

Impella Heart Pumps – Home of Heart Recovery

Did you know?

Impella heart pumps can improve clinical outcomes and ease patient management.

Improve quality
of life

1

Increase
survival rate

2

Enhanced product
portfolio

3

Ensure
economical
treatments

4

Contact us

5

 **ABIOMED**[®]

1

2

3

4

5

Quality of life

Improvement for high-risk PCI patients

22 to
29%

Improvement of LVEF

at 90-day follow-up ^{1,2,3}

58 to
76%

Reduction of heart failure symptoms

NYHA Class III/IV symptom improvement in HRPCI patients ^{1,3}

29 to
47%

Fewer adverse events

after 90 days (death, stroke, heart attack and need for further cardiac or vascular operation)^{1,7}

Results and survival

Improvement in cardiogenic shock outcomes

71 to
82%

Improved chances of survival

Best practice protocols in cardiogenic shock and protected PCI (USA, Europe and Japan)^{5,8,11}

13_x

Clinical guidelines

include Impella heart pumps (nationally and internationally)

Up to
2_x

Higher survival rate

for ECMO therapy with Impella unloading (ECpella)⁹



1

2

3

4

5

Product portfolio

Expand technology

10

Product innovations

to improve user-friendliness and patient management

9%

Reduction of the risk of bleeding

through continuous improvements to the technology^{3,13,14,15}

180+

Hospitals already benefit from

Impella Connect®

Ensure economical treatments

10+

World wide

Impella heart pump reimbursement fundings

1 to
14
days

Reduction in length of inpatient stay

for high-risk PCI and cardiogenic shock*

9x

Case Example Germany

In the last 11 years, the use of Impella heart pumps has increased ninefold in Germany.



1

Restore EF Data – Effectiveness of Protected PCI in Patients with and without Impaired EF

Did you know?

The Restore EF study **showed an improvement in LVEF of 29%** compared to the Protect II study's **improvement of 22%**.^{1,2,3}

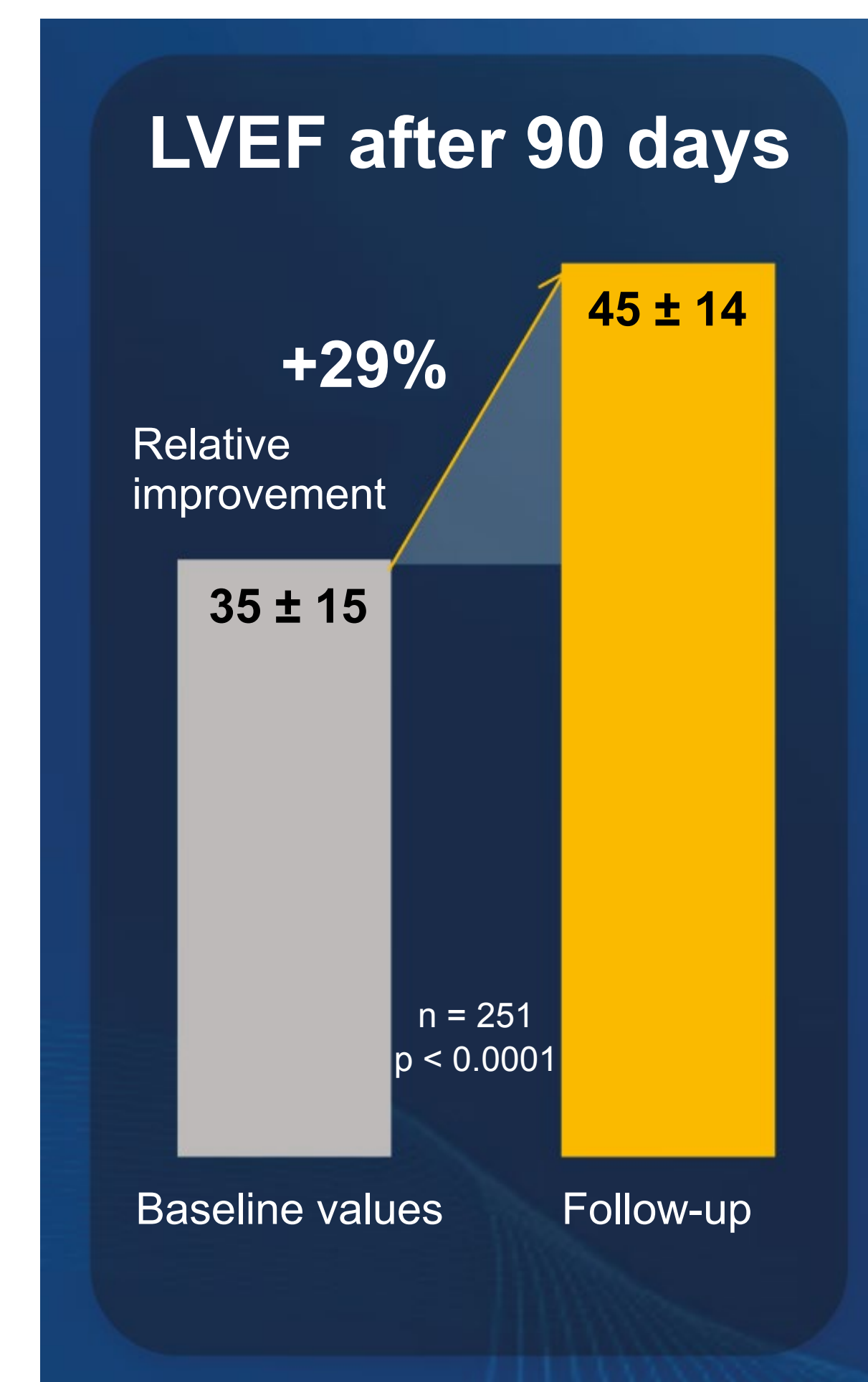
- 29% relative improvement in LVEF, 35% at baseline³
- Increase from baseline to 45% at the 90-day follow-up³
- More complete revascularisation was associated with greater improvement in LVEF

► **Proven LVEF improvement in HRPPI patients supported with Impella heart pumps.**

22 to
29%

Improvement of LVEF

at 90-day follow-up^{1,2,3}



Video



Data and
Sources



1

Restore EF Data – Effectiveness of Protected PCI in Patients with and without Impaired EF

Did you know?

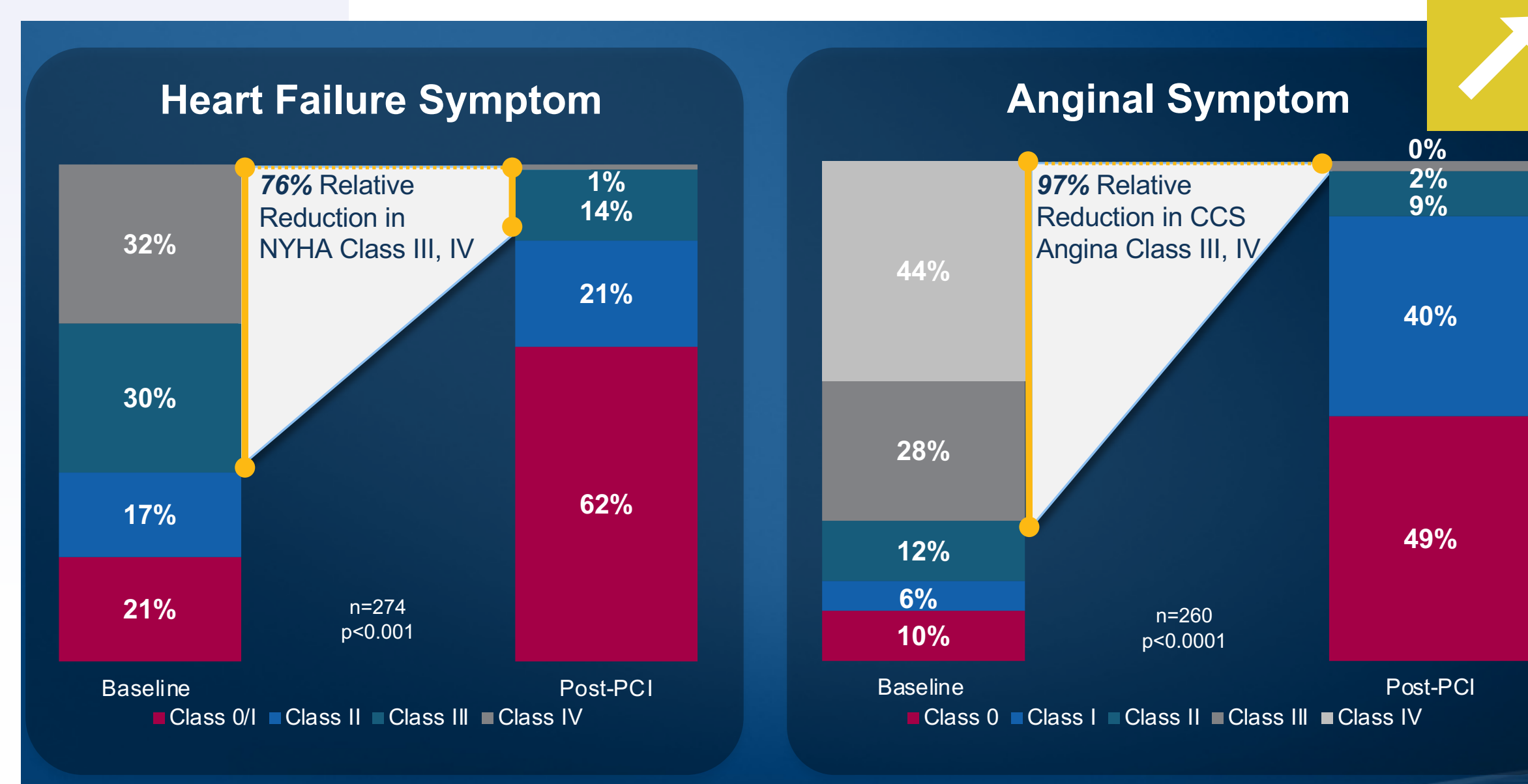
Restore EF was able to confirm the data from the Protect II and Protect III studies once again.

- Protect II showed a **47% reduction in MACCE events** (death, stroke, MI, repeat revascularisation) after discharge compared with IABP^{1,14}
- Newly published Restore EF data provides further evidence of this. Impella pumps supported patients with complex coronary disease, heart failure and angina pectoris showed significant symptom improvement: **76% reduction in NYHA Class III/IV HF symptoms**, 97% reduction in CCS Class III/IV angina pectoris³

58 to
76%

Reduction of heart failure symptoms

NYHA Class III/IV symptom improvement in HRPPI patients ^{1,3}



Video



Data and Sources



Did you know,

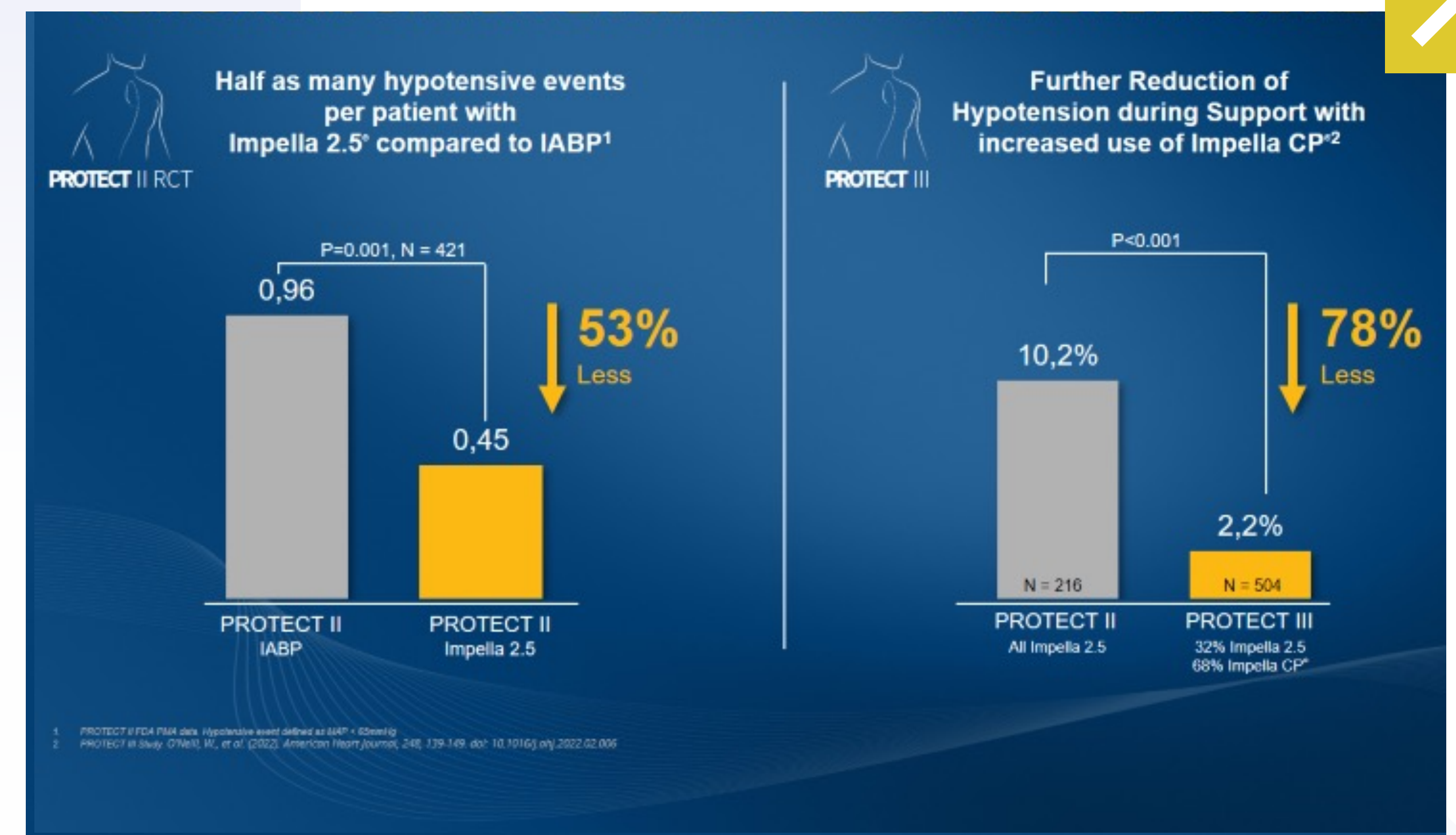
that the complexity of a patient's disease, concomitant diseases and/or haemodynamic compromise may cause the patient to become unstable during the procedure and your revascularisation plan may need to be changed?

- PII and PIII data show that Impella heart pumps ensure that patients are more stable by significantly reducing hypotensive events: **53% fewer hypotensive events compared to IABP in PII; 78% fewer events in PIII**^{14,18}
 - Although patients in PROTECT III were sicker, had more vessels treated and received more extensive revascularisation, the MACCE rate of **15.1% at 90 days was lower than in PROTECT II** (31% MACCE in the IABP arm).^{14,18}
- Haemodynamic stability makes it possible to achieve more complete revascularisation

29 to
47%

Fewer adverse events

after 90 days (death, stroke, heart attack and/or another surgery)^{1,14}



Article



Data and Sources



Did you know?

The clinical guidelines (ESC) changed in 2021 to include the use of short-term mechanical circulatory support (MCS) devices specifically for patients with **advanced heart failure and cardiogenic shock (Class IIa recommendation).**

Other clinical guidelines and **expert consensus documents support the early use of Impella heart pumps.**

13_x

Clinical guidelines

include Impella heart pumps
(nationally and internationally)

CLINICAL GUIDELINES FOR IMPELLA® HEART PUMPS

Cardiogenic Shock & Other Guidelines

2022 AHA/ACC/HFSA Guideline for the Management of HF (J Am Coll Cardiol)

- “Bridge to Recovery” or “Bridge to Decision” for patients with advanced HFrEF and hemodynamic compromise and shock: Class IIa

2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure (EHJ)

- Short-Term MCS should be used in patients with advanced heart failure (INTERMACS profiles 1 or 2) as BTD/BTR/BTB/BTT: Class IIa
- Short-term MCS should be considered in patients with cardiogenic shock as a BTR/BTD/BTB. Further indications include treatment of the cause of cardiogenic shock or long-term MCS or transplantation: Class IIa
- IABP is not routinely recommended in post-MI cardiogenic shock: Class III

2021 EAPCI/ACVC Expert Consensus Document on Percutaneous Ventricular Assist Devices (EuroIntervention)

- Indication for pVAD in AMI without CS: Impella CP use seems feasible as a preventive unloading strategy; IABP is not suggested; VA-ECMO should not be used
- Indication for pVAD in CS: Impella CP may be used as a short-term therapy in CS, stage C and D with potentially reversible underlying cause/transplant/VAD candidates; IABP routine use is not recommended; VA-ECMO may be used as short-term therapy in CS stage C, D and E and for selected patients in refractory cardiac arrest

2020 EACTS/ELSO/STS/AATS Expert Consensus on Post-Cardiotomy Extracorporeal Life Support in Adult Patients (Eur J Cardiothorac Surg)

- Percutaneous/axillary Impella or ECPELLA in severe isolated LV dysfunction: Class IIb
- IABP not recommended for severe LV or bi-V dysfunction in failure CPB weaning: Class III

IMP-3443 v2. Categories referencing Impella Devices include Percutaneous LVAD, PVAD, Non-durable MCS, TCS, and Percutaneous MCS

2019 HRS/EHRA/APHRS/LAHRS Expert Consensus Statement on Catheter Ablation of Ventricular Arrhythmias (Heart Rhythm)

- HF and EP collaboration regarding High-Risk VTA: Class I
- Hemodynamic Support During VTA: Class IIa
- Hemodynamic Support for Unstable VT: Class IIb

2013 ACCF/AHA Guideline for the Management of STEMI (Circulation)

- STEMI and Cardiogenic Shock: Class IIb
- STEMI and Urgent CABG: Class IIa

2013 ACCF/AHA Guideline for the Management of Heart Failure (J Am Coll Cardiol)

- “Bridge to Recovery” or “Bridge to Decision” for patients with acute, profound hemodynamic compromise: Class IIa

2013 International Society for Heart and Lung Transplantation Guidelines for MCS (J Heart Lung Transplant)

- Temporary mechanical support for patients with multi-organ failure: Class I

2012 Use of MCS (Circulation)

- Acutely decompensated heart failure patients: Class IIa

2011 ACCF/AHA/SCAI Guideline for PCI (J Am Coll Cardiol)

- PCI and Cardiogenic Shock: Class I



Video



Study



Data and
Sources



Did you know?

The Impella heart pump can make it possible to achieve a 30-day survival rate of over 80% following AMI in cases of cardiogenic shock.

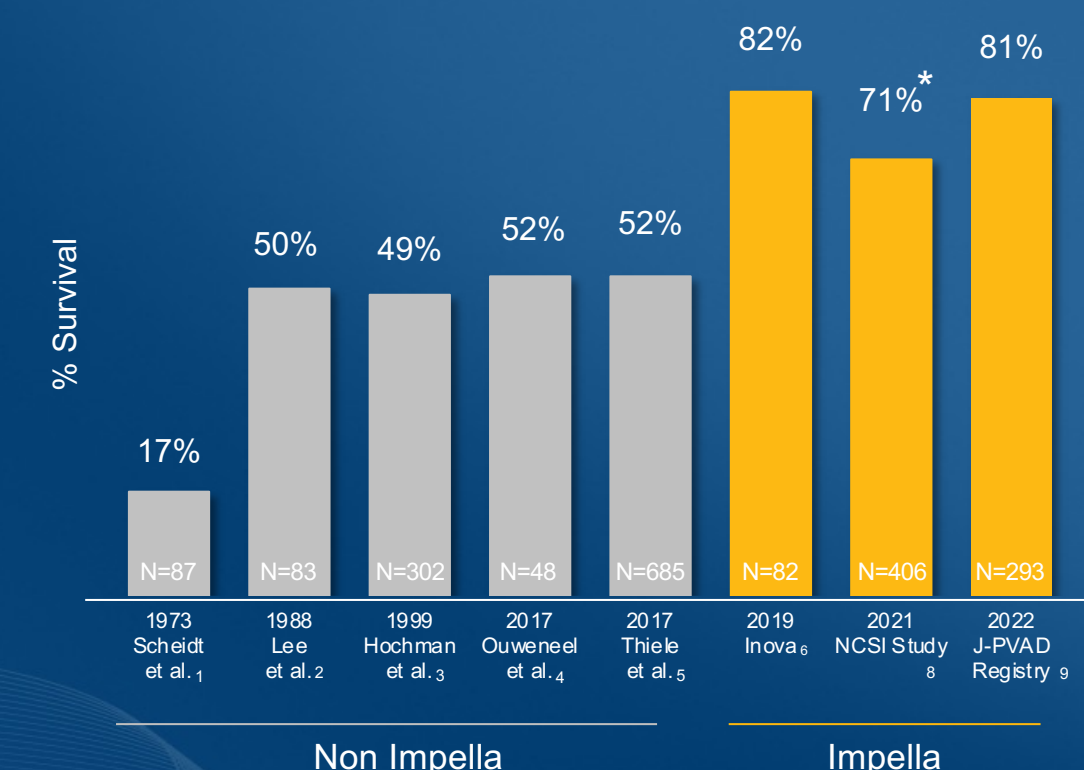
- By implementing **best practice procedures** in all 109 Japanese centres and American centres (cVAD, Inova, NCSI)
- Impella pump support achieved within six hours of shock diagnosis in 80% of AMICS patients ^{5,15,17}

71 to
82 %

Improved chances of survival

Best practice protocols in the USA and Japan ^{5,15,17}

IMPROVED SURVIVAL AND NATIVE HEART RECOVERY INVESTIGATOR-LED AMI CARDIOGENIC SHOCK STUDIES



Best Practice Protocols Include⁶⁻⁹

- Identify CS early and Impella® pre-PCI < 90 mins
- Aggressive down-titration of inotropes
- Identify RV dysfunction early and support
- Identify inadequate LV support and escalate
- Systematic use of RHC to guide therapy

* Survival to discharge⁸ with native heart recovery > 90%⁷

The J-PVAD Registry is a registry of ALL Impella patients in Japan, conducted by 10 Japanese professional societies, including the Japanese Circulation Society (JCS).

1. Scheidt, S., et al. (1973). *N Engl J Med*, 288(19), 979-984
 2. Lee, L., et al. (1988). *Circulation*, 78(6), 1345-1351
 3. Hochman, J., et al. (1999). *N Engl J Med*, 341(9), 625-634
 4. Ouweneel, D., et al. (2017). *J Am Coll Cardiol*, 69(3), 278-287
 IMPRESS in Severe Shock/Cardiac Arrest. ~10% Impella pre-PCI.

5. Thiele, H., et al. (2017). *N Engl J Med*, 377(25), 2419-2432. ~5% with Impella
 6. Tehrani, B., et al. (2019). *J Am Coll Cardiol*, 73(13), 1659-1669
 7. O'Neill, W., et al. (2020). *TCT Connect*
 8. Bassil, B., et al. (2021). *SCAI Scientific Sessions*
 9. Ako, J. (2022). *TCT: AMICS with Impella-only Support*



Data and
Sources



Video



2 Early Unloading Can Improve Survival in Cases of Cardiogenic Shock

Did you know?

Two independent meta-analyses show that the use of ECMO combined with the Impella heart pump (ECpella) can improve the survival of particularly severely ill patients in cardiogenic shock.

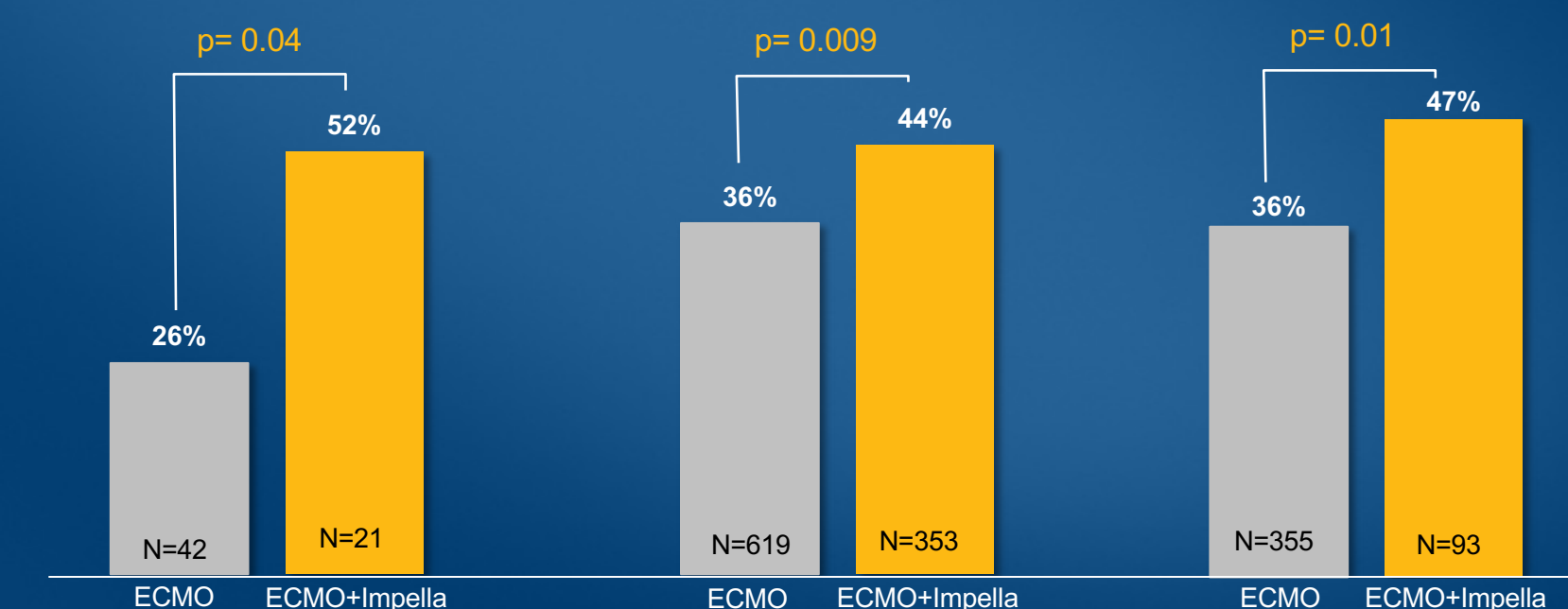
- The data suggest that an ECpella strategy can reduce 30-day mortality and improve left ventricular recovery despite increased bleeding rates compared with an ECMO-only strategy for treating patients in cardiogenic shock.^{16,17}
- Up to **2x higher survival rate** can be achieved in ECMO therapy with early support using the Impella system (ECpella)⁹

Up to
2 x

Higher survival rate

during ECMO therapy with Impella unloading (ECpella)⁹

IMPELLA®+ECMO VS ECMO ALONE IS ASSOCIATED WITH SURVIVAL BENEFIT IN LIFE-THREATENING CS



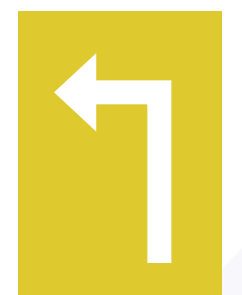
Pappalardo, F. et al. (2016) European Journal of Heart Failure, 19(3), 404–412.



Data and
Sources



Video



Are you familiar with

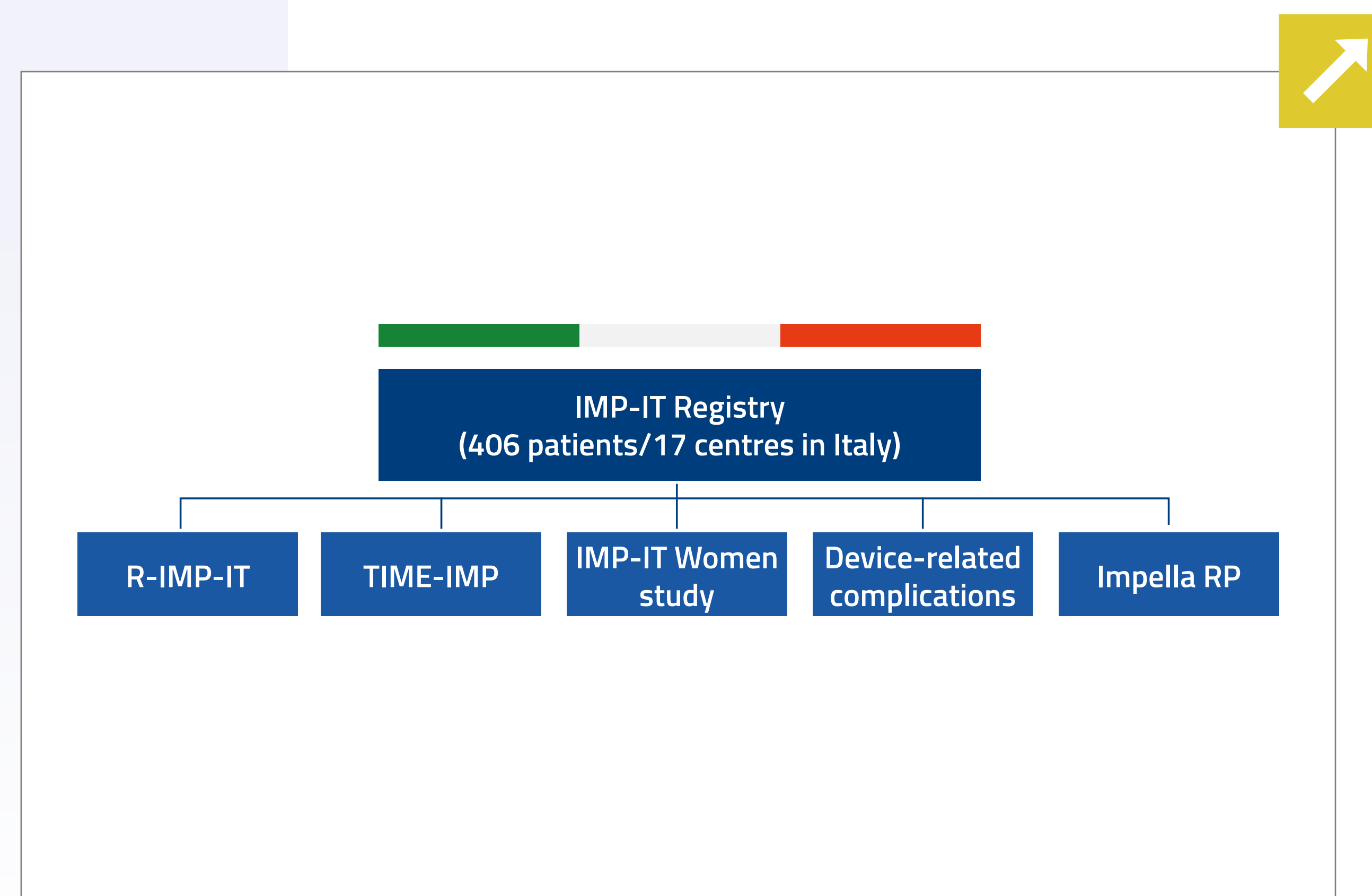
the largest European data series of patients with Impella support, showing real-life data on the use of Impella heart pumps in recent years?¹⁹

▶ In the Italian IMP-IT Registry, Impella was used in more than half of cardiogenic shock patients and, in most cases, the cause was AMICS.

- Early insertion of the Impella heart pump was associated with an improvement in 1-year survival in patients with AMI-CS

▶ Of these, 297 patients from this registry were re-evaluated for the extent of revascularisation (R-IMP IT).²⁰

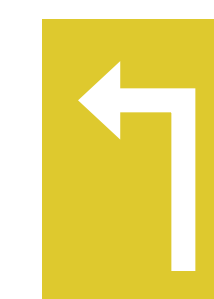
- More extensive revascularisation during Impella Protected PCI (revascularisation index (RI) ≥ 0.67) is associated with a **significant reduction** in the primary endpoint (high-risk PCI and patients with cardiogenic shock)



Data and
Sources



Study
Overview



Do you know,

how to optimize the use of Impella heart pumps in high-risk PCI patients?

„The Heart of the Matter: Best practice approach on high-risk percutaneous coronary intervention“ is a publication of 8 articles addressing **patient management** and **mechanical circulatory support** in the intensive care unit.

Procedural steps | Best practices

Patient Selection

- Complex anatomy (LM, MVD, long lesions, calcification ...)
- HFrEF or HFmrEF with hemodynamic relevant valve disease
- Co-morbidities (age, diabetes, renal failure, frailty ...)
- Surgical turn-down
- Patient preference

Anticoagulation

- Monitoring
 - Check ACT every 30 min (target: >250s)
 - Monitor total anticoagulation (heparine in purge fluid & i.v. heparine)
 - Consider bicarbonate to replace heparine in purge fluid
 - Balance bleeding risk vs. thrombotic risk in special populations (CKD, bleeding disorders)
- Haemolysis prevention (prevent interaction with papillary muscle, septal/valvular structures; check volume management)

Patient handling in the cathlab

- Briefing and debriefing of staff and patient
- Plan, check, adapt interventional strategy
- Monitoring hemodynamics (RHC, LV/RV function, arterial pressure), ECG, hemoglobin, and oxygenation
- Consider weaning after procedure vs. delayed weaning
- Confirm access-site closure: rule-out dissection, bleeding, fistula by angiography and confirm adequate limb perfusion (duplex sonography) before taking patient off the table

Pre-procedural work up

- Assess and prepare femoral access site: imaging (angiography, vascular US, MRT) and imaging-guided access
- Pre-closure device (suture-based devices highly recommended)
- Assess cardiac function (LV/RV contractility)
- Procedure planning (kidney function, coagulation, strategy)
- Team briefing
- Check materials and know your tool box

Revascularization

- Aim at extensive complete revascularization
 - Residual Syntax Score (rSS) >8
- Aim at high quality of revascularization
 - Lesion preparation (imaging, debulking)
 - Stent optimization (imaging)
- Consider single vs. staged procedure (contrast volume, radiation, renal insufficiency, patient condition)

Bailout- and complication management

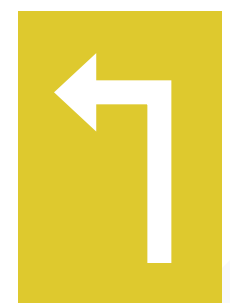
- Best complication management is prevention
- Standards of operations established & in place for major complications
- Be prepared for hemodynamic deterioration with cardiogenic shock despite MCS; access-site complications & bleeding, non-access site bleeding, vessel perforation, vessel thrombosis, dissection



Supplement
Site



Data and
Sources



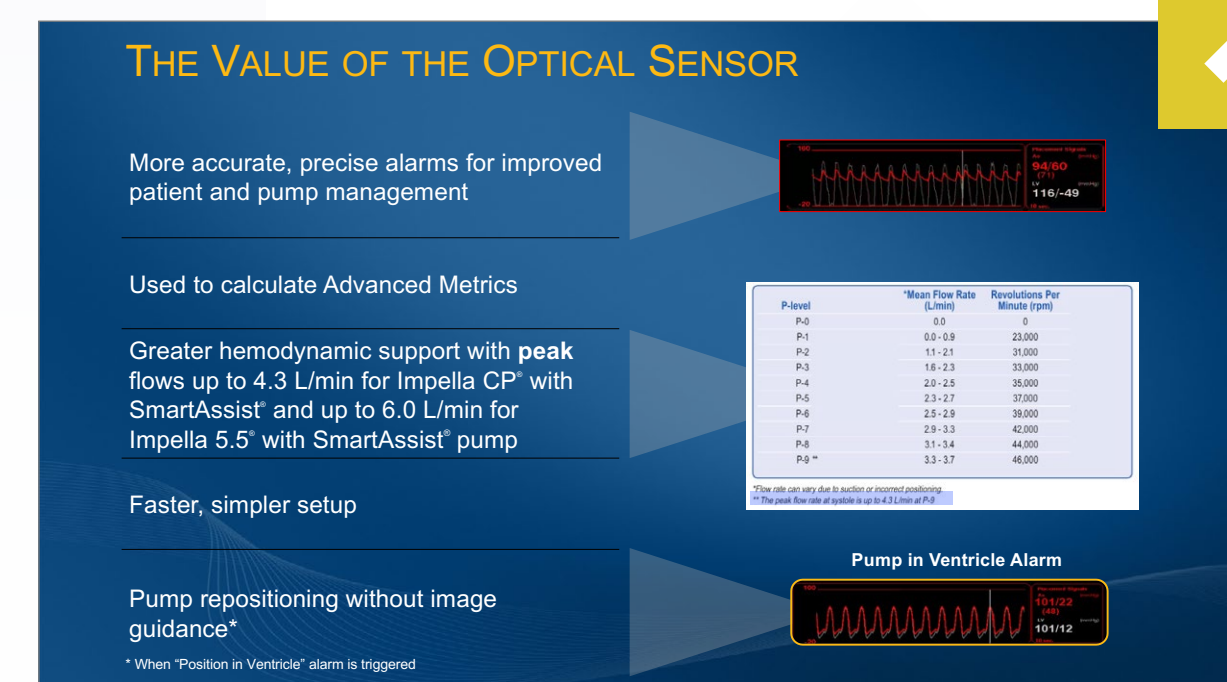
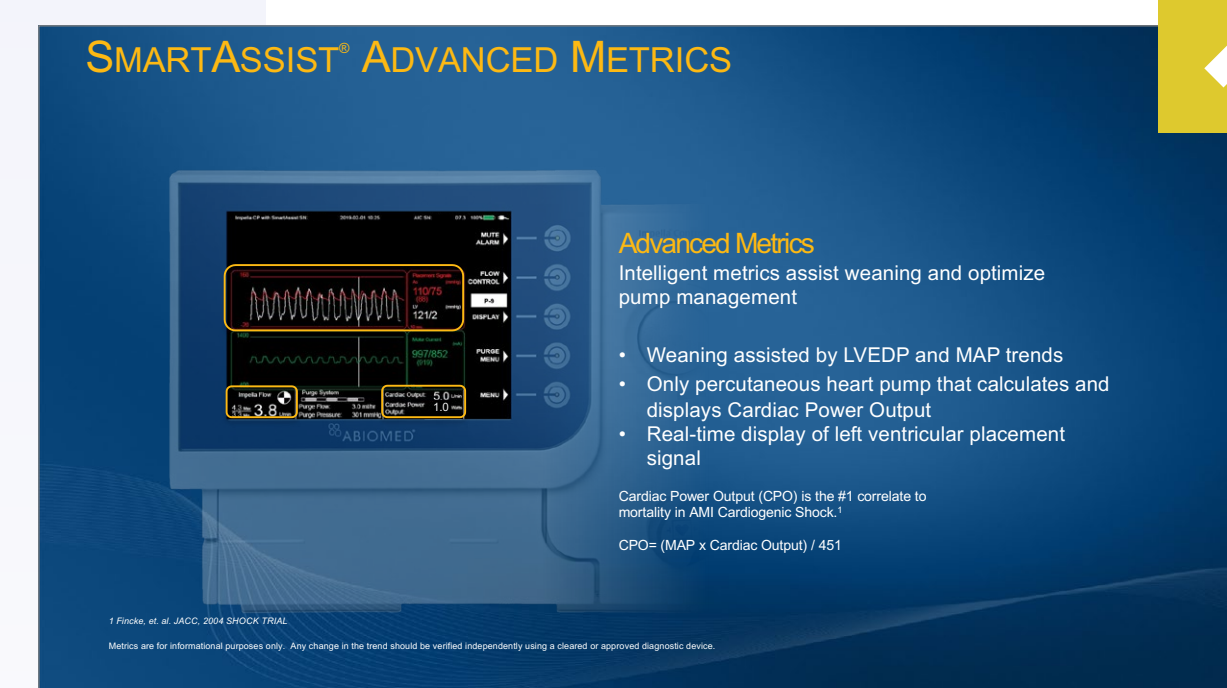
3 10 Product Innovations – Improving Patient Outcomes through Optimised Process Technologies

Did you know?

SmartAssist technology uses sensors on the heart pump to assist with positioning, management and weaning to improve patient outcomes.

Innovative product development: improving clinical outcomes with the SmartAssist platform

- **Market launch of Impella CP® with SmartAssist® and Impella 5.5® with SmartAssist®:** Both pumps offer the possibility of providing better support and repositioning without the need for imaging. Patient outcomes are improved using real-time data.
- **Advanced key indicators:** Additional smart metrics are now available on the Automated Impella Controller, such as left ventricular waveform and cardiac output information. These additional insights help to optimise pump and patient management.
- **Optical sensors:** The advantage of the optical sensor is that it provides more accurate alarms and better haemodynamic support due to its new position. It is used to calculate the advanced metrics, facilitates a faster and easier set-up and allows the pump to be repositioned without imaging assistance in the event of an alarm.



Video



Impella
Connect



Did you know?

Impella Connect provides secure, cloud-based remote monitoring of Impella status for its entire duration of use.

The system helps improve patient outcomes by using real-time intelligent data to optimise Impella positioning and handling, as well as weaning from the Impella system, all for better patient care.

In the process, the AIC transmits information to the cloud 24 hours a day so that the user can also respond better to patients' needs remotely.

180+

Hospitals already benefit from
Impella Connect® system

**1
of
6**

**hospitals using Impella
Connect**

is a university hospital

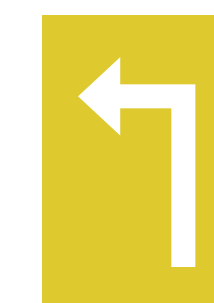
24/7

**On-demand support
from Abiomed**

at any time and from anywhere



**Impella
Connect**



Did you know?

The goal of the SmartAssist platform is to improve clinical outcomes through continuous optimisation and improvement of therapy.

- **Single access and tapered dilator:** fewer (bleeding) complications by reducing and minimising the number of access sites. The extended conical tip of the dilator facilitates catheter insertion, reduces the risk of blood loss during insertion and increases ease of use.
- **Y-connector removal and peel-away lock:** facilitates easy handling throughout the entire period of use
- **Heparin-free purge solution:** Ensures a higher level of independence in terms of anti-coagulation management and reduces heparin-associated risks
- **Sidearm retainer:** protects the side arm and allows for better mobilisation of the patient in prolonged cases and when walking.

10

Product innovations

to improve user-friendliness and patient management



**Heparin-free
Purge Solution**



**Data and
Sources**



3

9% Reduction in Bleeding Risk

Did you know?

The risk of bleeding has been reduced by almost 9% in the last 10 years.^{3,13,14,15}

► The reason for this is the continuous improvements made to our technology, further experience gained and use of best practice procedures, e.g. the single-access procedure:

Reduction in access sites. With this method, a single access site is used for the Impella CP with SmartAssist heart pump and an additional catheter. This leads to a lower risk of bleeding.

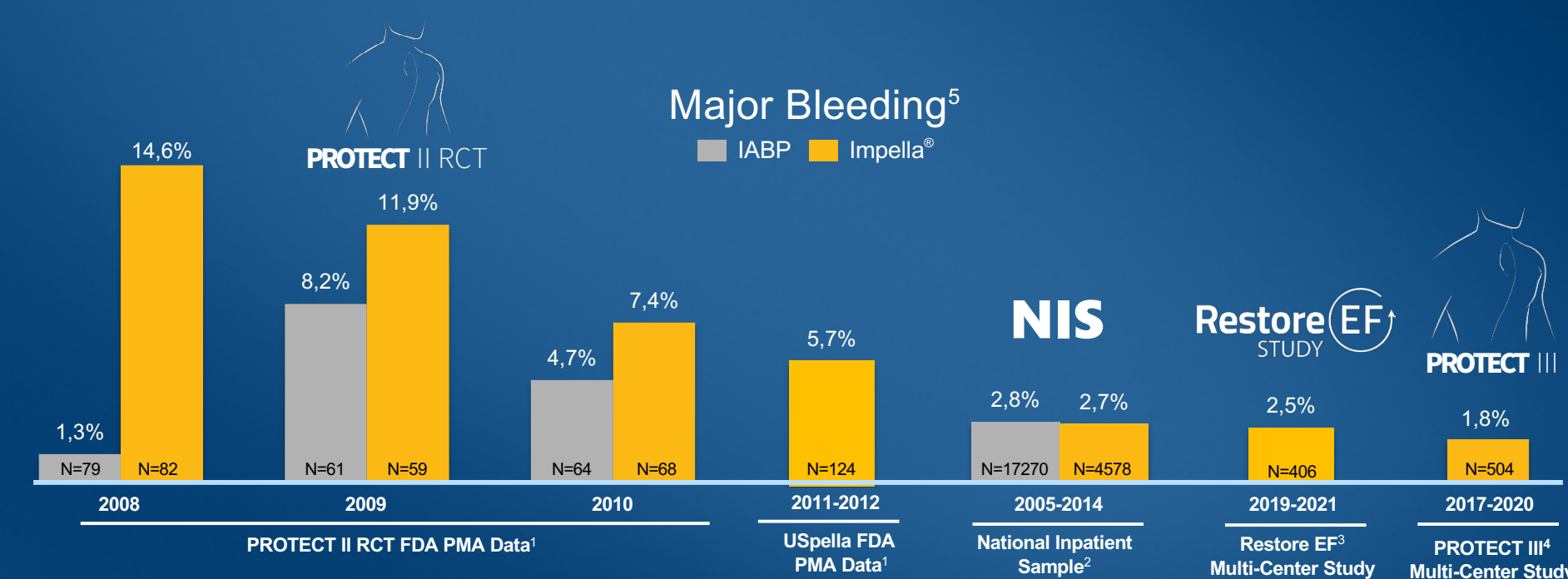
Improvement in treatment for the patient, as the additional sheath can be used to insert other catheters, including interventional devices.

9%

Reduction of the risk of bleeding

through continuous improvements to the technology^{3,13,14,15}

CONTINUOUS SAFETY IMPROVEMENT OVER TIME IN HIGH-RISK PCI



Continuous improvement with innovation, experience and best practices

1. FDA PMA Submission, Data on file (bleeding requiring transfusion)
2. Al-Khadiji, Y., et al. (2020). Catheter Cardiovasc Interv. 95(3), 503-512.
3. Wolmut, J., Patel, M., et al. (2022). JSCAI, 100350. <https://doi.org/10.1016/j.jscai.2022.100350>.
4. O'Neill, W., et al. (2022). American Heart Journal, 248, 139-149.
5. Available USA publications and FDA studies with device-specific major bleeding rates or bleeding requiring transfusion



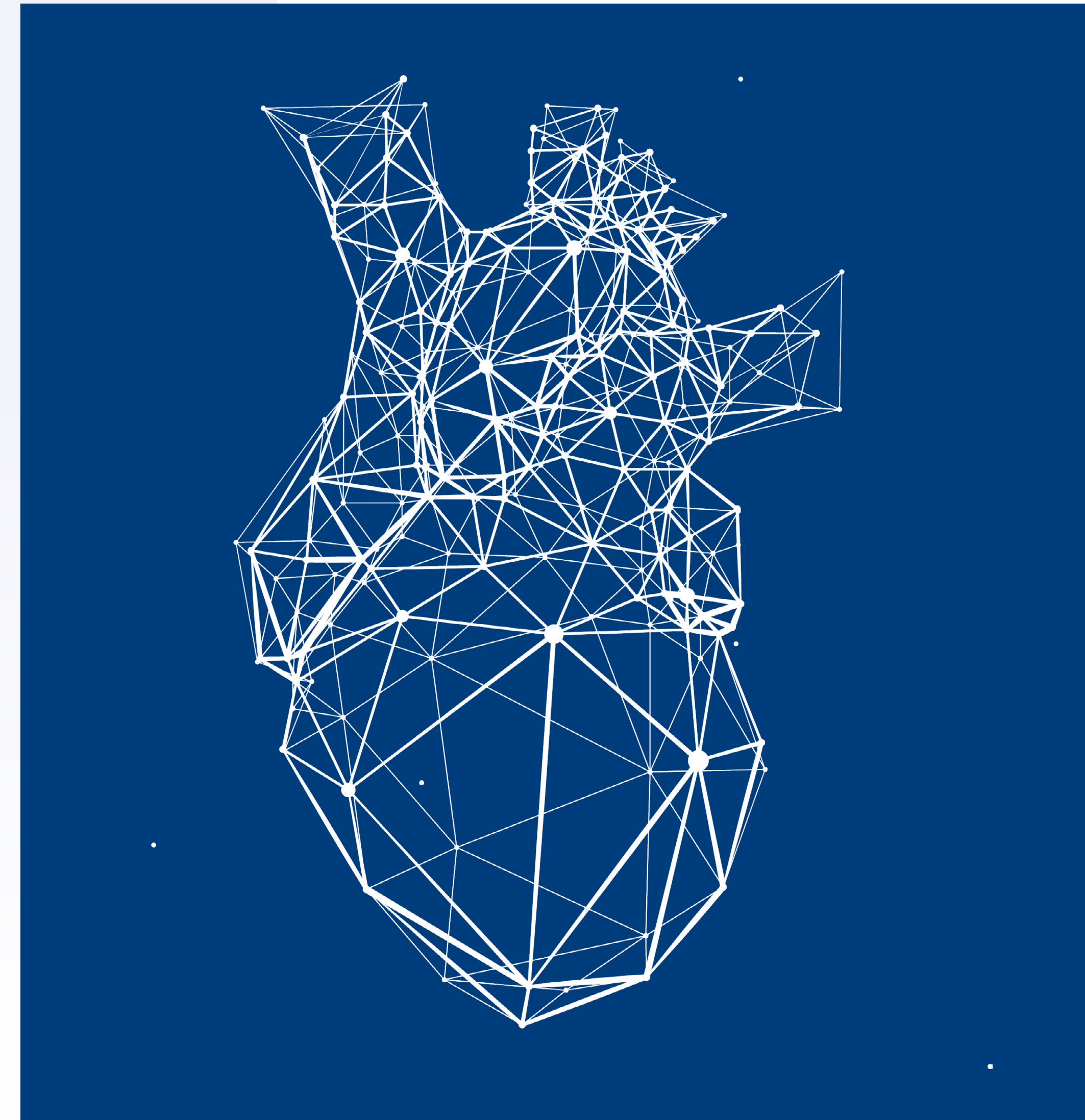
Video



Did you know?

We are always developing our portfolio to achieve the best results for our patients and users.

- **Impella CP with SmartAssist – the next generation:**
continuous improvement of the user experience through faster pump set-up and material optimisation of the pigtail for improved flexibility and associated reduction of bleeding risks
- **Smart pumping:**
Integrated diagnostics for precise pump and patient management
- **Impella Connect® system:**
Expanded and enhanced 24/7 support – on-site, on call, online

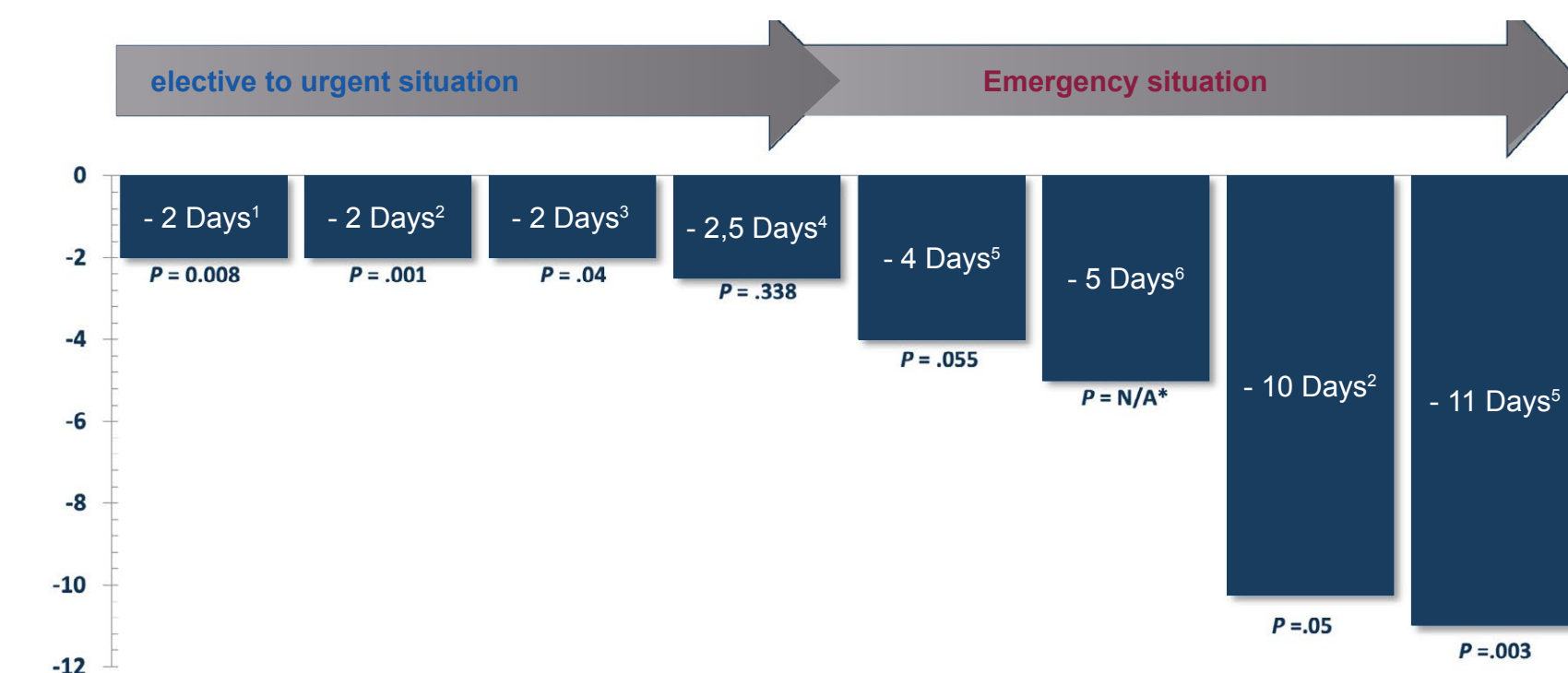


Did you know?

Impella heart pumps can help to reduce inpatient length of stay.

The systematic review by Maini et al. 2014 (Health economics of percutaneous hemodynamic support in the treatment of high-risk cardiac patients: a systematic appraisal of the literature) concluded that, depending on the clinical situation, a reduction in the length of stay could be.

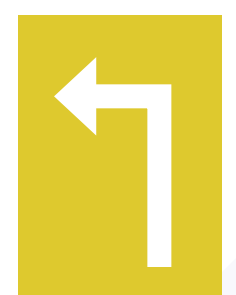
- in the elective setting between 2 and 2.5 days
- in the emergency setting between 4 and 11 days



*not available/not calculated

1. Gregory D, et al. *Am Health Drug Benefits*. 2013;6(2):88-99.
2. Gregory D, Scotti DJ. *J Manag Care Med*. 2013;16(1):61-69.
3. Aryana A, et al. *Heart Rhythm*. 2014;11(7):1122-1130.
4. Wohns D, et al. *Innovations (Phila)*. 2014;9(1):38-42.
5. Maini B, et al. *Catheter Cardiovasc Interv*. 2014;83(6):E183-E192.
6. Cheung A, et al. *J Am Coll Cardiol*. 2012;60(17 Suppl B):B110. Abstract TCT-385.

Maini, et al. (2014) *Expert Rev. Pharmacoecon. Outcomes Res* 14(3), 403-16.



Did you know?

Current analyses of DRG data from all German hospitals also show that the use of Impella heart pumps reduce the length of hospital stays.

-2.5 days on average across all indications

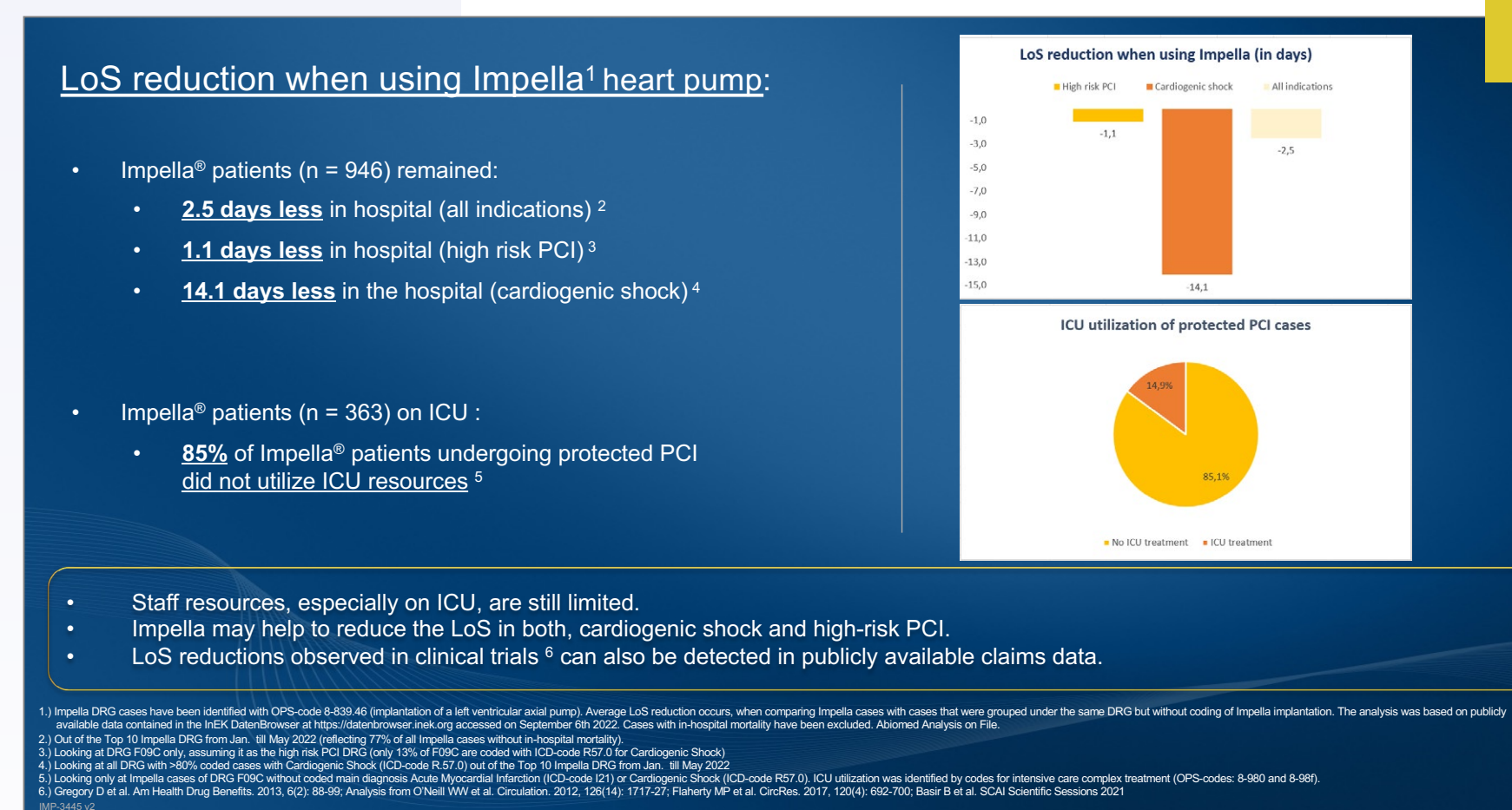
-1.1 days for high risk interventions

-14.1 days in cases of cardiogenic shock

1 to
14
days

Reduction in length of inpatient stay

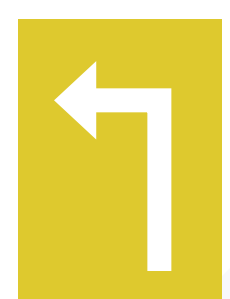
for high-risk PCI and cardiogenic shock*



* The analysis is based on data in the InEK DatenBrowser, which is publicly available at <https://datenbrowser.inek.org>, accessed on 6 September 2022 for the period January to May 2022. Cases including in-hospital mortality were excluded. Impella DRG cases were identified with OPS code 8-839.46 (implantation of a left ventricular axial pump). The average LOS reduction occurs when Impella cases are compared with cases grouped under the same DRG but without Impella implantation coding. Further assumptions for the analysis can be found in the chart "Analysis of inpatient length of stay (LOS) with 2022 DRG data (Jan.–May)"



Data and Sources



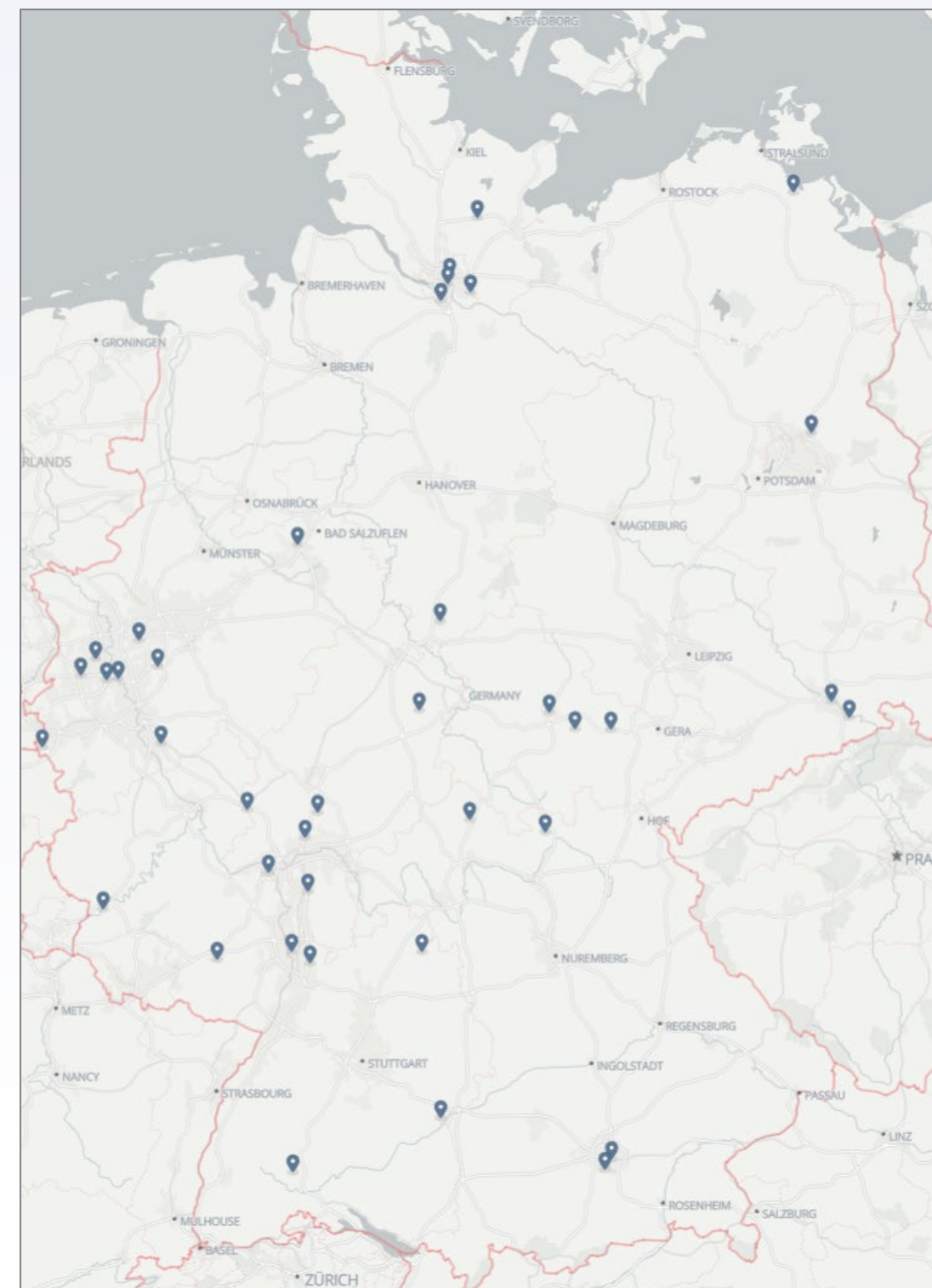
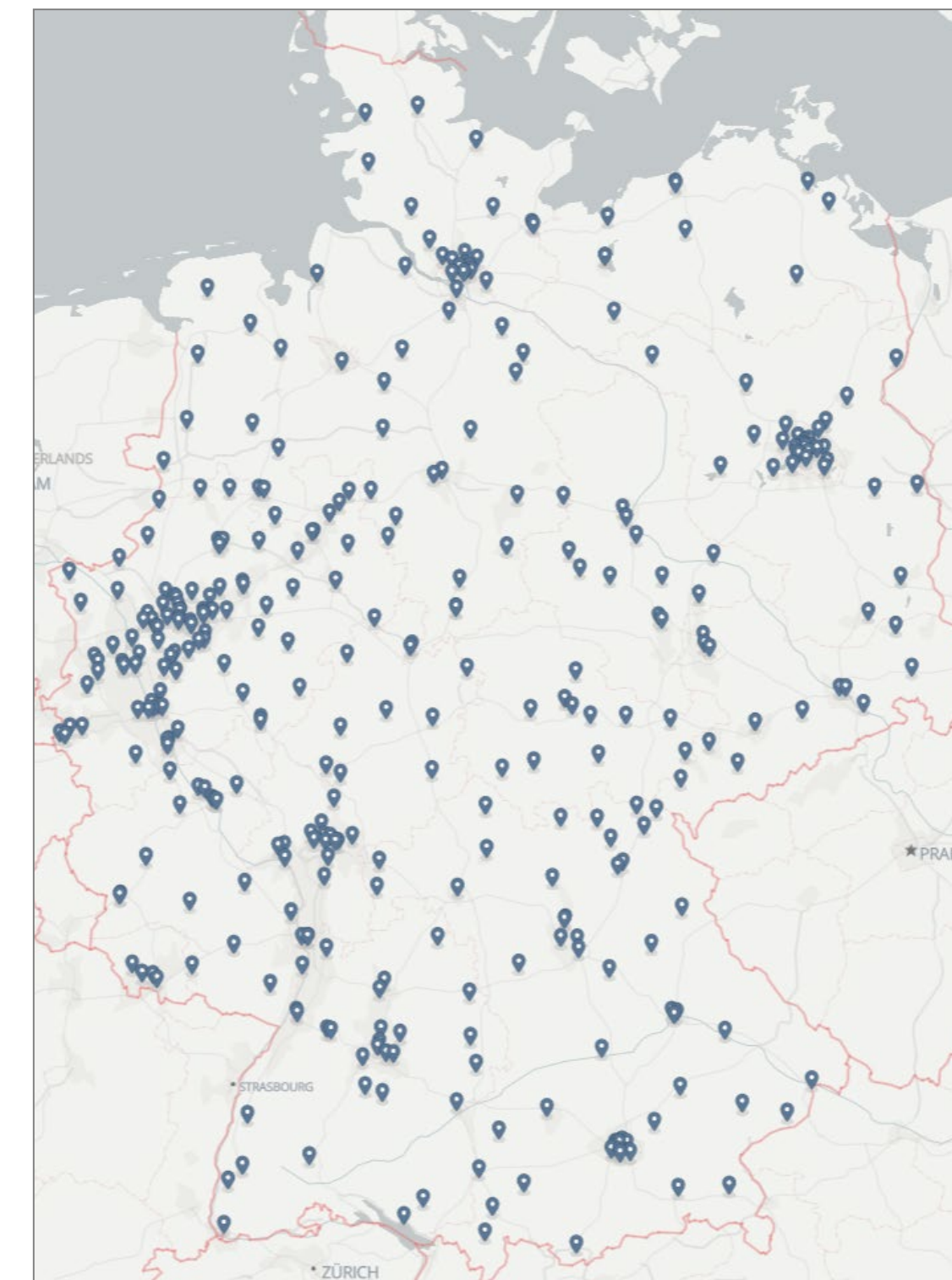
Did you know?

Did you know that the number of applications has increased ninefold over the last 10 years?

9_x

Case Example Germany

In the last 11 years, the use of Impella heart pumps has increased ninefold in Germany.

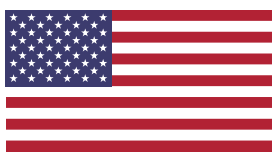
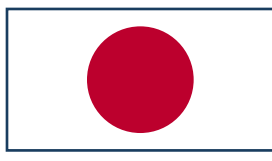

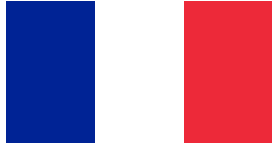

2010 (39)**2021 (355)**

**Data and
Sources**



4



	High-Risk PCI Coverage	Cardiogenic Shock Coverage
United States 	✓	✓
Japan 	Not applied for this indication	✓
Hong Kong 	Funding through Community Care Fund (CCF) and Samaritan Fund for patients with low income and financial difficulties	✓
France 	Not applied for this indication	✓
United Kingdom 	(Interventional Procedure Guidance IPG633 that published recommendation on safety and efficacy)	Not applied for this indication



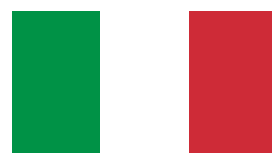


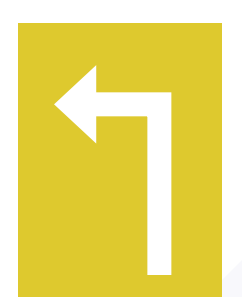
	High-Risk PCI Coverage	Cardiogenic Shock Coverage
Belgium 	Not applied for this indication	✓ All Shock
Austria 	Payment via Austrian-DRGs with no additional payments covering the entity of device costs for both indications (HRPCI &CS)	
Italy 	Payment via Italian-DRGs with additional payments covering the entity of device costs for both indications (HRPCI &CS)	
Germany 	Payment via German-DRGs with additional payments ("ZE") covering the entity of device costs for both indications (HRPCI &CS)	
Switzerland 	Payment via Swiss DRGs with additional payments ("ZE") covering the entity of device costs and increasing based on the duration of support for both indications	

Table 1 Summary table of Impella's reimbursement or funding in various countries based on their approved indications.



**Data and
Sources**



Please don't hesitate to request an in-person consultation.

Abiomed on
LinkedIn

CAMP

Knowledge on
demand

HCP Newsletter
Registration



Clinical Support Center
24 hours, 7 days a week:
00800 02246633

Abiomed Europe GmbH
Neuenhofer Weg 3
52074 Aachen, Germany
Telephone: +49 (0) 241 8860-0
Fax: +49 (0) 241 8860-111
Email: europe@abiomed.com

Reimbursement Requests:

eu_reimbursement@abiomed.com
uk_reimbursement@abiomed.com

Impella® Device Indication & Safety Information

To learn more about the Impella platform of heart pumps, including important risk and safety information associated with the use of the devices, please visit
<https://www.heartrecovery.eu/safety-information>

- or -

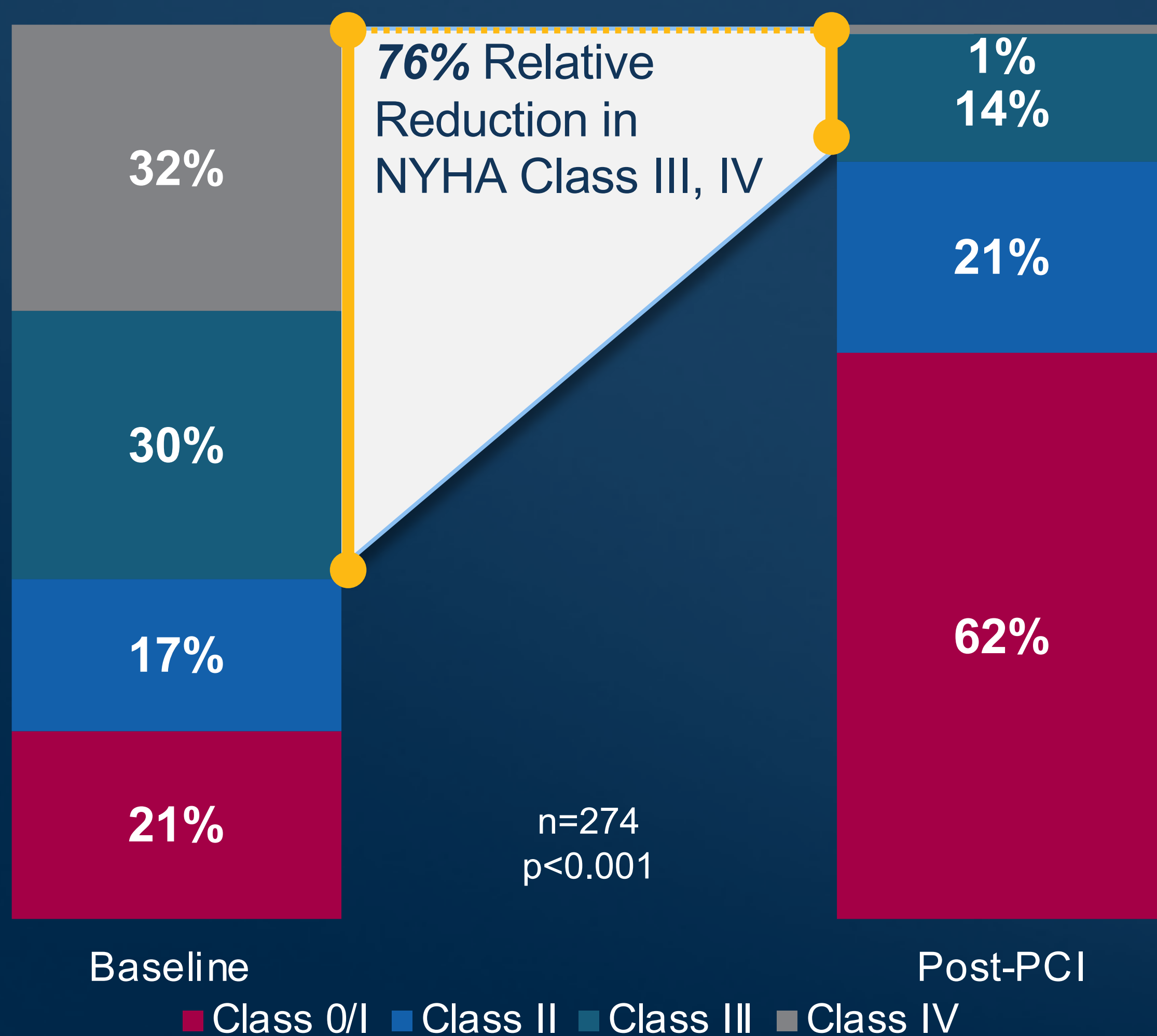
Scan code to learn more



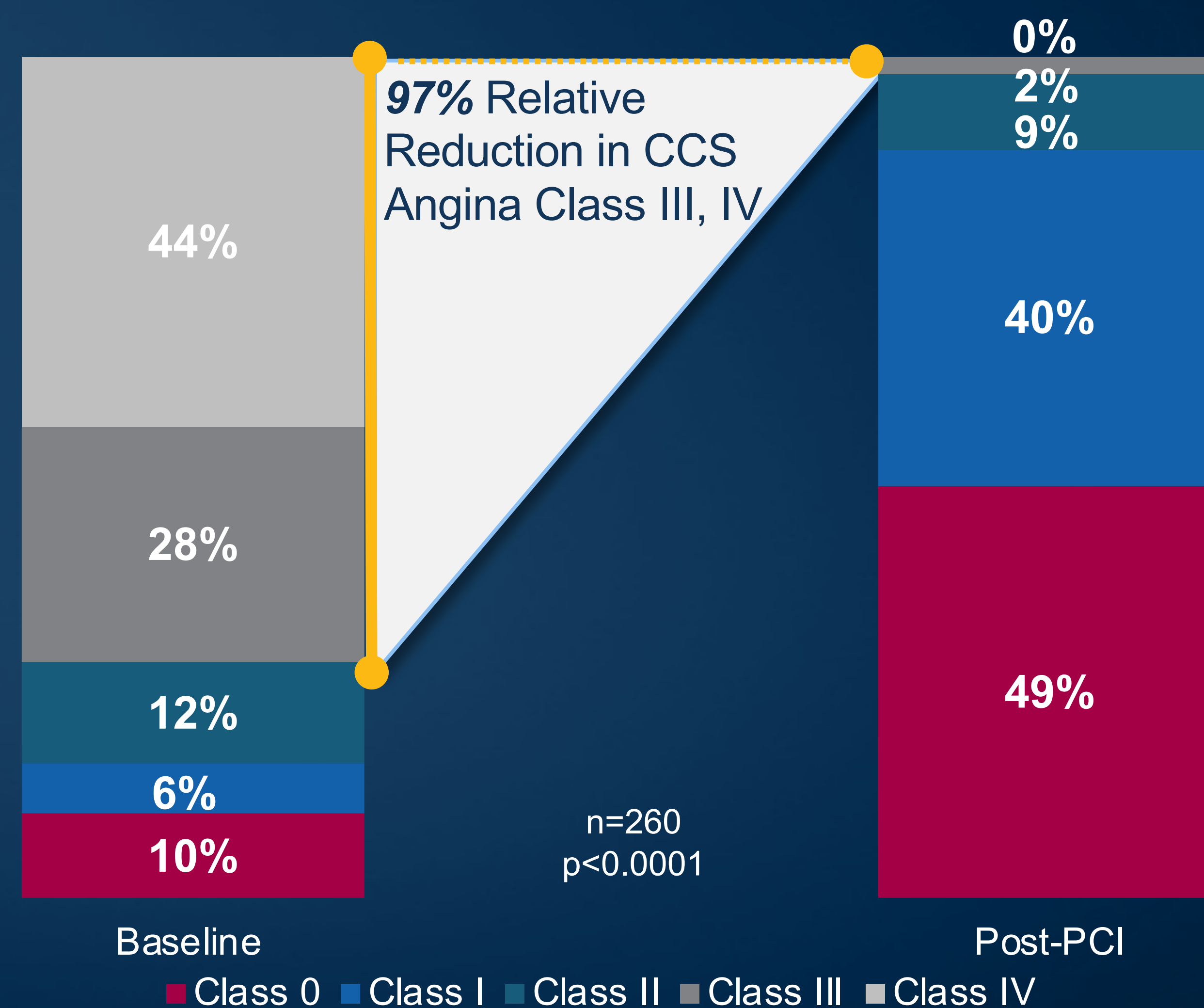
1

Restore EF Data – Effectiveness of Protected PCI in Patients with and without Impaired EF

Heart Failure Symptom



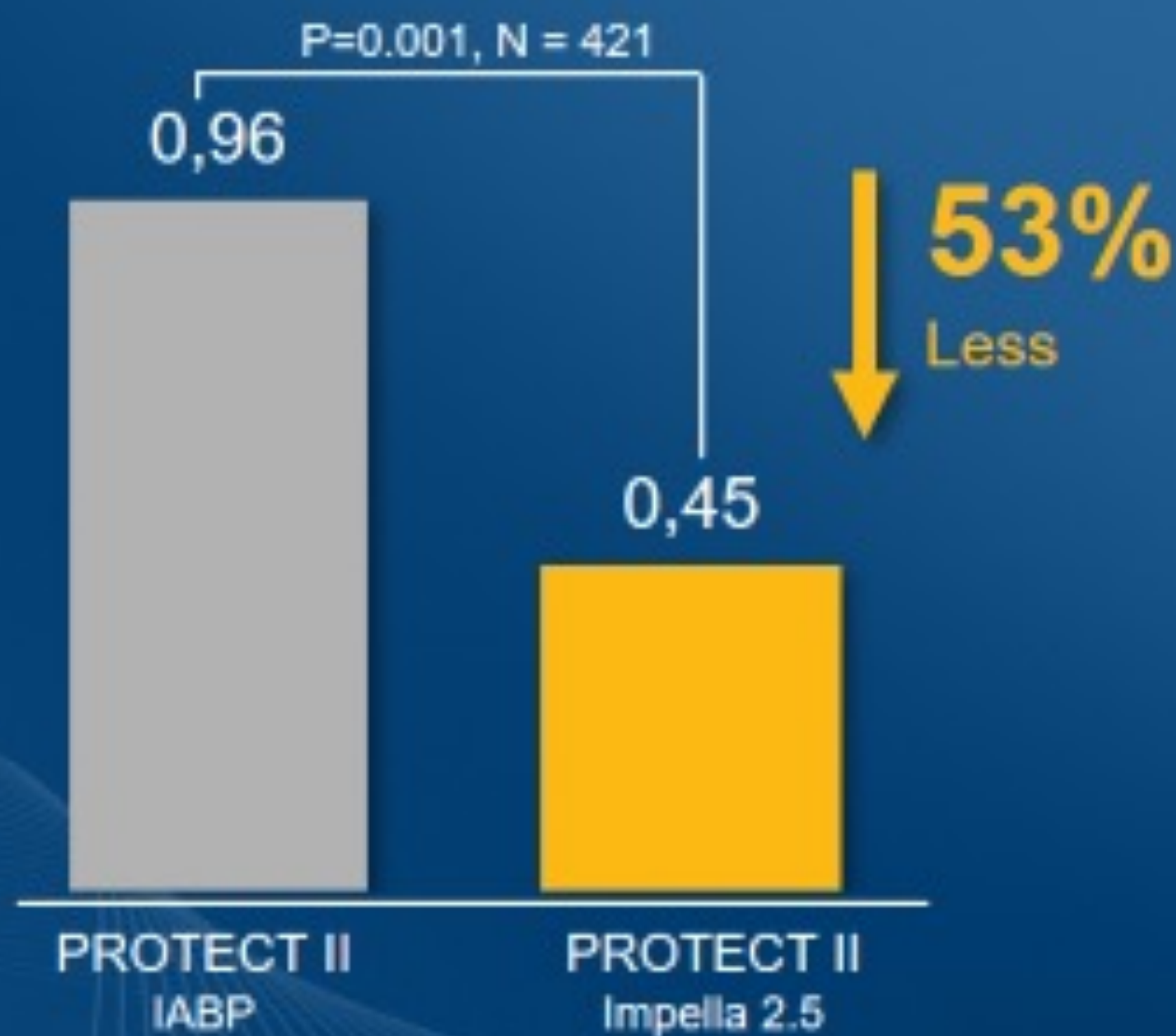
Anginal Symptom



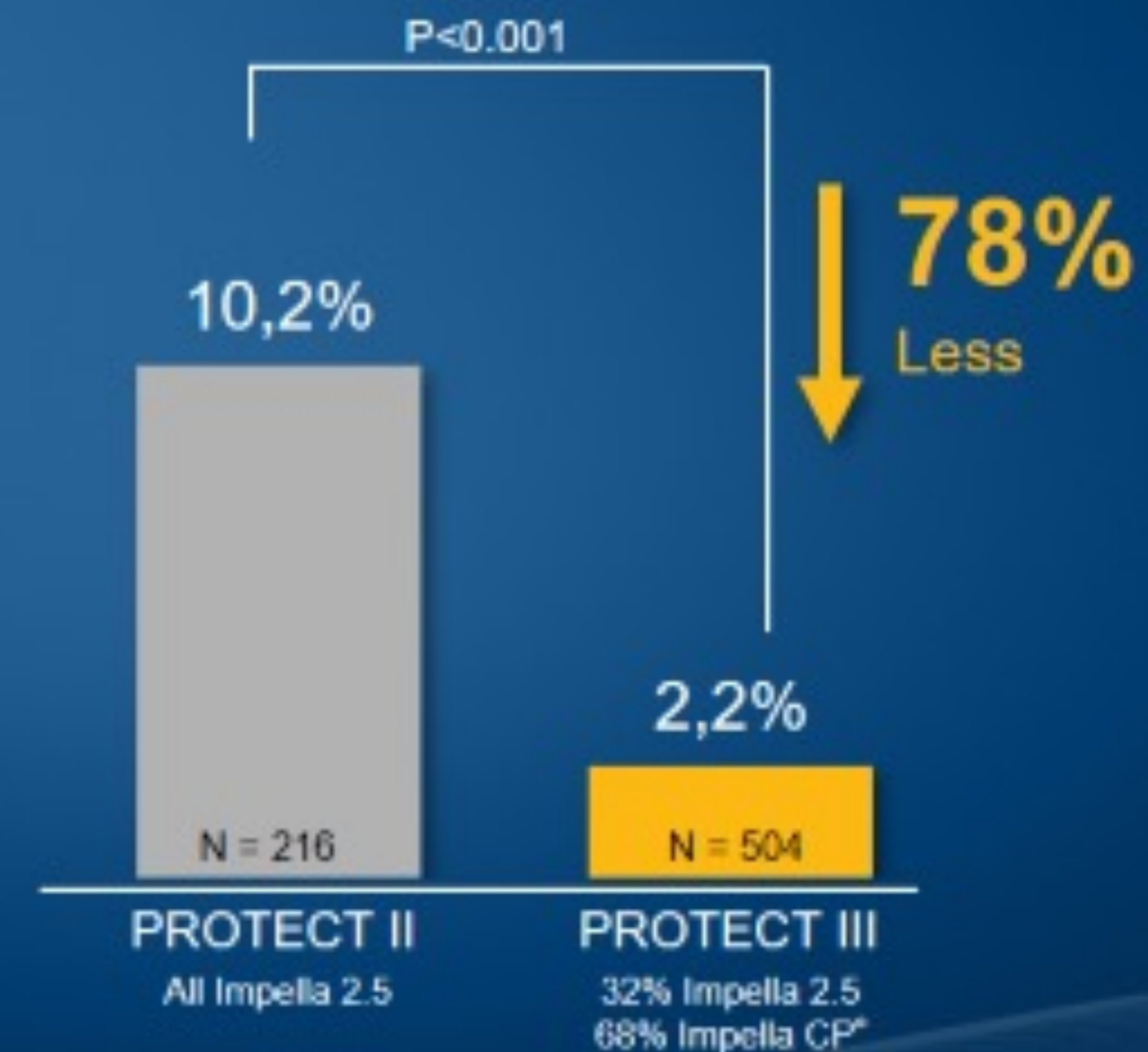
HEMODYNAMIC STABILITY ENABLING MORE COMPLETE REVASCULARIZATION



Half as many hypotensive events
per patient with
Impella 2.5[®] compared to IABP¹



Further Reduction of
Hypotension during Support with
increased use of Impella CP^{®2}



1. PROTECT II FDA PMA data. Hypotensive event defined as MAP < 65mmHg.
2. PROTECT III Study. O'Neill, W., et al. (2022). American Heart Journal, 248, 139-149. doi: 10.1016/j.ahj.2022.02.006



CLINICAL GUIDELINES FOR IMPELLA® HEART PUMPS

Cardiogenic Shock & Other Guidelines

2022 AHA/ACC/HFSA Guideline for the Management of HF (*J Am Coll Cardiol*)

- “Bridge to Recovery” or “Bridge to Decision” for patients with advanced HFrEF and hemodynamic compromise and shock: Class IIa

2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure (EHJ)

- Short-Term MCS should be used in patients with advanced heart failure (INTERMACS profiles 1 or 2) as BTD/BTR/BTB/BTT: Class IIa
- Short-term MCS should be considered in patients with cardiogenic shock as a BTR/BTD/BTB. Further indications include treatment of the cause of cardiogenic shock or long-term MCS or transplantation: Class IIa
- IABP is not routinely recommended in post-MI cardiogenic shock: Class III

2021 EAPCI/ACVC Expert Consensus Document on Percutaneous Ventricular Assist Devices (*EuroIntervention*)

- Indication for pVAD in AMI without CS: Impella CP use seems feasible as a preventive unloading strategy; IABP is not suggested, VA-ECMO should not be used
- Indication for pVAD in CS: Impella CP may be used as a short-term therapy in CS, stage C and D with potentially reversible underlying cause/transplant/VAD candidates; IABP routine use is not recommended; VA-ECMO may be used as short-term therapy in CS stage C, D and E and for selected patients in refractory cardiac arrest

2020 EACTS/ELSO/STS/AATS Expert Consensus on Post-Cardiotomy Extracorporeal Life Support in Adult Patients (*Eur J Cardiothorac Surg*)

- Percutaneous/axillary Impella or ECpella in severe isolated LV dysfunction: Class IIb
- IABP not recommended for severe LV or bi-V dysfunction in failure CPB weaning: Class III

2019 HRS/EHRA/APHRS/LAHRS Expert Consensus Statement on Catheter Ablation of Ventricular Arrhythmias (*Heart Rhythm*)

- HF and EP collaboration regarding High-Risk VTA: Class I
- Hemodynamic Support During VTA: Class IIa
- Hemodynamic Support for Unstable VT: Class IIb

2013 ACCF/AHA Guideline for the Management of STEMI (*Circulation*)

- STEMI and Cardiogenic Shock: Class IIb
- STEMI and Urgent CABG: Class IIa

2013 ACCF/AHA Guideline for the Management of Heart Failure (*J Am Coll Cardiol*)

- “Bridge to Recovery” or “Bridge to Decision” for patients with acute, profound hemodynamic compromise: Class IIa

2013 International Society for Heart and Lung Transplantation Guidelines for MCS (*J Heart Lung Transplant*)

- Temporary mechanical support for patients with multi-organ failure: Class I

2012 Use of MCS (*Circulation*)

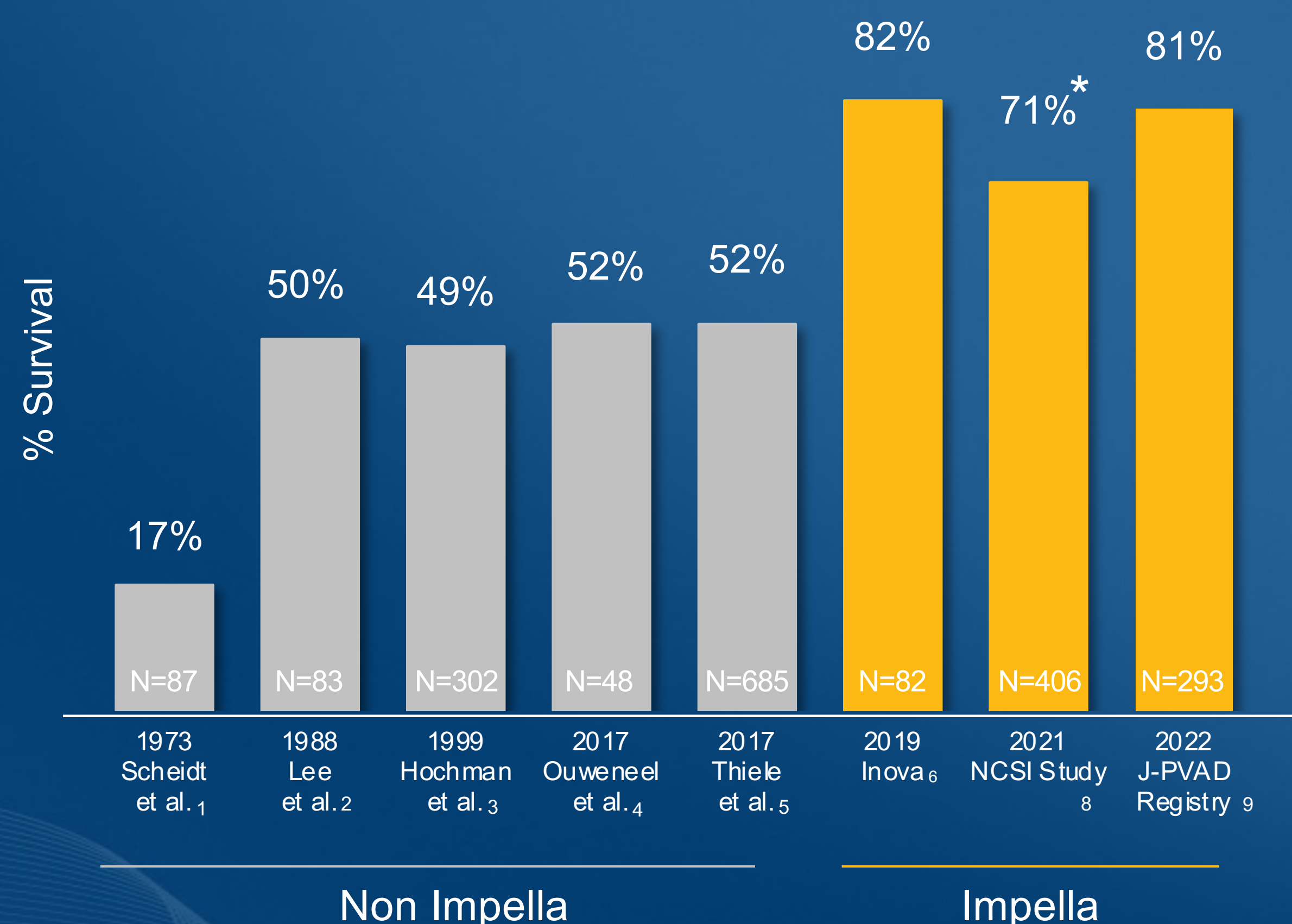
- Acutely decompensated heart failure patients: Class IIa

2011 ACCF/AHA/SCAI Guideline for PCI (*J Am Coll Cardiol*)

- PCI and Cardiogenic Shock: Class I

IMPROVED SURVIVAL AND NATIVE HEART RECOVERY

INVESTIGATOR-LED AMI CARDIOGENIC SHOCK STUDIES



Best Practice Protocols Include⁶⁻⁹

- Identify CS early and Impella® pre-PCI < 90 mins
- Aggressive down-titration of inotropes
- Identify RV dysfunction early and support
- Identify inadequate LV support and escalate
- Systematic use of RHC to guide therapy

* Survival to discharge⁸ with native heart recovery > 90%⁷

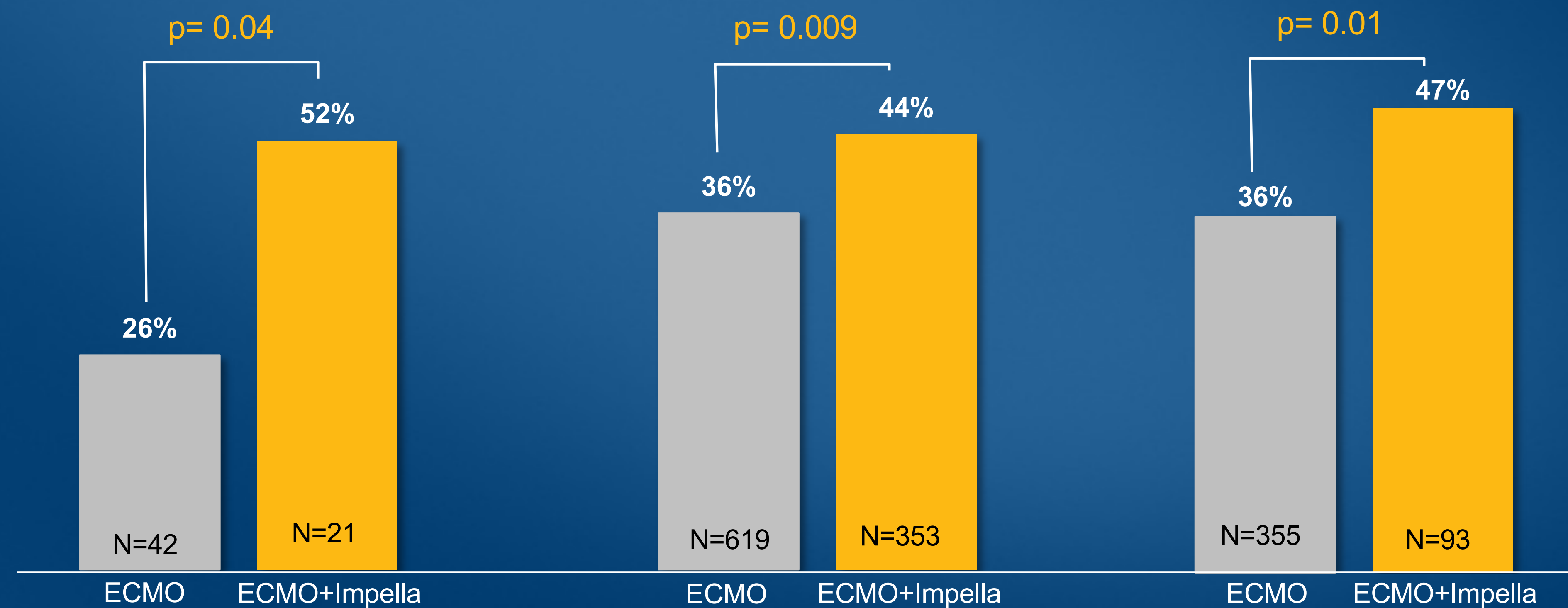
The J-PVAD Registry is a registry of ALL Impella patients in Japan, conducted by 10 Japanese professional societies, including the Japanese Circulation Society (JCS).

1. Scheidt, S., et al. (1973). *N Engl J Med*, 288(19), 979–984
2. Lee, L., et al. (1988). *Circulation*, 78(6), 1345–1351
3. Hochman, J., et al. (1999). *N Engl J Med*, 341(9), 625–634
4. Ouweneel, D., et al. (2017). *J Am Coll Cardiol*, 69(3), 278–287
IMPRESS in Severe Shock/Cardiac Arrest. ~10% Impella pre-PCI.

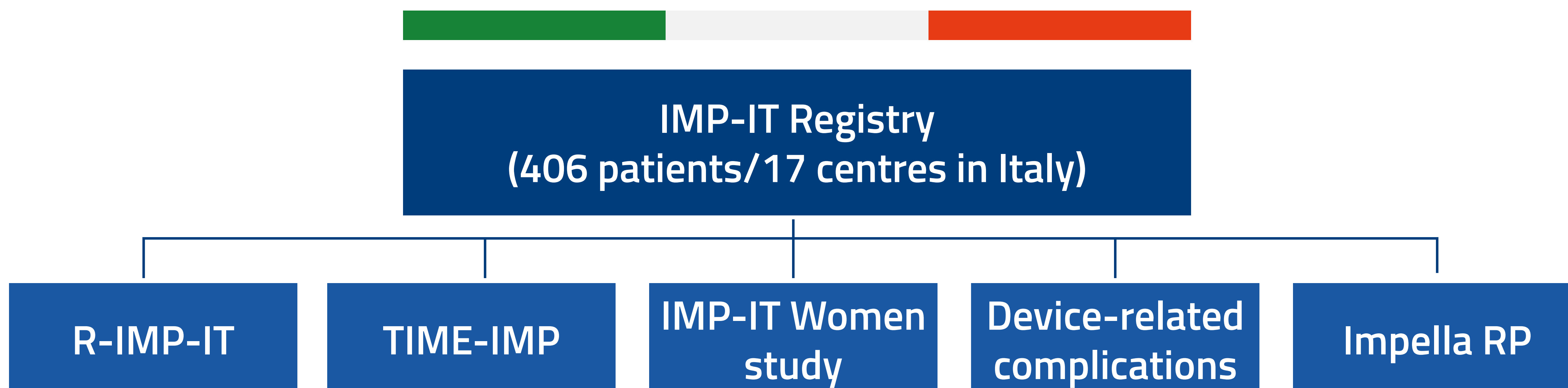
5. Thiele, H., et al. (2017). *N Engl J Med*, 377(25), 2419–2432. ~5% with Impella
6. Tehrani, B., et al. (2019). *J Am Coll Cardiol*, 73(13), 1659–1669
7. O'Neill, W., et al. (2020). *TCT Connect*
8. Basir, B., et al. (2021). *SCAI Scientific Sessions*
9. Ako, J. (2022). *TCT. AMICS with Impella-only Support*

2 Early Unloading Can Improve Survival in Cases of Cardiogenic Shock

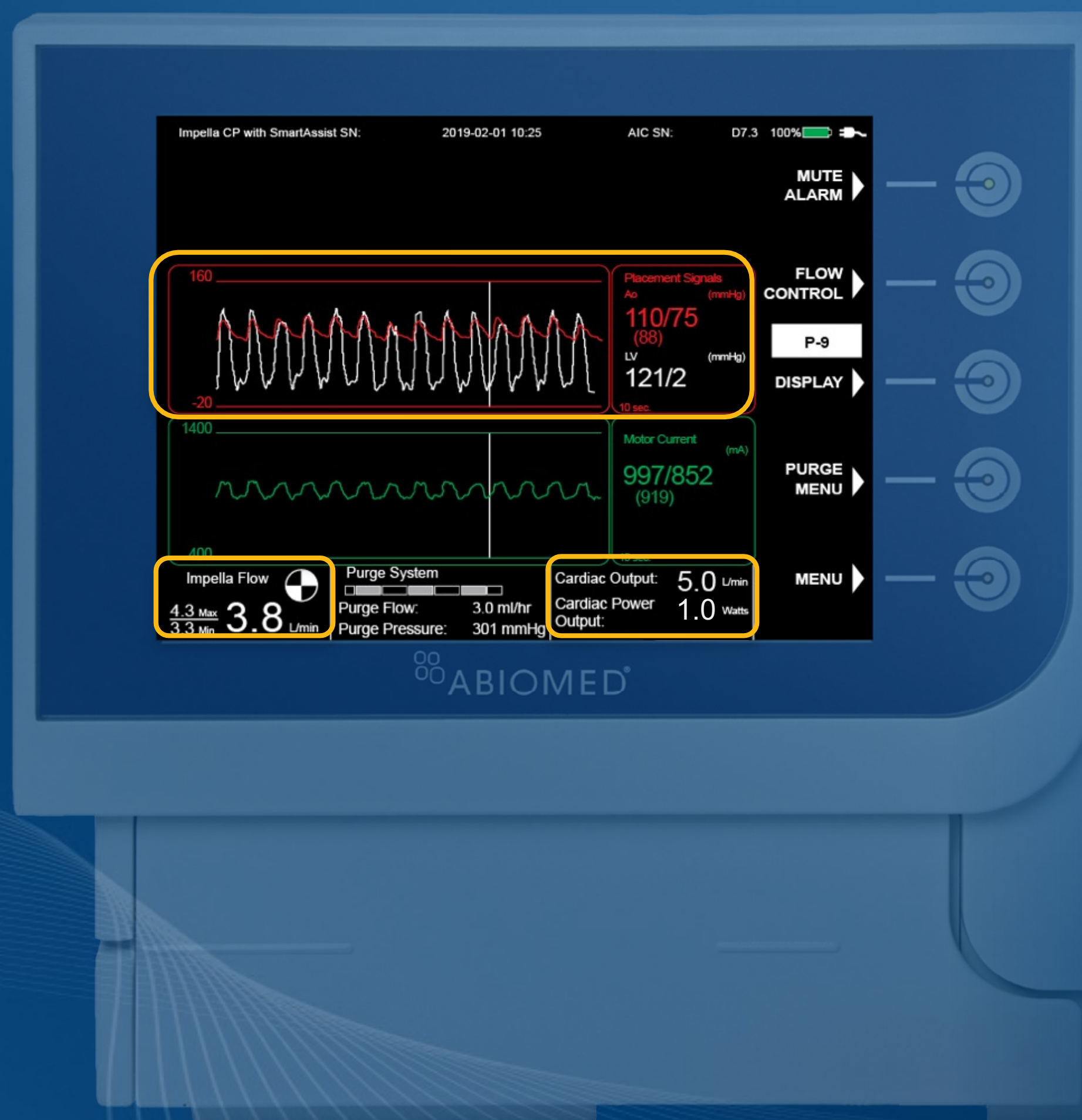
IMPELLA®+ECMO vs ECMO ALONE IS ASSOCIATED WITH SURVIVAL BENEFIT IN LIFE-THREATENING CS



Pappalardo, F, et al.,(2016).European Journal of Heart Failure, 19(3), 404–412.



SMARTASSIST® ADVANCED METRICS



Advanced Metrics

Intelligent metrics assist weaning and optimize pump management

- Weaning assisted by LVEDP and MAP trends
- Only percutaneous heart pump that calculates and displays Cardiac Power Output
- Real-time display of left ventricular placement signal

Cardiac Power Output (CPO) is the #1 correlate to mortality in AMI Cardiogenic Shock.¹

$$CPO = (MAP \times \text{Cardiac Output}) / 451$$

¹ Fincke, et. al. JACC, 2004 SHOCK TRIAL

Metrics are for informational purposes only. Any change in the trend should be verified independently using a cleared or approved diagnostic device.

THE VALUE OF THE OPTICAL SENSOR

More accurate, precise alarms for improved patient and pump management

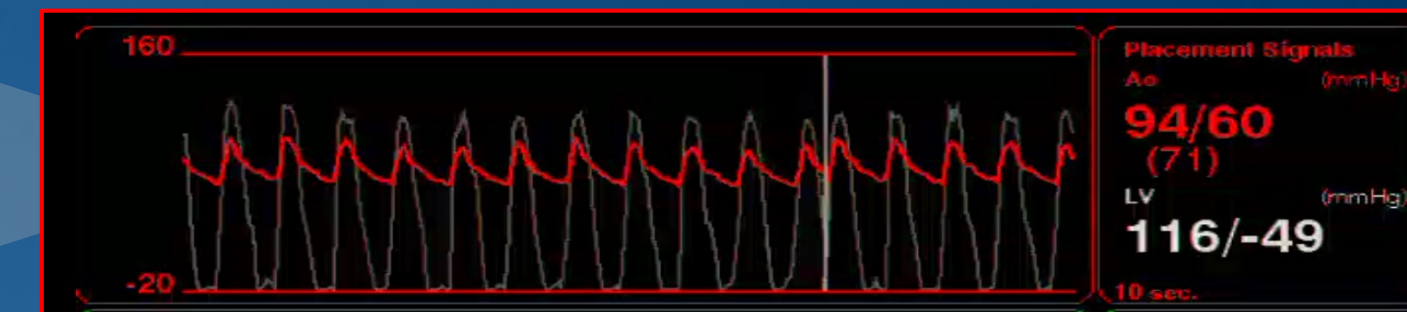
Used to calculate Advanced Metrics

Greater hemodynamic support with **peak** flows up to 4.3 L/min for Impella CP® with SmartAssist® and up to 6.0 L/min for Impella 5.5® with SmartAssist® pump

Faster, simpler setup

Pump repositioning without image guidance*

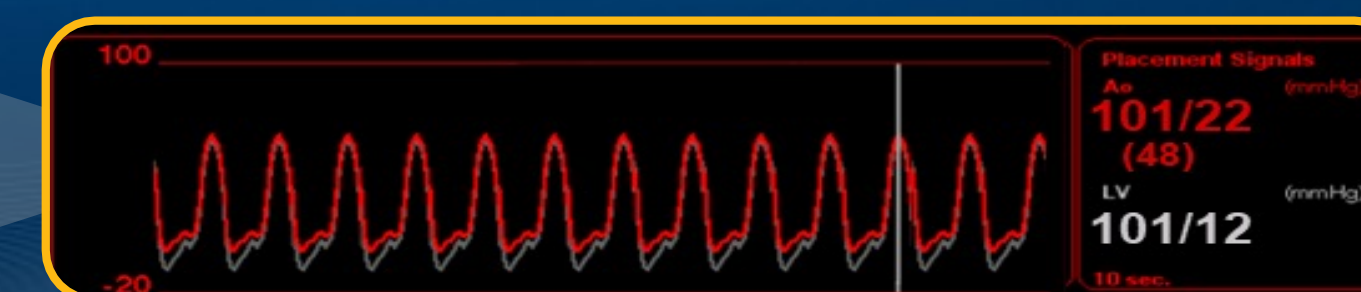
* When "Position in Ventricle" alarm is triggered



P-level	*Mean Flow Rate (L/min)	Revolutions Per Minute (rpm)
P-0	0.0	0
P-1	0.0 - 0.9	23,000
P-2	1.1 - 2.1	31,000
P-3	1.6 - 2.3	33,000
P-4	2.0 - 2.5	35,000
P-5	2.3 - 2.7	37,000
P-6	2.5 - 2.9	39,000
P-7	2.9 - 3.3	42,000
P-8	3.1 - 3.4	44,000
P-9 **	3.3 - 3.7	46,000

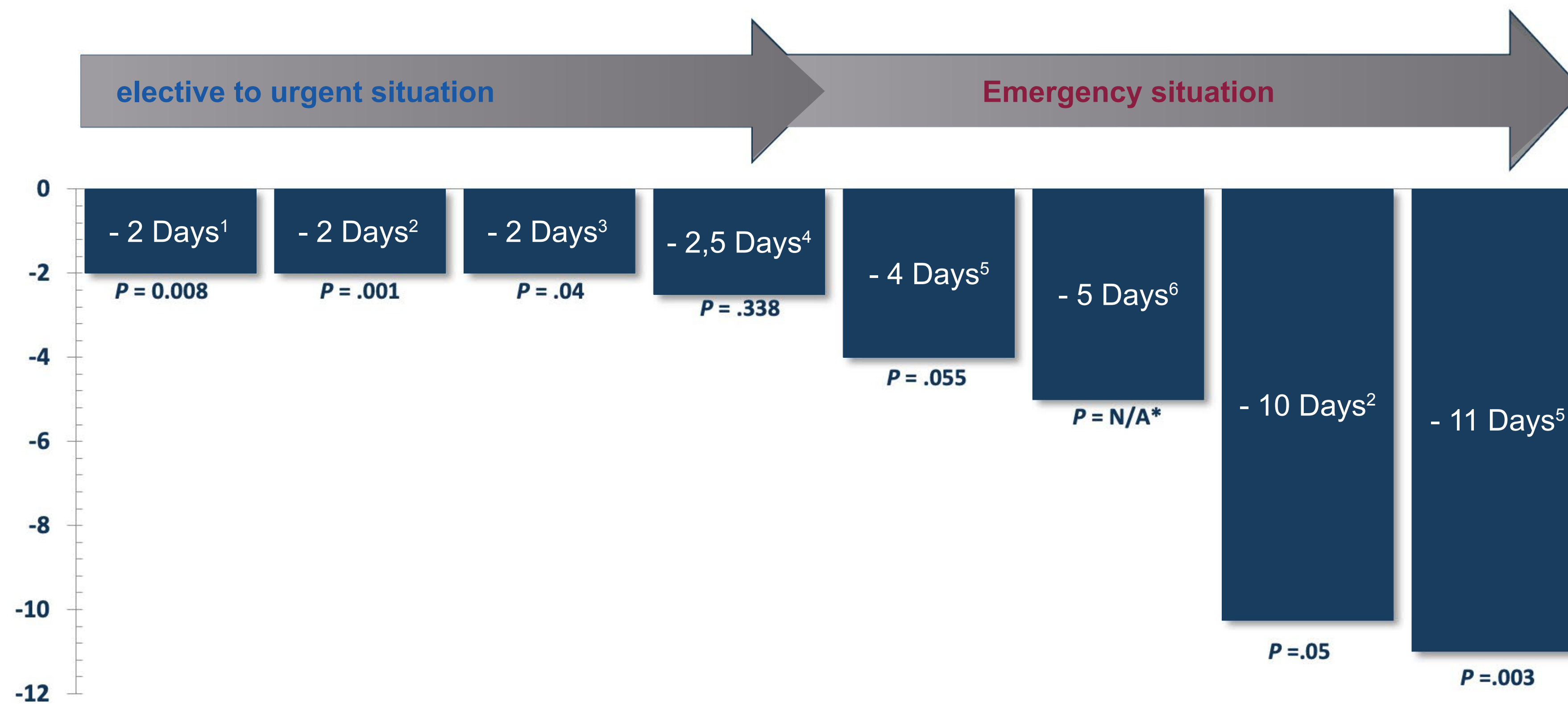
*Flow rate can vary due to suction or incorrect positioning.
 ** The peak flow rate at systole is up to 4.3 L/min at P-9

Pump in Ventricle Alarm



4

Reduction of Inpatient Length of Stay



*not available/not calculated

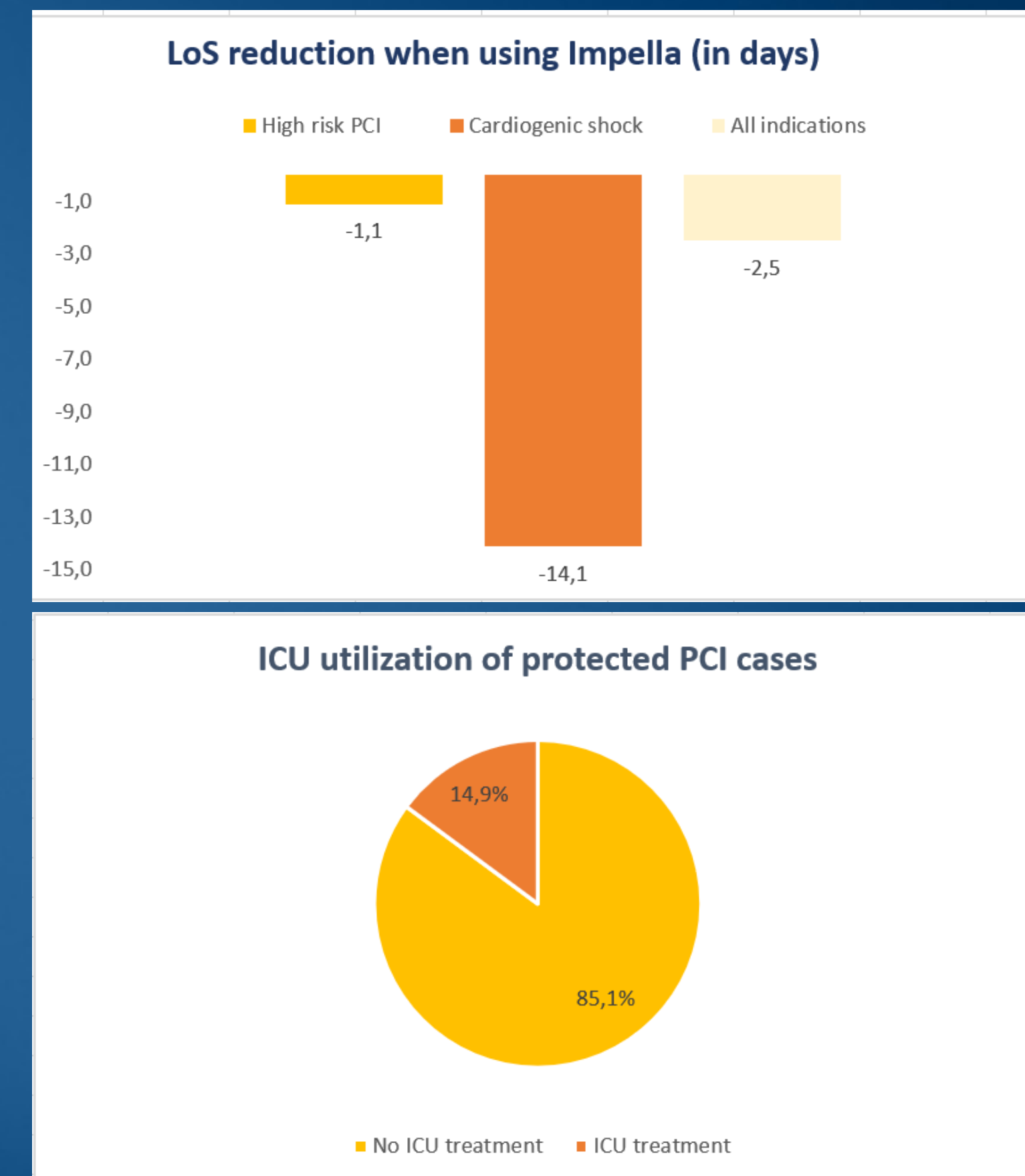
1. Gregory D, et al. *Am Health Drug Benefits*. 2013;6(2):88-99.
2. Gregory D, Scotti DJ. *J Manag Care Med*. 2013;16(1):61-69.
3. Aryana A, et al. *Heart Rhythm*. 2014;11(7):1122-1130.

4. Wohns D, et al. *Innovations (Phila)*. 2014;9(1):38-42.
5. Maini B, et al. *Catheter Cardiovasc Interv*. 2014;83(6):E183-E192.
6. Cheung A, et al. *J Am Coll Cardiol*. 2012;60(17 Suppl B):B110. Abstract TCT-385.

ANALYSIS OF GERMAN DRG DATA JAN.- MAY 2022 ON AVERAGE LENGTH OF STAY (LoS)

LoS reduction when using Impella¹ heart pump:

- Impella[®] patients (n = 946) remained:
 - **2.5 days less** in hospital (all indications) ²
 - **1.1 days less** in hospital (high risk PCI) ³
 - **14.1 days less** in the hospital (cardiogenic shock) ⁴
- Impella[®] patients (n = 363) on ICU :
 - **85%** of Impella[®] patients undergoing protected PCI **did not utilize ICU resources** ⁵



- Staff resources, especially on ICU, are still limited.
- Impella may help to reduce the LoS in both, cardiogenic shock and high-risk PCI.
- LoS reductions observed in clinical trials ⁶ can also be detected in publicly available claims data.

1.) Impella DRG cases have been identified with OPS-code 8-839.46 (implantation of a left ventricular axial pump). Average LoS reduction occurs, when comparing Impella cases with cases that were grouped under the same DRG but without coding of Impella implantation. The analysis was based on publicly available data contained in the InEK DatenBrowser at <https://datenbrowser.inek.org> accessed on September 6th 2022. Cases with in-hospital mortality have been excluded. Abimed Analysis on File.

2.) Out of the Top 10 Impella DRG from Jan. till May 2022 (reflecting 77% of all Impella cases without in-hospital mortality).

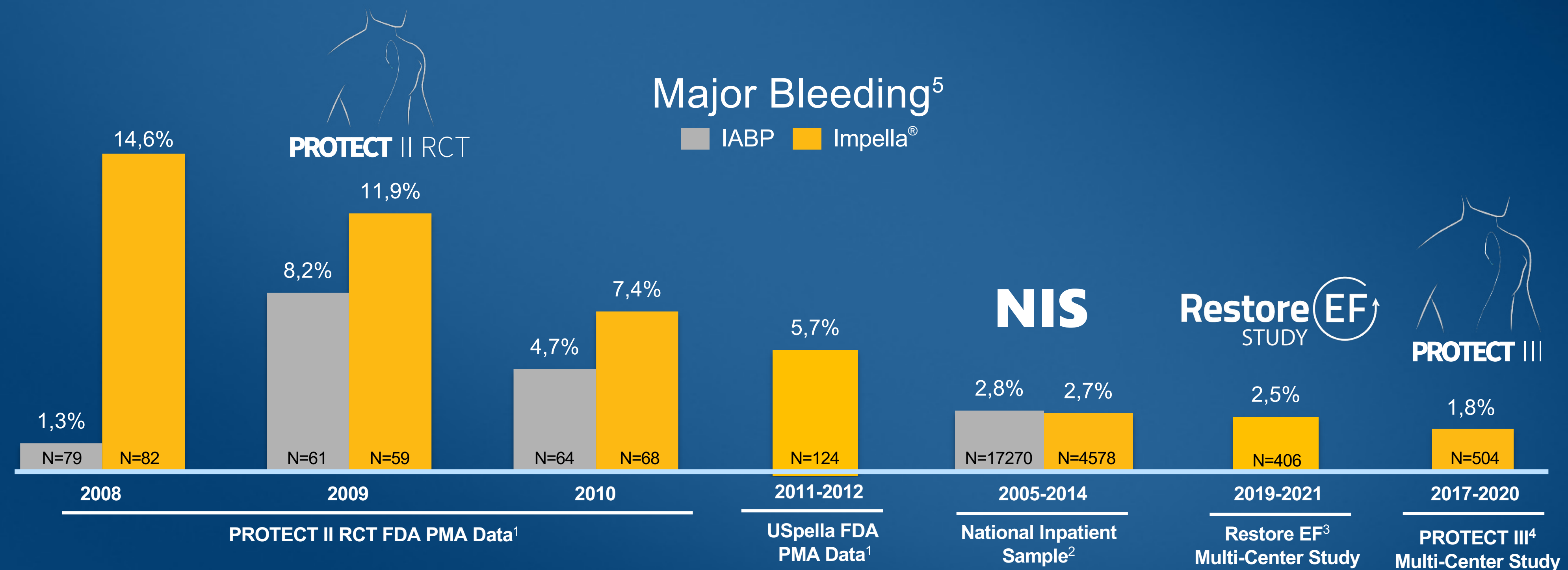
3.) Looking at DRG F09C only, assuming it as the high risk PCI DRG (only 13% of F09C are coded with ICD-code R57.0 for Cardiogenic Shock)

4.) Looking at all DRG with >80% coded cases with Cardiogenic Shock (ICD-code R.57.0) out of the Top 10 Impella DRG from Jan. till May 2022

5.) Looking only at Impella cases of DRG F09C without coded main diagnosis Acute Myocardial Infarction (ICD-code I21) or Cardiogenic Shock (ICD-code R57.0). ICU utilization was identified by codes for intensive care complex treatment (OPS-codes: 8-980 and 8-98f).

6.) Gregory D et al. Am Health Drug Benefits. 2013, 6(2): 88-99; Analysis from O'Neill WW et al. Circulation. 2012, 126(14): 1717-27; Flaherty MP et al. CircRes. 2017, 120(4): 692-700; Basir B et al. SCAI Scientific Sessions 2021

CONTINUOUS SAFETY IMPROVEMENT OVER TIME IN HIGH-RISK PCI



Continuous improvement with innovation, experience and best practices

1. FDA PMA Submission, Data on file (bleeding requiring transfusion)
 2. Al-Khadra, Y., et al. (2020). Catheter Cardiovasc Interv, 95(3), 503-512.
 3. Wollmuth, J., Patel, M. et al. (2022). JSCAI, 100350. <https://doi.org/10.1016/j.jscai.2022.100350>.
 4. O'Neill, W., et al. (2022). American Heart Journal, 248, 139-149.
 5. Available USA publications and FDA studies with device-specific major bleeding rates or bleeding requiring transfusion



Procedural steps | Best practices

Patient Selection

- Complex anatomy (LM, MVD, lang lesions, calcification ...)
- HFref or HFmEF with hemodynamic relevant valve disease
- Co-morbidities (age, diabetes, renal failure, frailty ...)
- Surgical turn-down
- Patient preference

Anticoagulation

- Monitoring
 - Check ACT every 30 min
 - Monitor total anticoagulation (heparine in purge fluid & i.v. heparine)
 - Consider bicarbonate to replace heparine in purge fluid
 - Balance bleeding risk vs. thrombotic risk in special populations (CKD, bleeding disorders)
- Haemolysis prevention (prevent interaction with papillary muscle, septal/valvular structures; check volume management)

Patient handling in the cathlab

- Briefing and debriefing of staff and patient
- Plan, check, adapt interventional strategy
- Monitoring hemodynamics (RHC, LV/RV function, arterial pressure), ECG, hemoglobin, and oxygenation
- Consider weaning after procedure vs. delayed weaning
- Confirm access site closure: rule-out dissection, bleeding, fistula by angiography and confirm adequate limb perfusion (duplex sonography) before taking patient off the table

Pre-procedural work up

- Assess and prepare femoral access site:
 - imaging (angiography, vascular US, MRT) and imaging guided access
- Pre-closure device (suture-based devices highly recommended)
- Assess cardiac function (LV/RV contractility)
- Procedure planning (kidney function, coagulation, strategy)
- Team briefing
- Check materials and know your tool box

Revascularization

- Aim at extensive complete revascularization
 - Residual Syntax Score (rSS) >8
- Aim at high quality of revascularization
 - Lesion preparation (imaging, debulking)
 - Stent optimization (imaging)
- Consider single vs. staged procedure (contrast volume, radiation, renal insufficiency, patient condition)

Bailout- and complication management

- Best complication management is prevention
- Standards of operations established & in place for major complications
- Be prepared for hemodynamic deterioration with cardiogenic shock despite MCS; access site complications & bleeding, non-access site bleeding, vessel perforation, vessel thrombosis, dissection