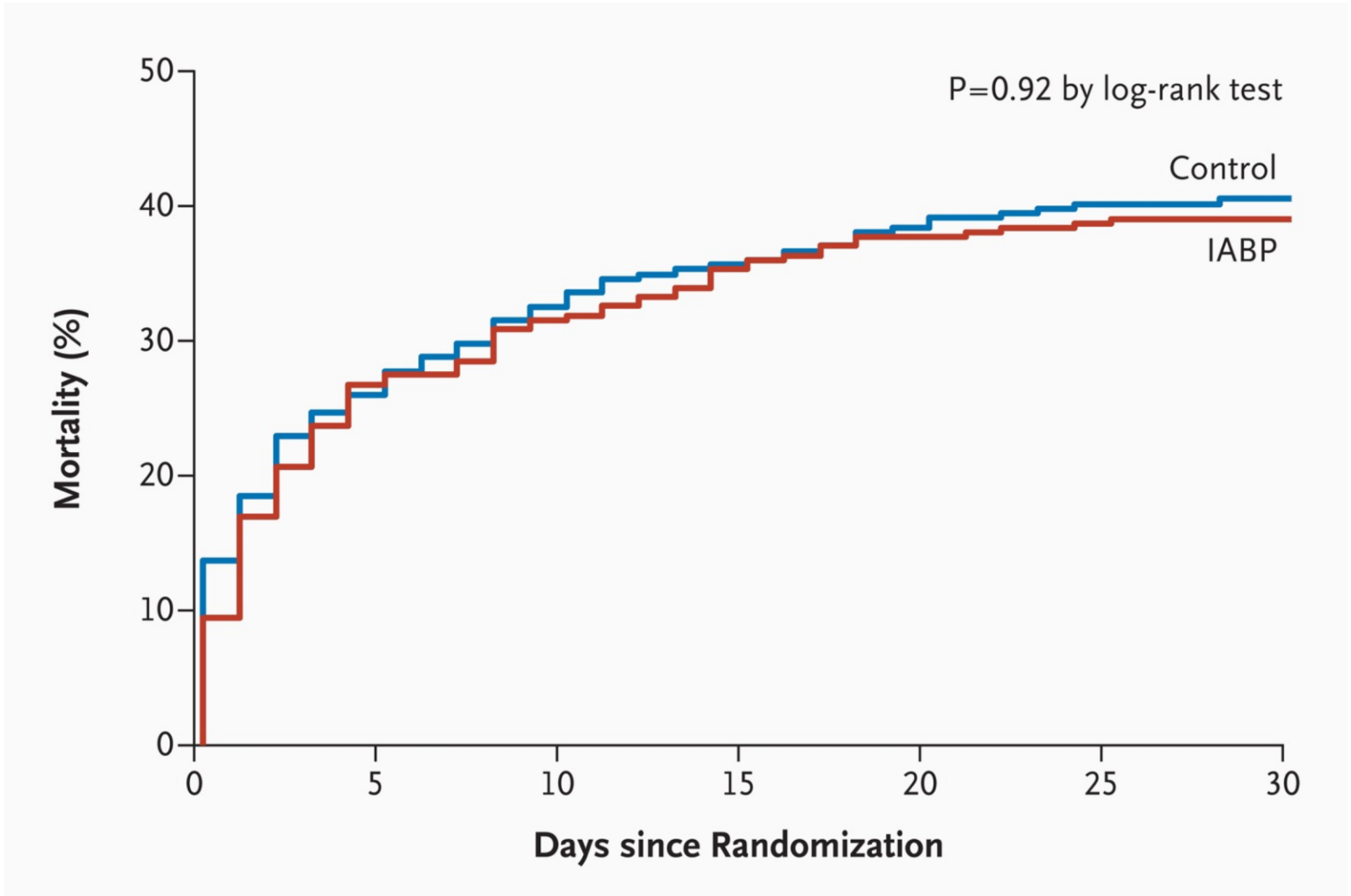

Picture courtesey: http://www.eonet.ne.jp/~hidarite/ce/sinpai06.html

# Evidence in upfront use

- BCIS-1 trial. Divaka et al. JAMA 2010.
- N=301
- IABP before high risk PCI (LVEF < 30% + extensive ds)
- MACCE 15.2% in IABP vs 16% in no-IABP (p=0.85)
- Assess site complication 3.3%
- 12% cross over to IABP group

# Evidence in shock

- IABP-SHOCK II trial. Holger et al. NEJM 2012.
- N=600
- IABP vs no IABP in AMI with cardiogenic shock


P=0.92 by log-rank test
Control
IABP
Mortality (%)
50
40
30
20
10
0
0
5
10
15
20
25
30
Days since Randomization

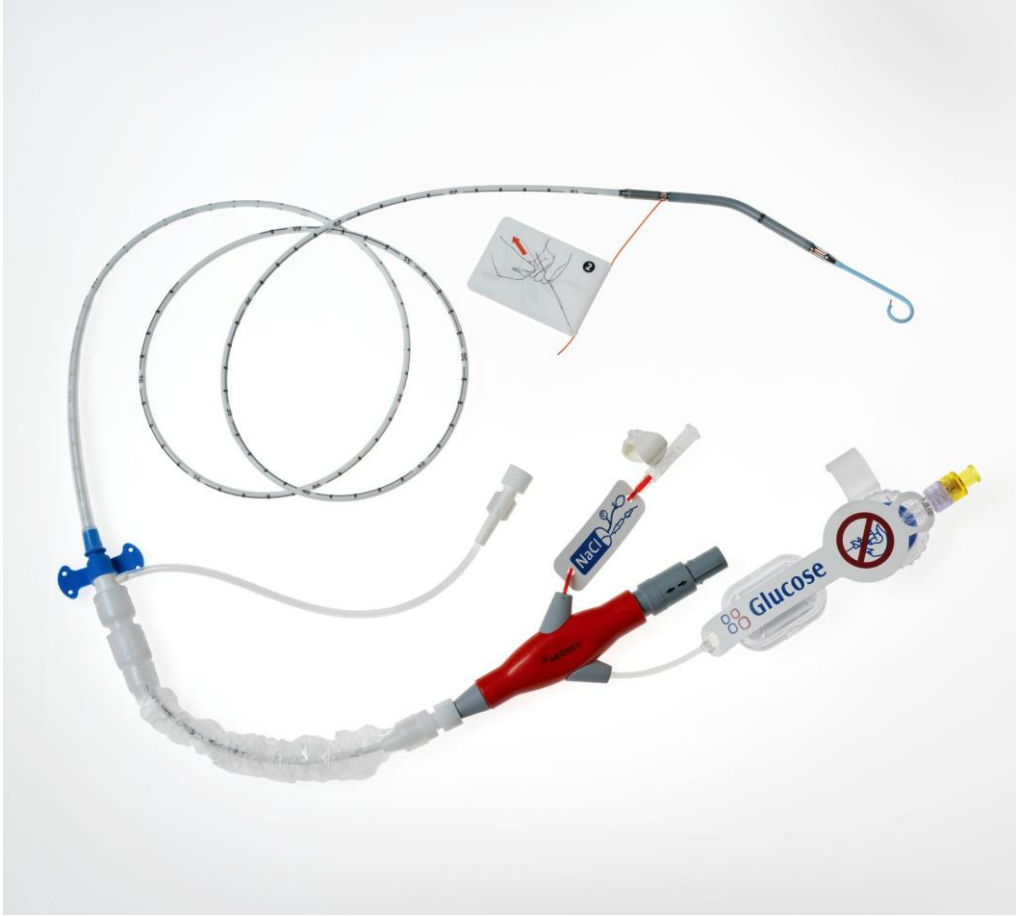
- Did not control timing for IABP insertion
  - Though subgroup analysis showed no diff in ‘before’ vs ‘after’ PCI group
- 10% cross-over rate
- Mechanical complications excluded
- Negative trial in general, but cannot exclude benefit in selected group

# IABP - conclusion

- Modest haemodynamic support
- No evidence in upfront setting
- No evidence in ad-hoc setting as well
  - Widely available and easy to set up, may have some role in ad-hoc setting if other MCS not a/v

# Impella

- Via femoral artery or axillary artery
- Different design provide different support
  - 2.5, CP, 5.0, 5.5, RP, LD
- Large bore
  - 13 – 23 Fr
- Up to 5 L/min in Impella 5.0



# Upfront use in CHIP

- Protect II Study. William et al. Circulation 2012.
- N=452.
- Impella 2.5 vs IABP in complex PCI with depressed LVEF.
- Primary endpoint (major adverse events) at 30 days no difference
- Trend favours Impella at 90 days (49.3% vs 40.6%, p=0.062 (ITT), 50.0% vs 40.0%, p=0.023(per protocol))

# Complications

- Limb ischemia 0.07-10%
- Bleeding 0.05-54%
- Haemolysis 7-8%


1. Subramaniam et al. Complications of Temporary Percutaneous Mechanical Circulatory Support for Cardiogenic Shock: An Appraisal of Contemporary Literature. Cardiol Ther 2019
2. Lauten et al. Percutaneous left-ventricular support with the Impella-2.5-assist device in acute cardiogenic shock: results of the Impella-EUROSHOCK-registry. Circ Heart Fail 2013

# Evidence in cardiogenic shock

- ISAR-SHOCK. Melchior et al. JACC 2008.
- Perspective randomized study. N=26.
- Impella 2.5 vs IABP in AMI CS pt
- Cardiac index increase more in Impella gp

# Evidence in cardiogenic shock

- Impress Study. Ouweneel et al. JACC 2017.
- N=48.
- IABP vs Impella CP in STEMI CS undergoing 1’ PCI
- All cause mortality 50% vs 46% (p=0.92)
- Limitation
  - Underpower
  - Pt critically ill (91% had cardiac arrest), majority death due to anoxic brain injury
  - ?passing point of no return

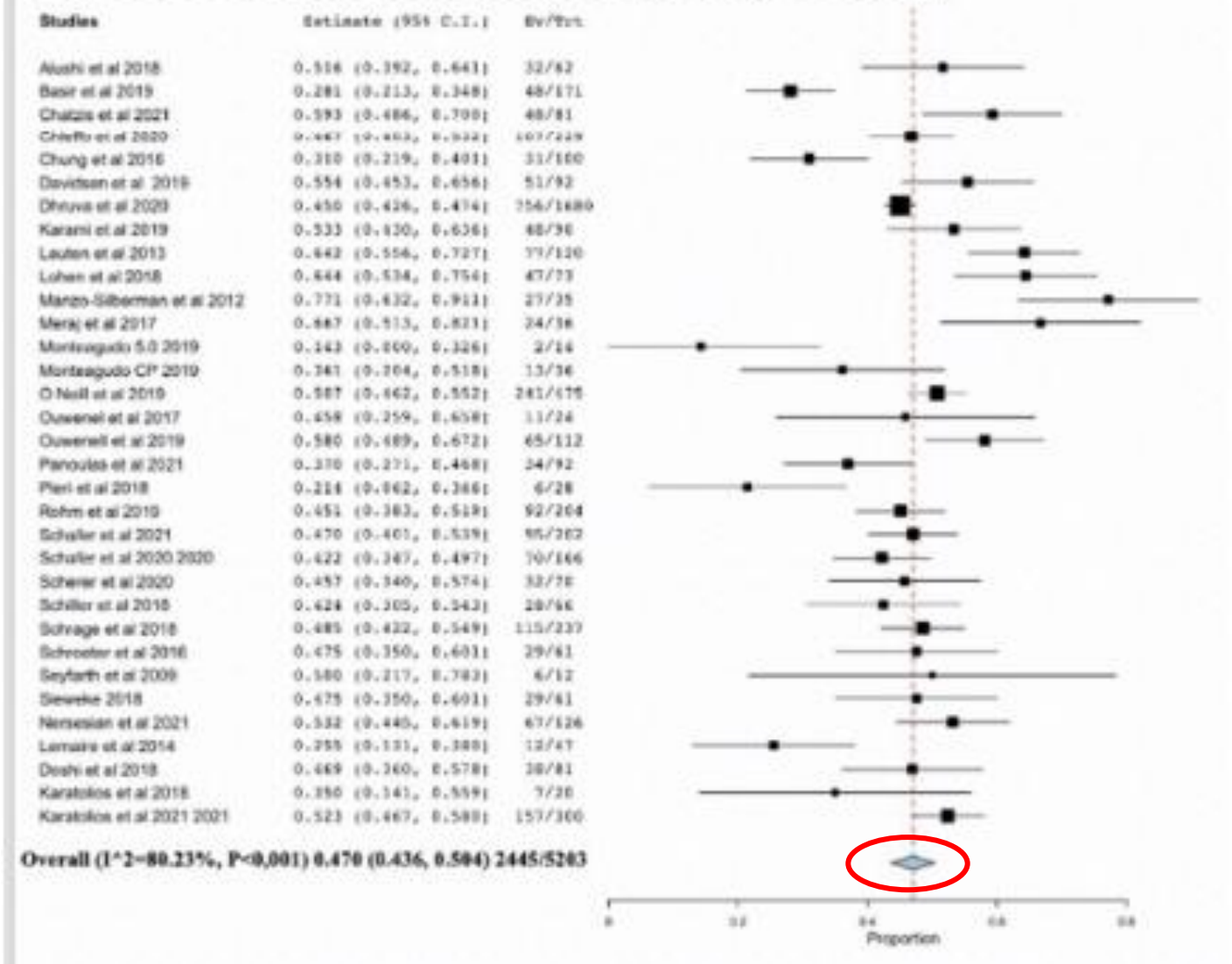
# Evidence in cardiogenic shock

- National Cardiogenic Shock Initiative (NCSI).
- Single arm perspective study. N=406
- Protocol driven approach in AMI CS pt by early use (before PCI) of MCS (mostly Impella)/ PAC
- Higher survival rate compare to historical data

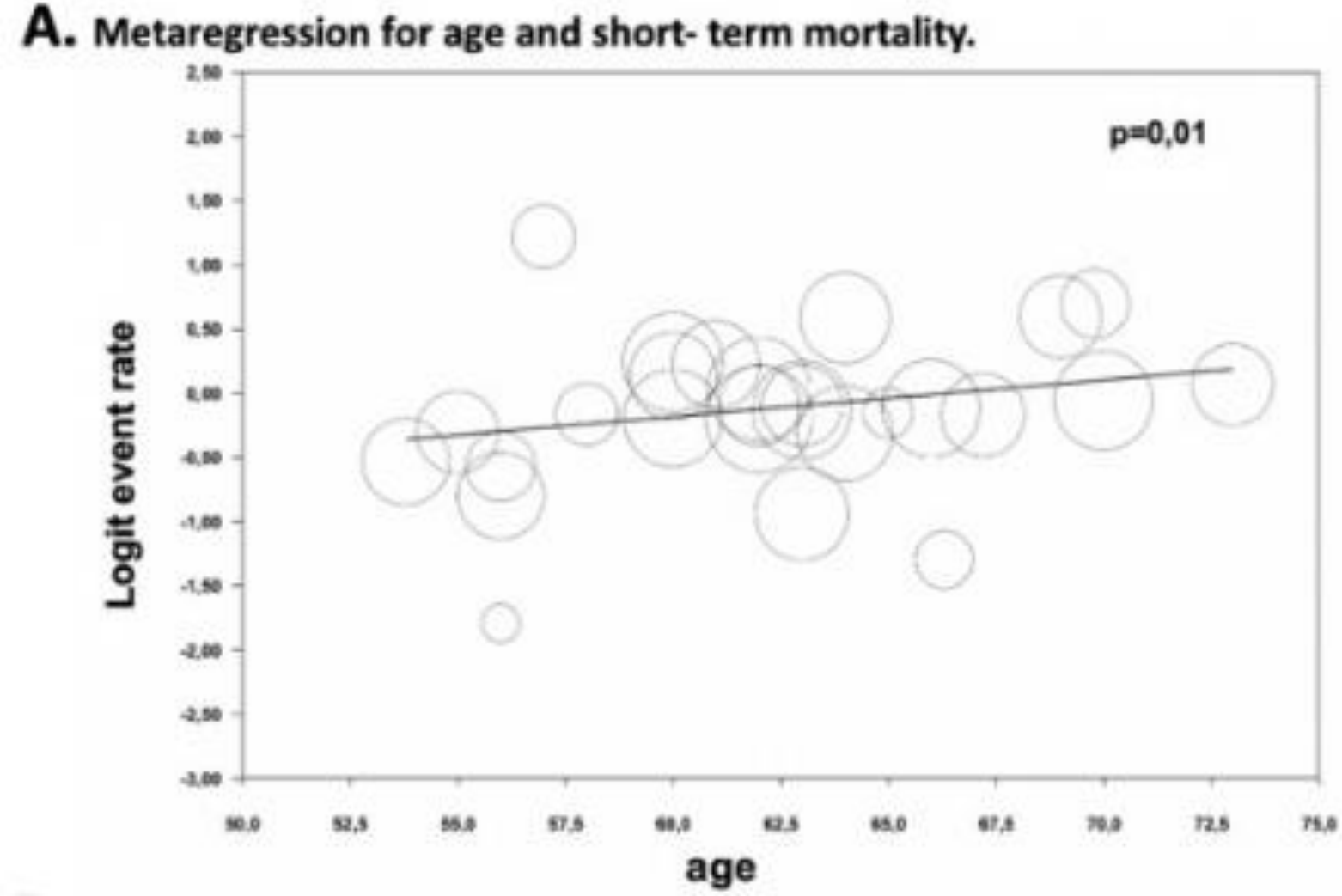
# Meta-analysis

- Use of Impella device in cardiogenic shock and its clinical outcomes: A systematic review and meta-analysis. IJC Heart & Vasculature, Volume 40, 2022
- 33 studies. 5024 patients included.
- Primary endpoint 30d mortality and in-hospital mortality.

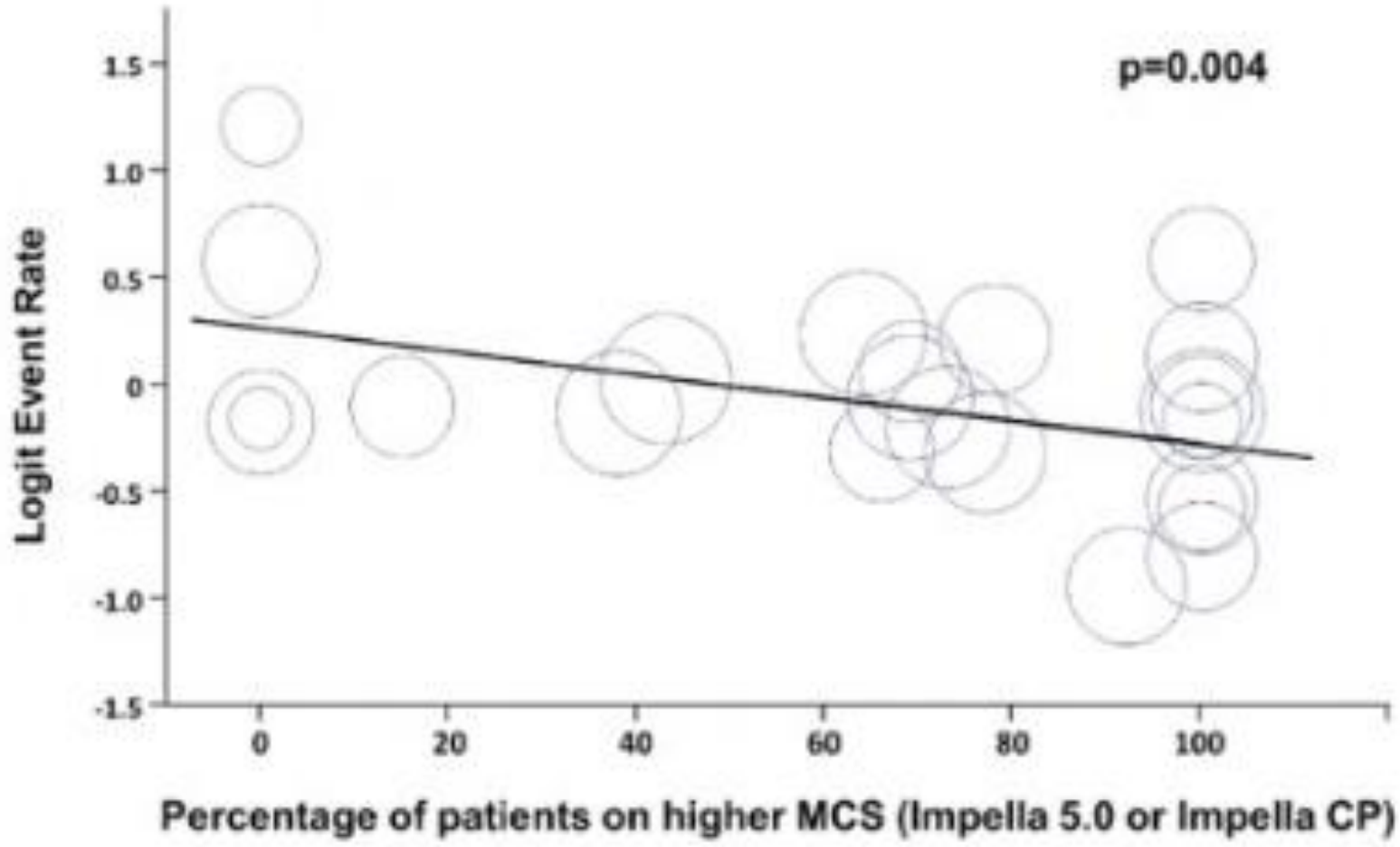
# A. Forrest Plot for short-term mortality.



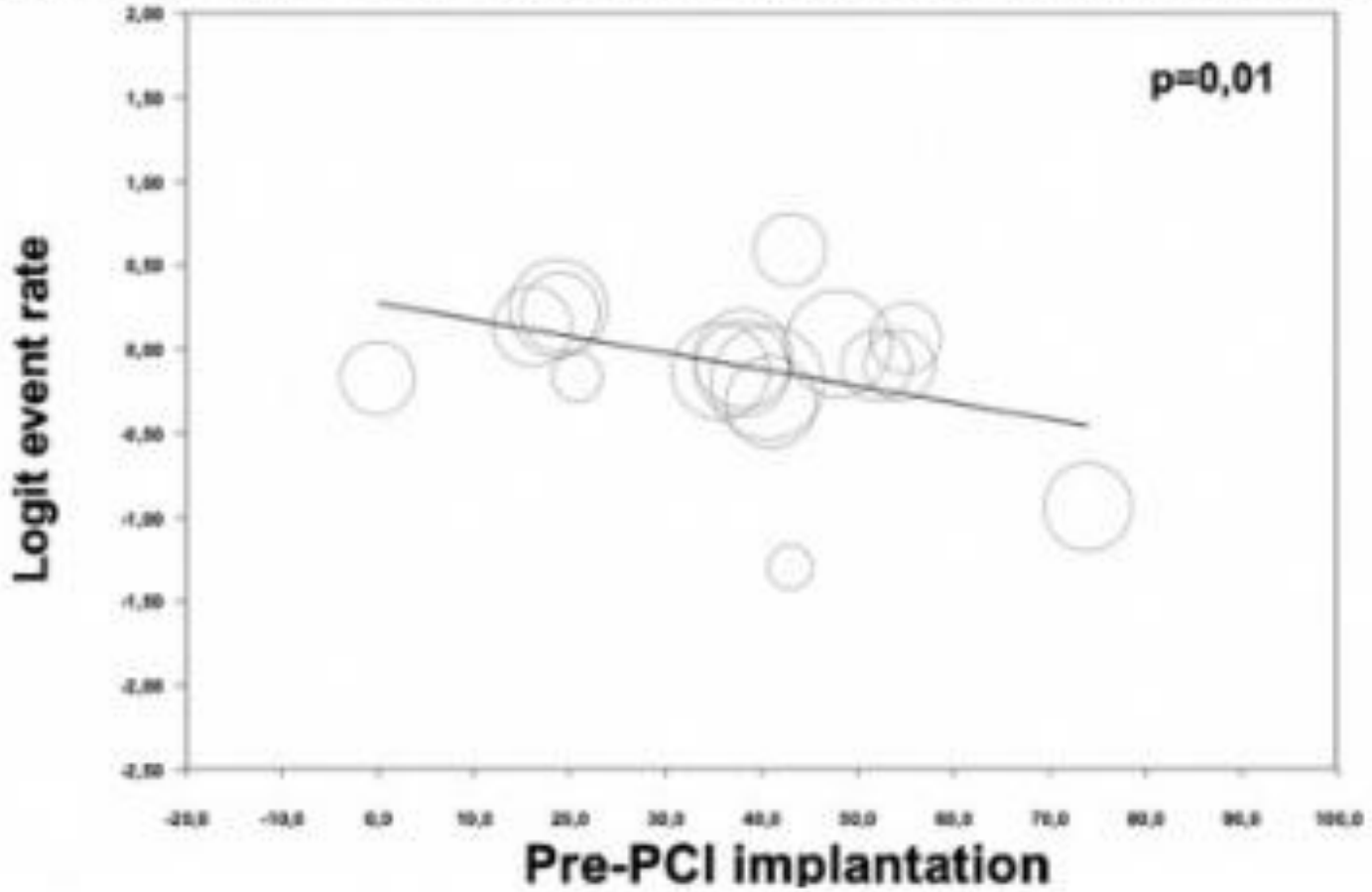
**A.** Metaregression for age and short- term mortality.



**B.** **Metaregression for Higher MCS on short-term mortality.**



**C.** **Metaregression for pre-PCI Impella Implantation on short-term mortality.**

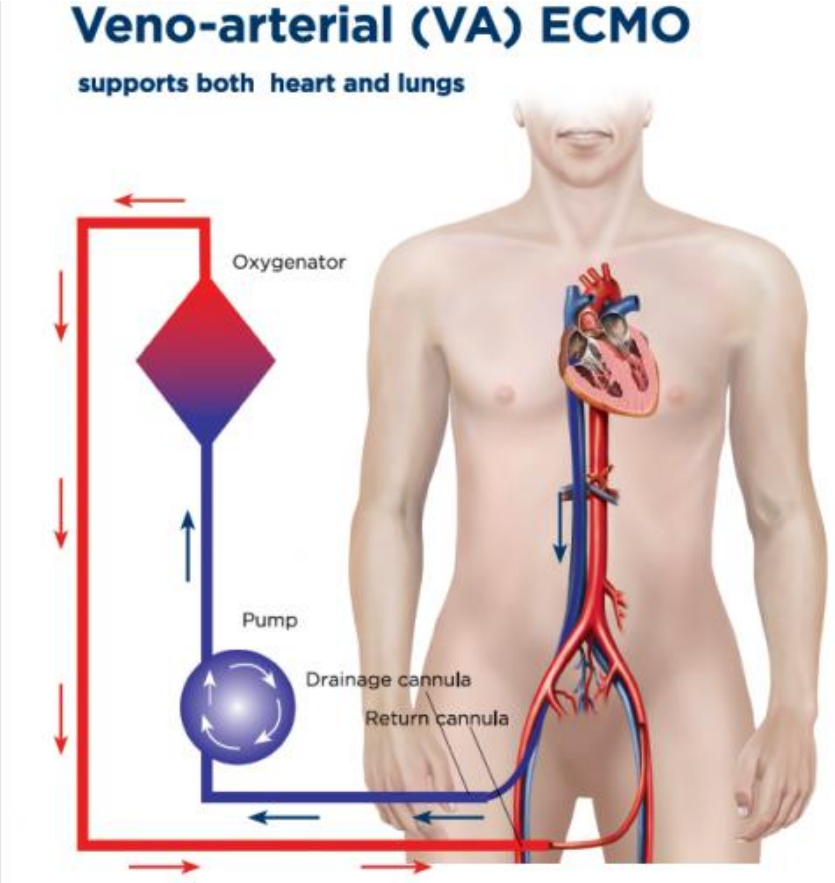


# Impella - Conclusion

- At the moment
  - no strong evidence for ad-hoc use in cardiogenic shock
  - Some evidence for upfront use
- Difficult to study
  - Heterogenic pt in CS
  - Timing is important, may pass the point of no return in some pt
  - Selection of pt is critical
- Multiple trials ongoing
  - Recover IV, DanGer Shock … … etc
- No RCT compare upfront use vs ad-hoc use
- Until more evidence available, reasonable choice in selected cardiogenic shock patients

# Extra Corporeal Membrane Oxygenation (ECMO)

- VA-ECMO provide up to 5 L/min support
- Also provide oxygenation support and control body temperature
- Involve both venous and arterial system
- 19-25 Fr for venous catheter
- 15-24 Fr for arterial catheter



# Drawback

- Increase LV afterload
  - Increase workload of the failing heart indeed
- Risk of limb ischaemia
  - Reperfusion catheter often needed if prolong insertion
- Haemolysis
- Thrombosis
- Often require surgical repair on removal

# Upfront ECMO for CHIP

- Case series of 14 pt by Brink et al. Neth Heart J 2020.
- High risk PCI with VA ECMO support.
- 71% pt with LM ds.
- 71% pt with LVEF < 35%.
- Median Syntax I score 34
- 93% survival till discharge.
- ECMO related complication 14%

# VA ECMO for Cardiogenic Shock

- Retrospective study by Vakil et al. J Cardiothoracic Surgery 2021.
- N=90
- Included cardiogenic shock and eCPR pt
- Survival to discharge in CS pt – 46% (compared to other registry for CS, survival rate 24.4% - 42%)

# VA ECMO for Cardiogenic Shock

- ECMO-CS Study. Circulation 2022.
- N=122.
- Rapidly deteriorating cardiogenic shock patients require repeated use of bolus inotropes
- Immediate ECMO vs No Immediate ECMO (allow downstream use)
- Primary endpoint (death from any cause, resuscitated arrest and use of other MCS at 30d) 63.8% vs 71.2% (p=0.21)
- 39% cross over to ECMO

# ECMO - conclusion

- Effective to maintain circulation even in arrested patient
- Higher complications rate compare with other MCS devices
  - And complication profile is different
- Increase afterload of LV
- Risk of AV closure and LV thrombosis

# ECMO - conclusion

- Strong evidence lacking in both upfront and ad-hoc use
- No alternatives available
- RCT on going
  - Euro Shock, ECLS Shock etc … …
- Risk benefit ratio seems favour ad-hoc use over upfront use

# Take home messages

- IABP
  - No evidence in both upfront and ad-hoc setting, but widely available and easy to set up, may have some role in ad-hoc setting
- Impella
  - Evidence favors use in complex PCI with depressed LVEF
  - Yet, not direct comparison between upfront insertion vs ad-hoc insertion
  - Routine use not without complications, especially vascular complications
- VA-ECMO
  - No strong evidence yet
  - But highest level of hemodynamic support provided
  - Significant complication rate, seems not favor upfront use

# Conclusion

- Different MCS devices have different characteristics
- No black and white rules to suggest which devices should be use in what setting
- Be familiar risk and benefit of each device

Table 3: Temporary mechanical circulatory support devices

| MCS Device | IABP | Impella 2.5/CP/5.5 | TandemHeart | VA-ECMO |
|---|---|---|---|---|
| | A IABP  | B Impella  | C Tandem Heart  | D ECMO  |
| CO (L/min) | 0.5–1.0 | 2.5/3.0–4.0/5.0 | 4.0–5.0 | 4.0–10.0 |
| Haemodynamic effects | LV pressure or volume unloading | LV pressure or volume unloading | LV volume unloading | Biventricular pressure and volume unloading |
| Peripheral resistance | Decreased | Decreased | Mildly increased | Highly increased |
| LV unloading | + | ++ | ++ | – |
| Pump mechanism | Pneumatic | Axial flow | Centrifugal | Centrifugal |
| Cannula size | 7–9 Fr | 13–22 Fr | Drainage 21 Fr; Return 15–17 Fr | Drainage 18–21 Fr; Return 15–22 Fr |
| Advantages | Bedside insertion; no anticoagulation | Direct ventricular unloading | Addition of pulmonary support | Addition of pulmonary support |
| Disadvantages | Minimal haemodynamic support | Mandatory anticoagulation; haemolysis | Immobilization | Incomplete LV unloading |
| Complications | Limb/spinal cord ischaemia; bleeding; aortic dissection | Limb ischaemia; bleeding; haemolysis; ventricular arrhythmias | Cardiac perforation; tamponade bleeding; air embolism; residual ASD | Limb ischaemia; bleeding; stroke; air embolism; circuit clots; DIC; oxygenator failure; altered drug pharmacokinetics |
| Contraindications | Severe PAD; AAA; significant AI | LV thrombus; mechanical AV; severe PAD | VSD; significant AI; left atrial thrombus | Severe PAD; significant AI; aortic dissection |

*AAA = abdominal aortic aneurysm; AI = aortic insufficiency; ASD = atrial septal defect; AV = aortic valve; CO = cardiac output; DIC = disseminated intravascular coagulation; ECMO = extracorporeal membrane oxygenation; IABP = intra-aortic balloon pump; LV = left ventricle; PAD = peripheral arterial disease; VA = venoarterial; VSD = ventricular septal defect.*

Heart International. 2022;16(1):37–48