

luzerner kantonsspital
KUTZEN SPARTE WIL-RODEN

Cardiology Division – Heart Center, Luzerner Kantonsspital

LUCCA 3.0 – Impella® Workshop

MCS indications for high-risk interventions and shock management
– When would you use an Impella® device ...?

PD Dr. Adrian Attlinger, MD & PD Dr. Matthias Bossard, MD
Senior Consultants Interventional Cardiology

Lucerne, February 22, 2024



1

• WHAT'S YOUR EXPERIENCE WITH THE IMPELLA™ DEVICE?

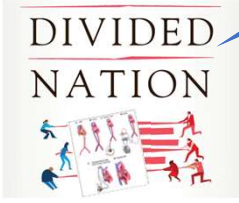
Who has experience with mechanical circulatory support devices?

Who has experience with the Impella® device?

2

• OUR EXPERIENCE WITH THE IMPELLA™ DEVICE

Are there only pVAD / Impella enthusiasts in Lucerne?



NO!!!


vs.

3

• OUR EXPERIENCE WITH THE IMPELLA™ DEVICE

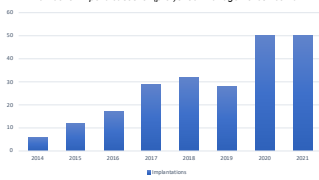
Cardiogenic shock and heart failure management using the Impella™ device
– Cardiology Division – LUKS: Almost one decade of experience

Indications for Impella implants in CS cases



• OHCA • CS/ACS • CS from other causes

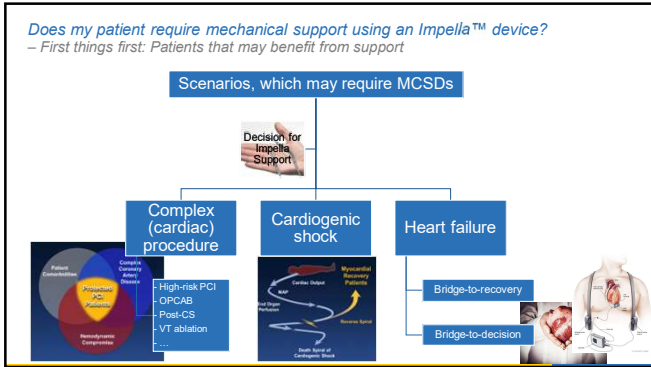
Number of Impella cases for (pre-)shock management since 2014



• Indications for use of the Impella™ device in Lucerne:

1. (pre-)shock & OHCA (approx. 80%)
2. Heart failure & high-risk PCI
3. Bridge to recovery/ HTX/ LVAD

4



5

Which patients are eligible for an Impella™ device?
 – Balance the risk and benefits of pVADs?

PRO:

- (Cardiogenic) shock: Deteriorating hemodynamics
- At risk for shock: Post-cardiac surgery, large AMI...
- (Advanced) heart failure patient - Awaiting HTX, LVAD,...
- Complex cardiac procedure - PCI, VT ablation, OPCAP, ...

CONS:

- "Hostile" aorta, severe PAD
- Mechanical aortic valve
- Intracardiac thrombus
- (Severe AS/AR)
- Endocarditis (VSD / ASD)
- Advanced age/ frailty (Active bleeding)

6

Assess your patient for eligibility
 – Use your clinical judgement, echocardiography (and fluoroscopy)...

What is your patient's will?

DNR - Palliative Care

Full code

- CPR
- ACLS
- Shock
- Intubation
- DNR/DNI
- Resuscitation

Use echocardiography

Assess the vascular status

7

The (optimal) Impella implantation setting
 – It doesn't need much to implant the device ;-)

Cath lab Hybrid OR OR CCU/ ICU

Fluoroscopic guidance

TOE guidance for implant

8

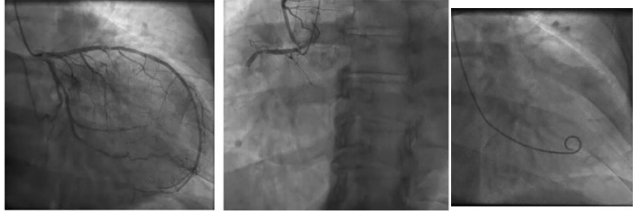
*Mechanical circulatory support devices...
– It's getting boring...*

**Educative cases:
Let's discuss!**

9

*A case example
– The acute heart failure patient...*

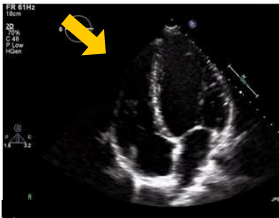
45 y/o male, SOB NYHA IV, acute heart failure (LVEF 20%)



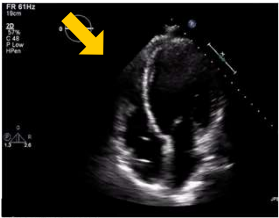
10

*Why do we need "protection" or "support" for PCI
– Protected PCI?!*

Who needs support?



Normal heart function

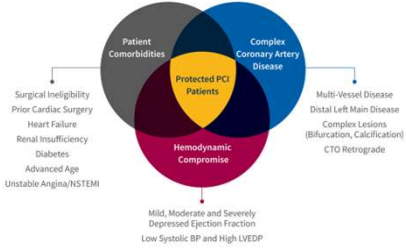


Severely depressed LV function

11

Case selection for protected PCI

**Complex & High-Risk Patients
Appropriate for Protected PCI**



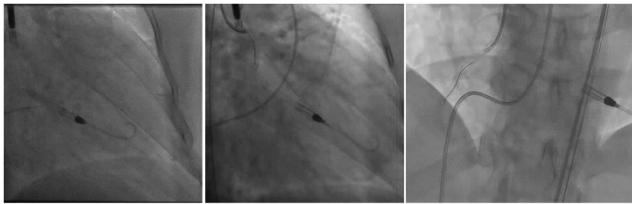
Protected PCI Patients

- Complex Coronary Artery Disease:** Multi-Vessel Disease, Distal Left Main Disease, Complex Lesions (Bifurcation, Calcification), CTO Retrograde
- Hemodynamic Compromise:** Mild, Moderate and Severely Depressed Ejection Fraction, Low Systolic BP and High LVEDP
- Other factors:** Surgical Ineligibility, Prior Cardiac Surgery, Heart Failure, Renal Insufficiency, Diabetes, Advanced Age, Unstable Angina/NSTEMI

12

A case example
 – The acute heart failure patient...

45 y/o male, SOB NYHA IV, acute heart failure (LVEF 20%)

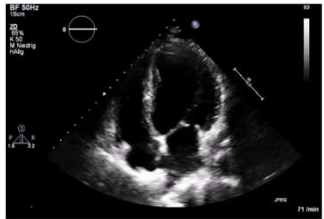


13

A case example
 – The acute heart failure patient...

1.5 years later...

1. No more SOB (NYHA I).
2. Normal daily functioning
3. Recovery of heart function

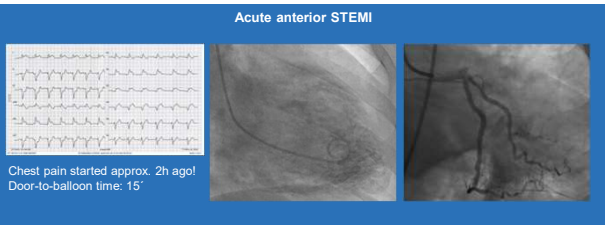


14

▪ A CONTEMPORARY STEMI CASE...

60 y/o female with diabetes & anterior STEMI

Acute anterior STEMI

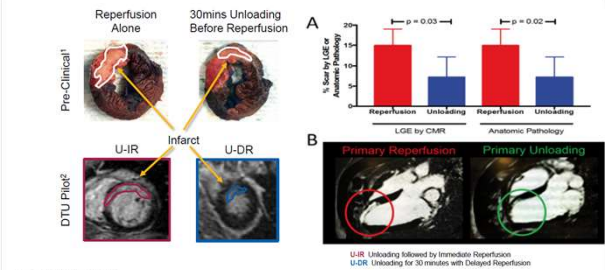


Chest pain started approx. 2h ago!
 Door-to-balloon time: 15'

No previous MI – BP 110/80mmHg; HR 90pbm – Cold clammy; Lactate 1.8mmol/L

15

▪ VENTRICULAR UNLOADING IN STEMI
 – SUCCESSFUL TRANSLATION FROM PRE-CLINICAL SCIENCE TO PATIENTS



A

Method	% Scar (LGE or Anatomic Pathology)
Reperfusion	~15
Unloading	~8
Reperfusion + Unloading	~15
Unloading	~8

B

Primary Reperfusion (DTU Photo) vs Primary Unloading (DTU Photo)

U-IR: Unloading followed by Immediate Reperfusion
 U-DR: Unloading for 30 minutes with Delayed Reperfusion

1. Egeleski M, et al. JACC. 2018
 2. Nagueh SF, et al. Circulation. Ahead of Print. 2018, 10.1161
 3. Prasad MS, et al. JAMA. 2014

Copyright: Elsevier

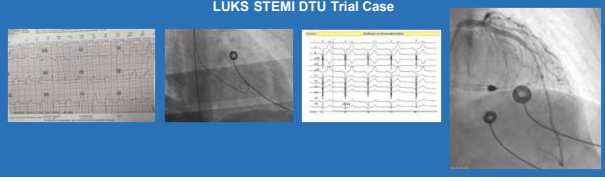
16

• MY STEMI-DTU TRIAL EXPERIENCE – IS IT FEASIBLE?

63 y/o gentleman with acute anterior STEMI

No previous MI – No comorbidities – BP 105/70mmHg; HR 60bpm – No evident shock

LUKS STEMI DTU Trial Case



Chest pain approx. 1.5h ago!
Door-to-unloading time: 20'

→ Chest pain free after 5'!
ST-resolution!


→ PCI to LAD - 10'

17

The tale of a young patient with refractory VF
– 37 y/o male with chest pain & VF

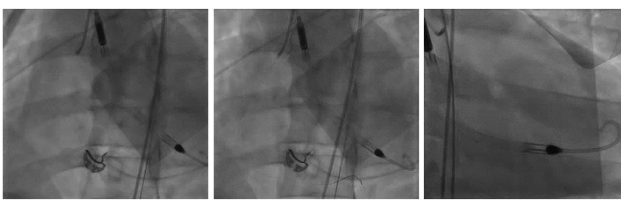
- Previously healthy; smoker
- Chest pain → Witnessed cardiac arrest; VF
 - Down time 0'; professional CPR in the field 40'
 - Refractory VF; >15x defibrillation
 - Cath lab transfer (with AutoPulse®)
 - Profound shock (SCAI E); Lactate 24mmol/L

What's next?



18

The tale of a young patient with refractory VF
– Inferior STEMI with VF

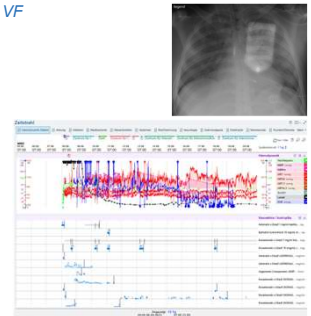


eCPR with Impella?!

19

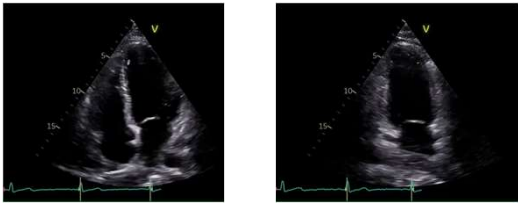
The tale of a young patient with refractory VF
– Further course...

- Collateral damage:
 - Abdominal compartment syndrome → Urgent laparotomy
 - Compartment syndrome of all 4 extremities
 - AKI → Hemofilter required
 - DIC / bleeding
 - Critical illness polyneuropathy
 - Prolonged weaning...
 - But evidence for neurological recovery...
- Multiple surgical interventions ...
- Impella support for 48h → Surgical removal



20

The tale of a young patient with refractory VF
 – Further course... (part 2)



- **Course of recovery:**
 - Neuro-rehab for CIP
 - Dialysis stopped
 - Recovery of LV-function

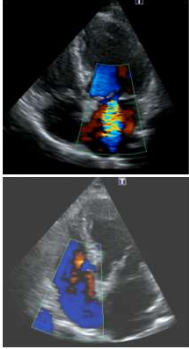
21

Case vignette

76yo female

- **Severe MR** – myxomatous degeneration of MV, posterior prolapse
 - Progressive SOB (NYHA II-III)
 - Paroxysmal Afib
 - Normal LVEF, normal coronaries
 - sPAP at rest 35mmHg; exertion >50mmHg

Heart team decision: Surgical MVR

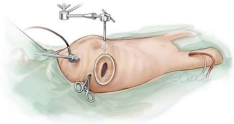
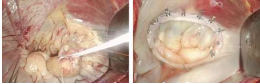


22

The surgical procedure
 – Minimal invasive MVR using anterolateral thoracic access

The surgical procedure:

- Anterolateral access
- Implantation of Physio™ II ring, neochordae x1
- Closure of clefts and indentures
- *Anatomically challenging, but successful procedure!*

Procedure recordings:

- Procedure duration: 6:53h
- Bypass time: 111'
- Aortic cross clamp time: 225'
- Reperfusion time 64'
- Hypothermia 28°C

Khalilguyen et al. Minimally invasive mitral valve surgery is associated with a low rate of complications. J Thorac Cardiovasc Surg. November 2019; Page 614-620


23

Further course: Rapid deterioration
 – „Things are about getting worse...“

What's next?

- **Upon arrival on ICU:**
 - Hemodynamically unstable
 - Sliding demand of catecholamines
 - Rapid Afib, LVEF 10%
 - PEA → Resuscitation

This patient needs urgent SUPPORT!



24

Postcardiotomy shock (PCS) requiring hemodynamic support
 – Which device helps us most?

**What's next?
 What are the options?**

25

Our case – Emergency management
 – „Taking the evacuation route“

- Urgent angiogram
- Transfemoral implantation of Impella™ CP

26

Our case – How did the patient do in hospital?
 – Did things smoothen out?

- LV unloading with Impella™ device: 5 days
- Recurrent rapid Afib requiring ECV
- Surgical site bleeding/ hemothorax
- ICU/ IMC discharge after 13 days
- In hospital stay: 24 days
- At discharge: LVEF 25%, mild MR

27

Our case – Long-term follow-up
 – Three years later...

- Prior to hospital discharge: LVEF 30%
- 2 months after MVR: LVEF 40%
- 3 years later: LVEF 50-55%, mild-moderate MR
- Patient is fine and active (NYHA I)

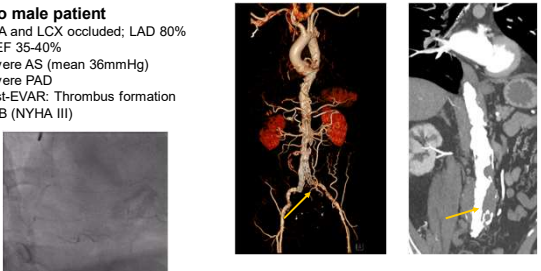
Aim: Patients should not just survive; we should also aim for myocardial protection & recovery!

28

Case vignette: Severe PAD, CAD and AS
 – A hostile trias

76 y/o male patient

- RCA and LCX occluded; LAD 80%
- LVEF 35-40%
- Severe AS (mean 36mmHg)
- Severe PAD
- Post-EVAR: Thrombus formation
- SOB (NYHA III)



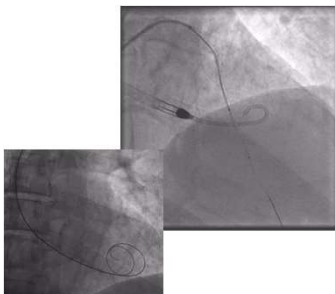
29

Case vignette: Severe PAD, CAD and AS
 – A hostile trias

Management:

→ **Left axillary access**

- Surgical cutdown / sheath insertion (14F)
- BAV using TrueFlow™ Balloon (18mm)
- Impella CP Smart Assist advancement
- Single access / 6F sheath for guider
- LAD PCI (1xDES)
- Surgical device removal / access closure




30

Why do we need alternative access routes for Impella implantation?
 – There is no one size fits all!

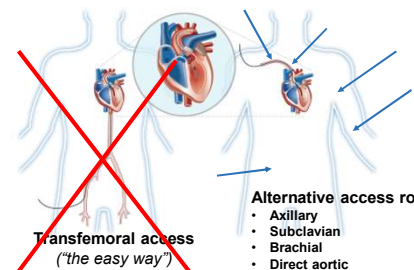
Possible factors requiring alternative access:

- Peripheral artery disease (PAD)
- Aortic ulcers or thrombi
- Tortuosity of the femoral/ iliac arteries
- Elongation of the aorta
- (Post-EVAR)
- Morbid obesity (BMI >35-40kg/m²)
- Prolonged support requirement expected (e.g. >1 week)
- ...



31

Alternative access routes for Impella implantation
 – What options do we have?



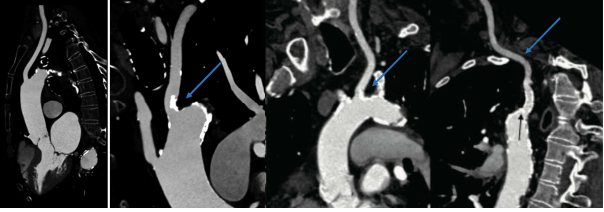
Transfemoral access
 ("the easy way")

Alternative access routes:

- Axillary
- Subclavian
- Brachial
- Direct aortic
- Transcaval

32

Factors prohibiting transaxillary/subclavian access for Impella implantation
– Atherosclerosis along the subclavian artery



LIMA-LAD-Graft

Cardiovascular Diagnosis and Therapy, Vol 12, No 1 February 2020

33

Implantation of an Impella device requires team effort
– Get everybody involved

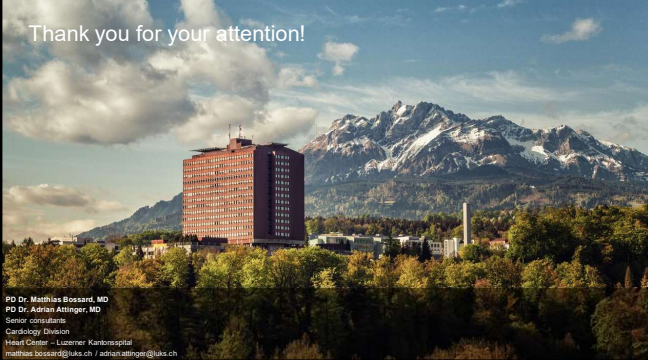
Teamwork! **Train your staff!**

34

Questions?
– Get involved ... ☺

35

Thank you for your attention!



PD Dr. Matthias Bossard, MD
PD Dr. Adrian Attinger, MD
Senior consultants
Cardiology Division
Heart Center – Luzerner Kantonsspital
matthias.bossard@kss.ch / adrian.attinger@kss.ch

36

Access closure following Impella support
– It's so simple :-)

Access closure	Outcomes
MANTA® device (n=31)	MANTA® vs. manual compression
Manual compression (n=56)	Successful MANTA deployment: 29 cases (93.5%)
	Immediate hemostasis: 90.3% vs. 60.7%*
	VARC bleeding (overall): 6.5% vs. 39.3%*
	VARC vascular complications: 16.1% vs. 21.4%
	All-cause death: 22.6% vs. 19.6%

Casali et al. Scientific Reports | (2022) 12:14060

37

A challenging scenario: Morbid obese patient in need for MCS support
– Which route should I take?

71 y/o male patient

- 3-v-CAD, LM stenosis
- LVEF 30%
- T2DM
- BMI 48kg/m²
- Poor mobility due to osteoarthritis

Which access route would you choose?

Surgical turnaround:
→ Heart team decision: Protected PCI with Impella

38

A challenging scenario: Morbid obese patient in need for MCS support
– How it went...

Percutaneous Impella implant

- US-guidance for puncture
- PCI of LM, LAD, LCX
- Planned access closure using MANTA™ device

MANTA™ device does not seal puncture site
→ 8-10cm tissue in-between

Massive bleeding → Crossover using balloon occlusion does not seal access site

Urgent surgical repair necessary

39

▪ WIESO BRAUCHT ES BEI EINER PCI "PROTECTION" ODER "SUPPORT"?


2 Szenarien:
Patient mit schlechter Herzfunktion & komplexer KHK

"Quick & Dirty" – Minimalistische PCI **PCI mit Pumpen-Unterstützung**

40

• WIE GEHEN WIR VOR BEI DER PROTECTED PCI?

Planung und Vorbereitung sind essentiell!



1. *Aktenstudium und Aufklärung!*
(Begleiterkrankungen & Patientenwünsche sind zentral)
2. *Abklärung und Früherkennung von Problemen*
(mit Labor, Ultraschall, CT uvm.)
3. *Teamwork* → Unterstützung durch andere Fachdisziplinen (Anästhesie, IPS, Herzchirurgie, Gefäßchirurgie, uvm.)
4. *Material* → Ultraschall, Impella, (ECMO), Drähte, Ballone, Rotablator, Imaging uvm.

Teamwork!

45

• WIE GEHEN WIR VOR BEI DER PROTECTED PCI?

Planung und Vorbereitung sind essentiell!





Teamwork!

46

• EIN FALLBEISPIEL...

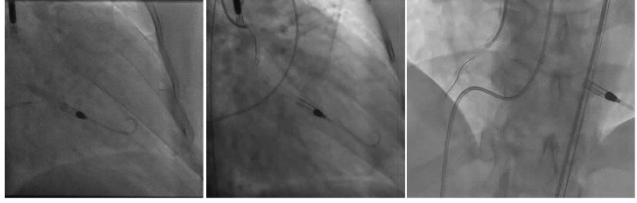
45 jähriger Patient mit schwerer Atemnot und schlechter Herzfunktion:
Wie weiter?



47

• EIN FALLBEISPIEL...

45 jähriger Patient mit schwerer Atemnot und schlechter Herzfunktion:
Was wir gemacht haben...



48

• EIN FALLBEISPIEL...

45 jähriger Patient mit schwerer Atemnot und schlechter Herzfunktion:
Wie ging es weiter?

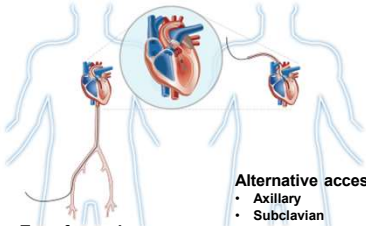
Knapp 1 Jahr später:

1. Keine Atemnot mehr.
2. Normale Belastbarkeit
3. Erholung der Herzfunktion!



49

Access site selection
– Anticipate support duration



Transfemoral access
("the easy way")


Alternative access routes:

- Axillary
- Subclavian
- Brachial
- Direct aortic
- (Transcaval)


50

Toolbox for a (regular) Impella™ implantation
– What do we need?

Access tools:




Needle and sheaths




Ultrasound with vascular


Impella accessoires:




Impella CP with SmartAssist Introducer Kit



Impella Axillary Insertion Kit

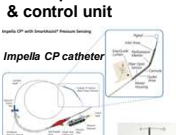


Dextrose Solution




Placement Guidewire


The Impella device & control unit



Impella CP catheter



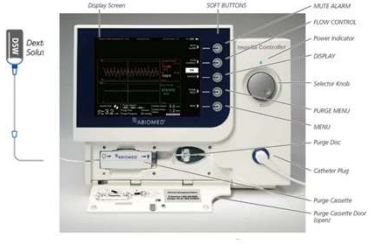
Purge Cassette



Controller unit

51

Setting up the Impella™ device
– Connect all the wires and tubes correctly



Set-up Configuration of the Automated Impella Controller, Impella CP with SmartAssist

<https://www.kia.go.jp/medica/143767/download>

52

Implantation of an Impella device requires team effort
– Get everybody involved

Teamwork!

Train your staff!

53

Questions?

– Get everybody involved...

54

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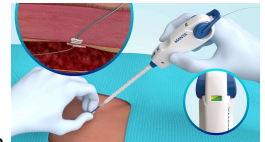
→ Heart team decision: Protected PCI with Impella

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Urgent surgical repair necessary

56

Right heart failure & MCSD
 – A complex state, which needs to be recognized rapidly

Definition of RHF
 (i.e. ≥ 2 criteria) despite continuous infusion of high-dose inotropes* and any of the following:
 • CO* <math>< 3.5</math> l/min/m<sup>2²
 • CVP/ICVP > 0.20 or
 • Evidence to severe global RV dysfunction on echocardiography defined as one of the following criteria:
 • Global RV hypokinesia
 • TAPSE score of ≤ 16 mm
 • RV diameter at base >math>40</math> mm
 • RV short axis (or mid-cavity) diameter >math>35</math> mm</sup>

https://www.thoraxtimes.com/right-ventricular-dysfunction

57

Right heart failure & MCSD
 – Clinical signs and biochemical markers of RV failure

Clinical signs	Biochemical markers
Hypoxaemia	Increased lactate levels
Signs of systemic congestion	Elevated natriuretic peptides (BNP or NT-proBNP)
Jugular venous distension, hepatojugular reflux	Elevated cardiac troponin I or T
Peripheral oedema, pericardial effusion, congestive hepatosplenomegaly, ascites, anasarca*	Abnormal liver biochemistry (e.g. elevated transaminases, bilirubin, prolonged prothrombin time)
Signs of right ventricular dysfunction	Abnormal renal function (blood urea nitrogen, creatinine)
Third heart sound, systolic murmur of tricuspid regurgitation, hepatic pulse, signs of concomitant left ventricular dysfunction	D-dimer levels [†]
Paradoxical pulse	
Signs of low cardiac output state	
Hypotension, tachycardia, cool extremities, central nervous system abnormalities, oliguria	

Hepdal et al. European Journal of Heart Failure (2016) 18, 235–241

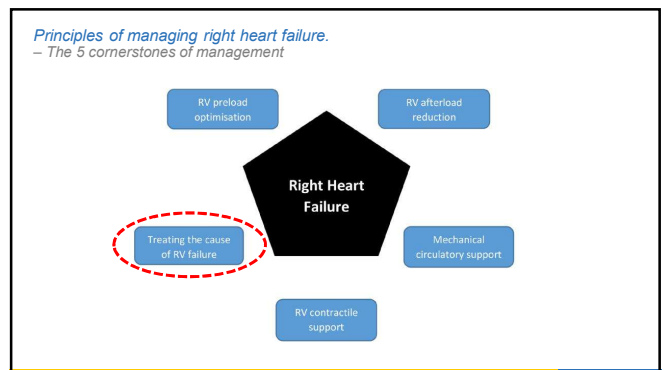
58

Right heart failure & MCSD
 – Causes of acute RV failure

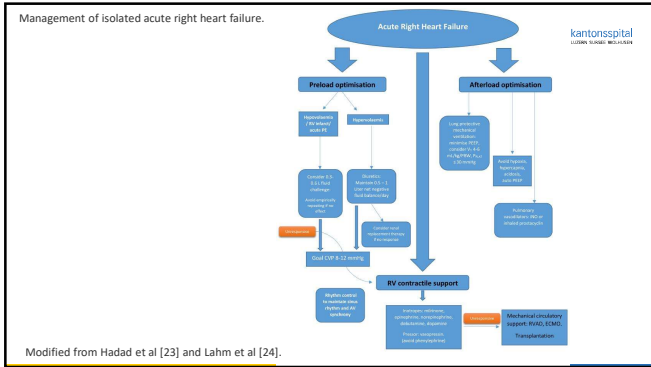
- Acute left ventricular failure
- Right ventricular ischaemia/infarction
- Acute pulmonary embolism
- Exacerbation of chronic lung disease and/or hypoxia
- Acute lung injury or respiratory distress syndrome
- Sepsis
- Chronic pulmonary hypertension (groups 1–5)
- Pericardial disease (tamponade)
- Arrhythmias (supraventricular or ventricular tachycardia)
- Congenital heart disease (e.g. atrial or ventricular septal defect, Ebstein's anomaly)
- Valvulopathies (e.g. tricuspid valve regurgitation, pulmonary valve stenosis)
- Cardiomyopathies (e.g. arrhythmogenic right ventricular dysplasia, familial, idiopathic)
- Mycarditis or other inflammatory diseases**
- Cardiac surgery** (e.g. cardiac transplant or left ventricular assist device implantation)
- Haematological disorders (e.g. acute chest syndrome in sickle cell disease)

Hepdal et al. European Journal of Heart Failure (2016) 18, 235–241

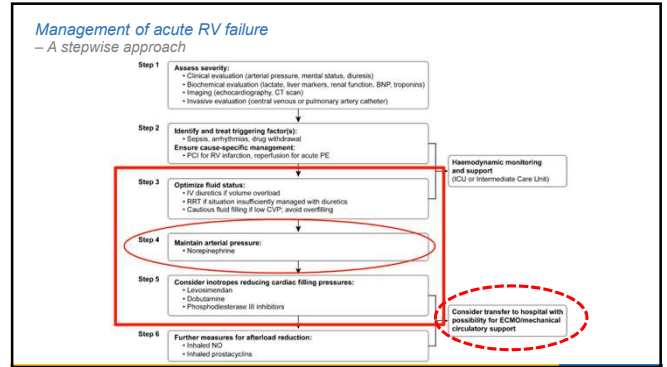
59



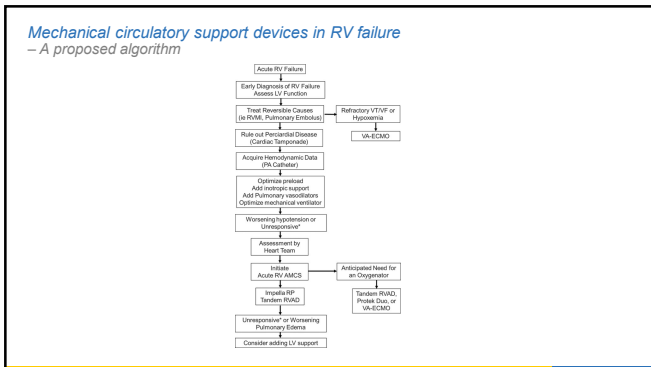
60



61



62



63

Mechanical circulatory support devices for RV failure – Currently available devices

Device	Mechanism/Configuration	Advantages	Disadvantages	Optimal Use
Protek Duo RVAD (Lea/Novo)	<ul style="list-style-type: none"> Centrifugal flow, extracorporeal Percutaneously implanted Conical dual-lumen cannula 	<ul style="list-style-type: none"> Percutaneously deployed Single access site Blood flow up to 4-5 l/min 	<ul style="list-style-type: none"> May cause SVC syndrome with larger cannula size 	RV failure following durable LVAD implantation
Impella RP (Abbot)	<ul style="list-style-type: none"> Microaxial flow Percutaneously implanted RAVJ to RA blood flow 	<ul style="list-style-type: none"> Percutaneously deployed Single access site Blood flow up to 4.5 l/min 	<ul style="list-style-type: none"> Obligate femoral venous access Risk of thrombosis at lower levels of anticoagulation 	RV failure following durable LVAD implantation
Tandem RVAD (Abbot)	<ul style="list-style-type: none"> Centrifugal flow, extracorporeal Surgically implanted RAVJ to RA blood flow 	<ul style="list-style-type: none"> Blood flow up to 5 l/min Lower rate of red blood cell damage 	<ul style="list-style-type: none"> Surgical implantation 	In combination with venting LVAD use
Veno-arterial ECMO	<ul style="list-style-type: none"> Centrifugal flow, extra-corporeal Percutaneously or surgically implanted RAVJ/SVC to aorta blood flow 	<ul style="list-style-type: none"> Percutaneous deployment possible Emergency/bedside deployment Blood flow up to 3-5 l/min 	<ul style="list-style-type: none"> Intrinsically LV afterload Systemic arterial embolic events Risk of limb ischaemia 	Massive pulmonary embolus or decompensated pulmonary hypertension
HeartMate 3 (Abbot)	<ul style="list-style-type: none"> Centrifugal flow Surgically implanted RAVJ to RA blood flow 	<ul style="list-style-type: none"> Fully implantable device (i.e. dischargeable) Blood flow up to 4-6 l/min 	<ul style="list-style-type: none"> Surgical implantation 	In combination with durable LVAD implantation for dischargeable patient

AVC = inferior vena cava; LVAD = left ventricular assist device; RA = pulmonary artery; RA = right atrium; RV = right ventricle; SVC = superior vena cava.

64

Right Ventricular Support Devices

luzerner kantonsspital
St. Lukes AG Luzern

Current and Emerging Strategies for RV Shock Management in the Setting of RV Infarct - American College of Cardiology (acc.org)

65

Impella™ RP for acute RV failure – Unloading the RV

https://www.abimed.de/prod/impella-rp-impella-rp-impella-rp

66

Impella™ RP for acute RV failure – Patient selection

Clinical conditions in which the Impella RP is not recommended

- Active infection with positive blood cultures
- RA, RV or PA thrombus
- Mechanical valves in the right heart*
- Unrepaired ASD, PFO, or aortic dissection
- PA conduit
- Anatomic abnormalities precluding insertion
- Moderate to severe pulmonary valve stenosis or insufficiency
- Severe pulmonary hypertension (PAPs > 60mmHg)
- Documented DVT and/or presence of IVC filter
- Patients on right-sided support or ECMO
- Allergy or intolerance to contrast
- HIT or sickle cell disease

Allegier et al. Euro. Cardiol. Med. 23 March 2022
See European Agency for the Medicines and Health Products (EMA) website

67

Impella™ devices as a bridge to ... – pVADs as an option to bridge a potentially fatal scenario

Impella™ devices as bridge to:

- RECOVERY
- HTX (L)VAD

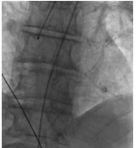
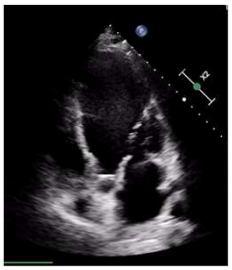
Hegsel et al. European Journal of Heart Failure (2016) 18, 235-241

68

Case vignette: Patient with end-stage heart failure in his early seventies
 – How far should we go?

72 y/o male patient

- Ischemic heart disease
- Cardiogenic shock 2014: LM occlusion
- Multiple coronary interventions
- ICD-implant 2014
- Rather stable for 7 years
- **2021:** Electric storm → Cardiogenic shock

69

Case vignette: Patient with end-stage heart failure in his early seventies
 – How far should we go?

72 y/o male patient

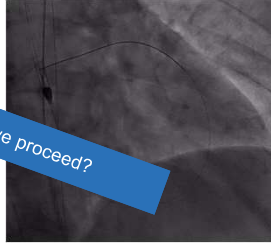
- End-stage HF – electric storm & CS

Meds:

- Amiodarone / sedation
- No effect!

Further course:

- pVAD Support → VT ablation
- Futile VT ablation
- Decision for LVAD implant
- Patient is at home (1.5y later)



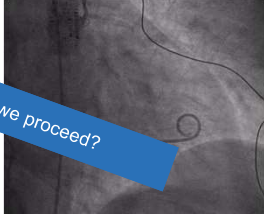
How should we proceed?

70

Case vignette: Late presentation of a STEMI
 – Chest pain for >12hours and now things start to spiral

70 y/o female patient

- Ongoing chest pain for >12 hours
- Anterior Q-Waves and ST-segment depression
- Normal BP (I)
- Lactate 2.2mmol/L, clammy skin



How should we proceed?

71

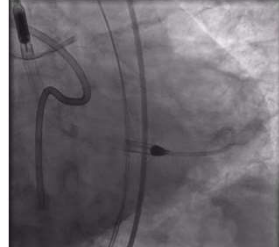
Case vignette: Late presentation of a STEMI
 – Chest pain for >12hours and now things start to spiral

70 y/o female patient

- Cardiogenic shock secondary to MI
- Mechanical support first: Impella CP implantation
- Severe 3-V-CAD (incl. LM disease, occluded LAD)

Proceedings:

- Futile PCI attempt to LAD
- Cardiac tamponade due to LAD perforation ☹️
- PCI of LM/ LCX
- Transfer to ICU



72

Case vignette: Late presentation of a STEMI
– Shock management using Impella – All fine?!

70 y/o female shock patient

- Profound shock – Catecholamines required
- «Insufficient support»

What options do we have?
ECMO? IABP? Impella 5.0/ 5.5?

- Proceedings:
 - Upsize Impella → 5.0 / transsubclavian access
 - 7 days support with Impella 5.0
 - Surgical removal → Transfer to community hospital
 - Hospital discharge after 21 days
 - 3 months FU → LVEF 35-40%; NYHA I-II

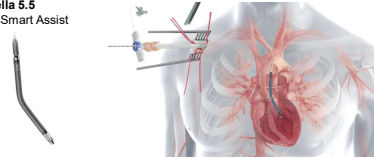


73

Impella™ devices as a bridge to ...
– pVADs as an option to bridge a potentially fatal scenario

- Globally increasing number of patients suffering from advanced heart failure
- No. of patients requiring HTX for end-stage HF is growing
- Global organ shortage!
- pVADs (namely Impella™ devices) as bridge to recovery/ decision!

Impella 5.5
With Smart Assist



74

Conclusions

- The term "stable" CAD should be avoided
- Nonmodifiable and modifiable determine the risk for adverse events in CAD patients.
- Novel antithrombotic regimens, lipid-lowering and inflammation-modifying agents reduce ischemic events.
- Plaque-characterization is important for risk stratification.

75