



Protected PCI With Impella Pump in High Risk Patients

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Impella Support

Safe, Simple Use



- World's Smallest Heart Pump
- Independence of Timing Signals and Inotropes

Systemic Hemodynamic Support

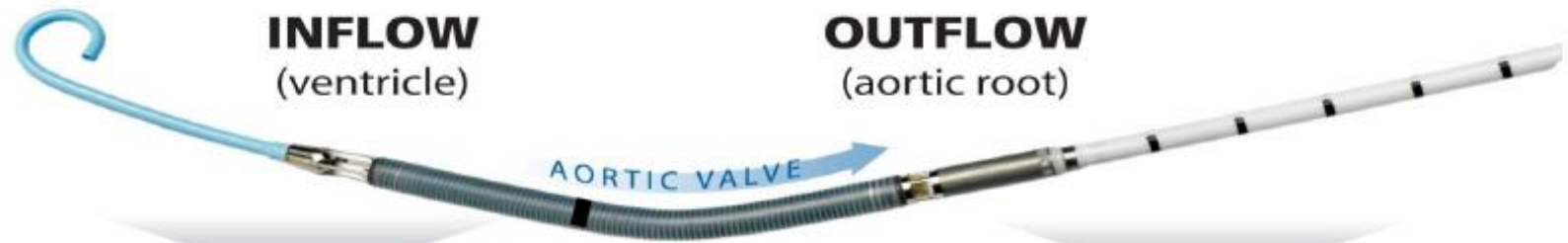


- Restores or Increases Net Cardiac Output

Myocardial Protection



- Reduces O₂ Demand
- Increases O₂ Supply



EDV, EDP




AOP

Flow

O₂ Demand

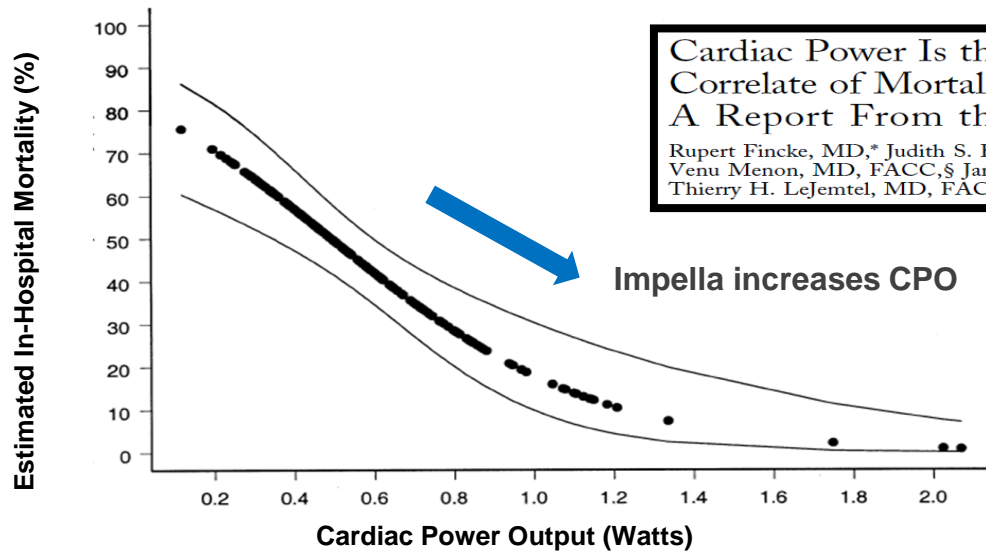
O₂ Supply

Cardiac Power Output

| | Impella 2.5 | Impella CP | Impella 5.0 | Impella LD |
|------------------------------|---|--|---|---|
| |  | |  |  |
| Flow rate (max L/min) | 2.5 | 4.0 | 5.0 | 5.0 |
| Catheter size | 9 Fr | 9 Fr | 9 Fr | 9 Fr |
| Pump size | 12 Fr | 14 Fr | 21 Fr | 21 Fr |
| Insertion method | Percutaneous via 13 Fr introducer sheath | Percutaneous via 14 Fr introducer sheath | Peripheral via arterial cut-down | Direct, surgical insertion |
| Guidewire | 0.018" Silicone | 0.018" PTFE | 0.025" | N/A |
| Placement measurement | Fluid-filled pressure lumen | Fluid-filled pressure lumen | Differential pressure sensor | Differential pressure sensor |
| Cannula geometry | Curved, Pigtail | Curved, Pigtail | Curved, Pigtail | Straight |

Impella 2.5 and 5.0 Derivates of Cardiac Output

| Index | Abbr | Units | Typical Range (Normal Heart) | Expression |
|----------------------|------|----------------------|------------------------------|--|
| Cardiac Output | CO | L/min | 5 - 7 | Stroke Volume × Heart Rate |
| Cardiac Index | CI | L/min/m ² | 2.5 – 3.5 | CO / Body Surface Area (BSA) |
| Cardiac Power Output | CPO | Watts | 1 – 1.5 | CO × Mean Arterial Pressure (MAP) × 0.0022 |
| Cardiac Power Index | CPI | Watts/m ² | 0.5 – 0.7 | CI × MAP × 0.0022 |

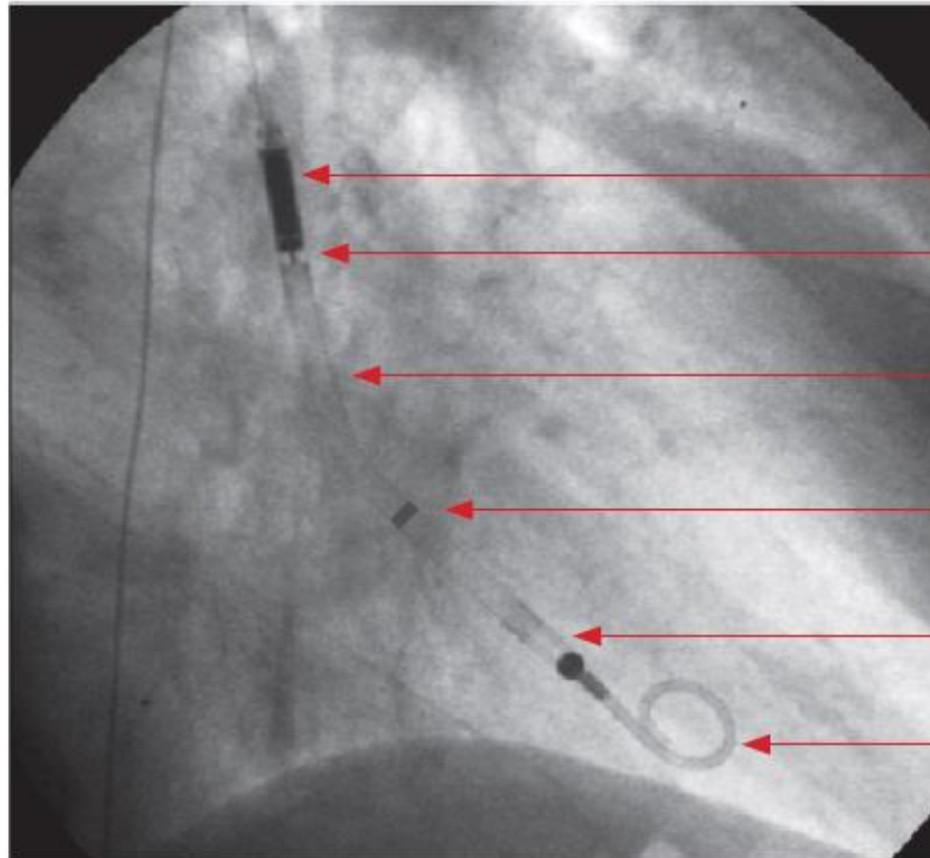


Cardiac Power Is the Strongest Hemodynamic Correlate of Mortality in Cardiogenic Shock: A Report From the SHOCK Trial Registry
 Rupert Fincke, MD,* Judith S. Hochman, MD, FACC,† April M. Lowe, MS,‡ Venu Menon, MD, FACC,§ James N. Slater, MD, FACC,† John G. Webb, MD, FACC,|| Thierry H. LeJemtel, MD, FACC,¶ Gad Cotter, MD, FACC,‡# for the SHOCK Investigators

Impella Device



Verifizierung der richtigen Platzierung mittels Durchleuchtung



Impella® Motor

Auslassbereich

Kanüle

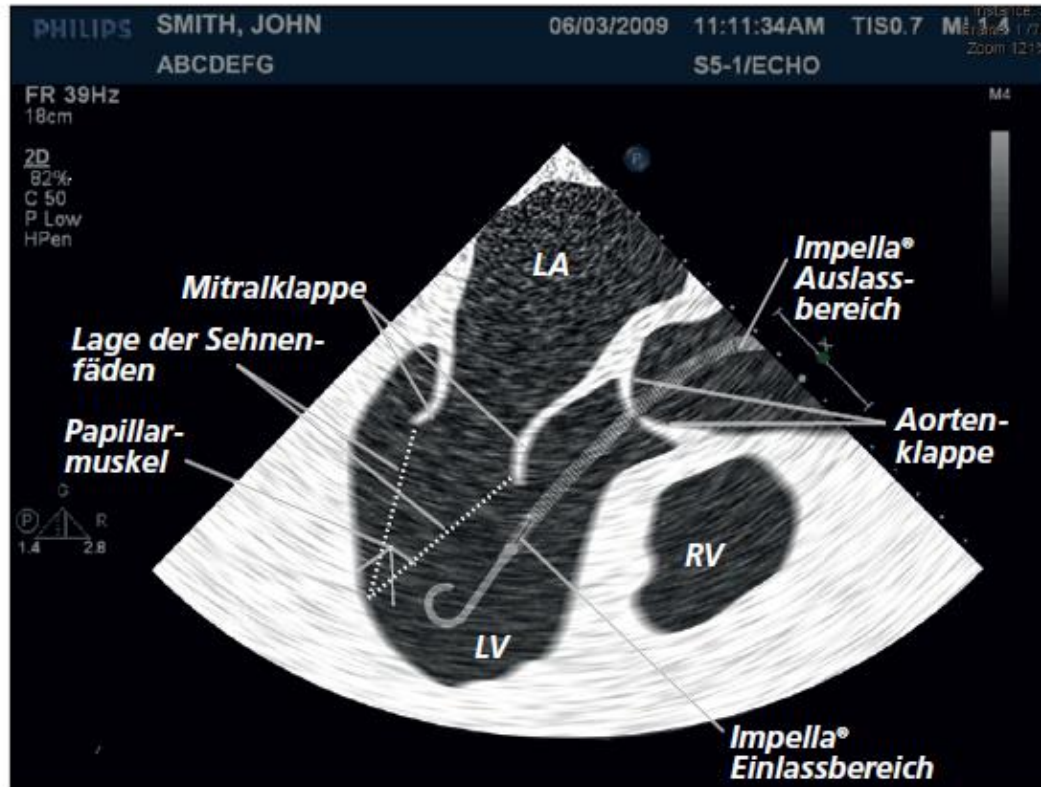
Röntgendichte Markierung
in Höhe des Aortenklappen-
Annulus

Einlassbereich

Pigtail

Ansichtsebene RAO: 25 CAUD: 5.1 plane
Die Kanüle liegt mittig in der Aortenklappenebene.

Ansicht der korrekten Impella® 2.5 Lage im TEE



Transösophageales Echokardiogramm (TEE) der Impella® 2.5

Checkliste für optimale Positionierung:

- Pumpeneinlassbereich 3,5 cm unterhalb der Aortenklappe
- Pumpenauslassbereich deutlich oberhalb der Aortenklappe
- Pumpe tendenziell ausgerichtet zum Apex des linken Ventrikels – freiliegend, ohne am Endokard anzuliegen, ohne in den Sehnenfäden verfangen zu sein und ohne die Mitralklappe zu blockieren.

Indication for Impella

The Impella® (intracardiac pump for supporting the left ventricle) is intended for clinical use in cardiology and in cardiac surgery for up to 5 days for the following indications, as well as others:

- **The Impella® is a circulatory support system for patients with reduced left ventricular function, eg, post-cardiotomy, low output syndrome, cardiogenic shock after acute myocardial infarction, or for myocardial protection after acute myocardial infarction**
- The Impella® may also be used as a cardiovascular support system during coronary bypass surgery on the beating heart, particularly in patients with limited preoperative ejection fraction with a high risk of postoperative low output syndrome
- **Support during high risk percutaneous coronary intervention (PCI)**

Clinical Use of an Impella Support in HR-PCI

Counteract hemodynamical instability during procedures related ischemic episodes

Reduction peri- und postprocedural adverse events (AE+SAE)

Safety and efficiency in over 1600 patients

| SCIENTIFIC EVIDENCE TO SUPPORT PMA APPLICATION | TOTAL NUMBER OF PATIENTS IN THE COHORT | NUMBER OF IMPELLA 2.5 PROTECTED PCI PATIENTS |
|--|--|--|
| PROTECT I | 20 | 20 |
| PROTECT II | 452 | 225 |
| U.S. IMPELLA REGISTRY | 1,322 | 637 |
| LITERATURE REVIEW (N=215) | 2,537 ¹ | 756 |
| TOTAL | 4,331 | 1,638 |

Protected PCI

Figure 1: Revascularization Strategy by Risk Category

| | | SURGICAL RISK | | |
|---------------|--------|---------------|-------------|---------------|
| | | Low | Medium | High |
| ANATOMIC RISK | Low | PCI | PCI | PCI |
| | Medium | CABG or PCI | CABG or PCI | Support & PCI |
| | High | CABG | CABG or PCI | Support & PCI |

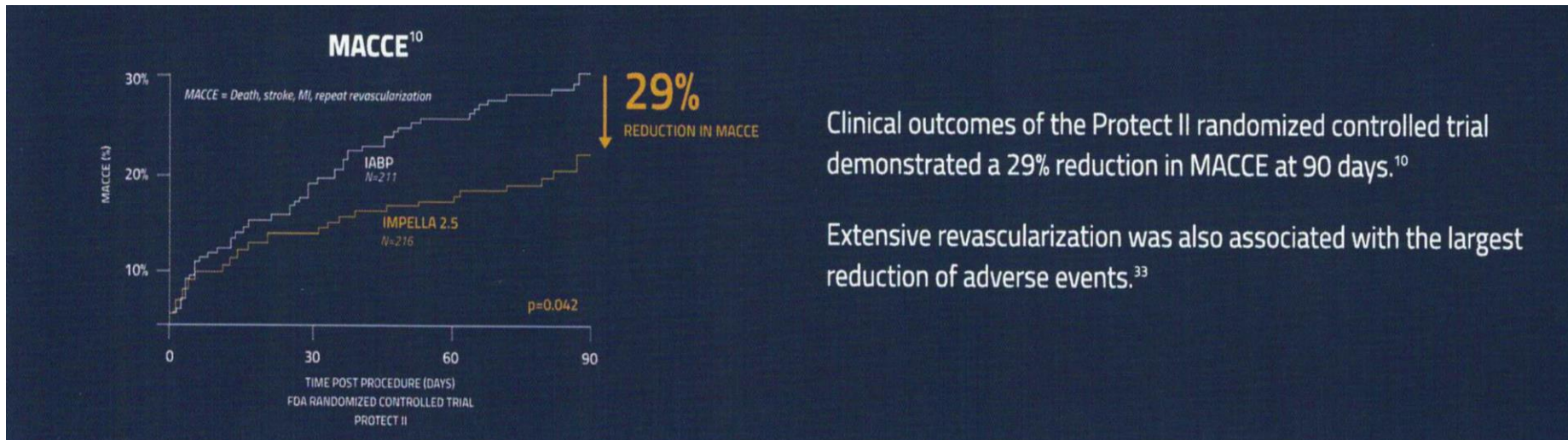
SYNTAX STUDY

Protected PCI
FDA-indicated
Safe & effective
ACC/AHA PCI Guidelines^{3, 15}

A High Risk Profile of the Protect II Patient Population

The Protect II population was perhaps the sickest elective and urgent PCI population ever studied in contemporary medical history. Patients were symptomatic and presented with high risk features including complex coronary anatomy (mean SYNTAX score= 30 ± 13), depressed left ventricular ejection fraction (mean LVEF= $24 \pm 6\%$) and other comorbidities including prior procedures, making most of them ineligible as surgical candidates (average Society of Thoracic Surgery (STS) score= $6 \pm 6\%$) (See Figure 1 and Table 2).

Protect II



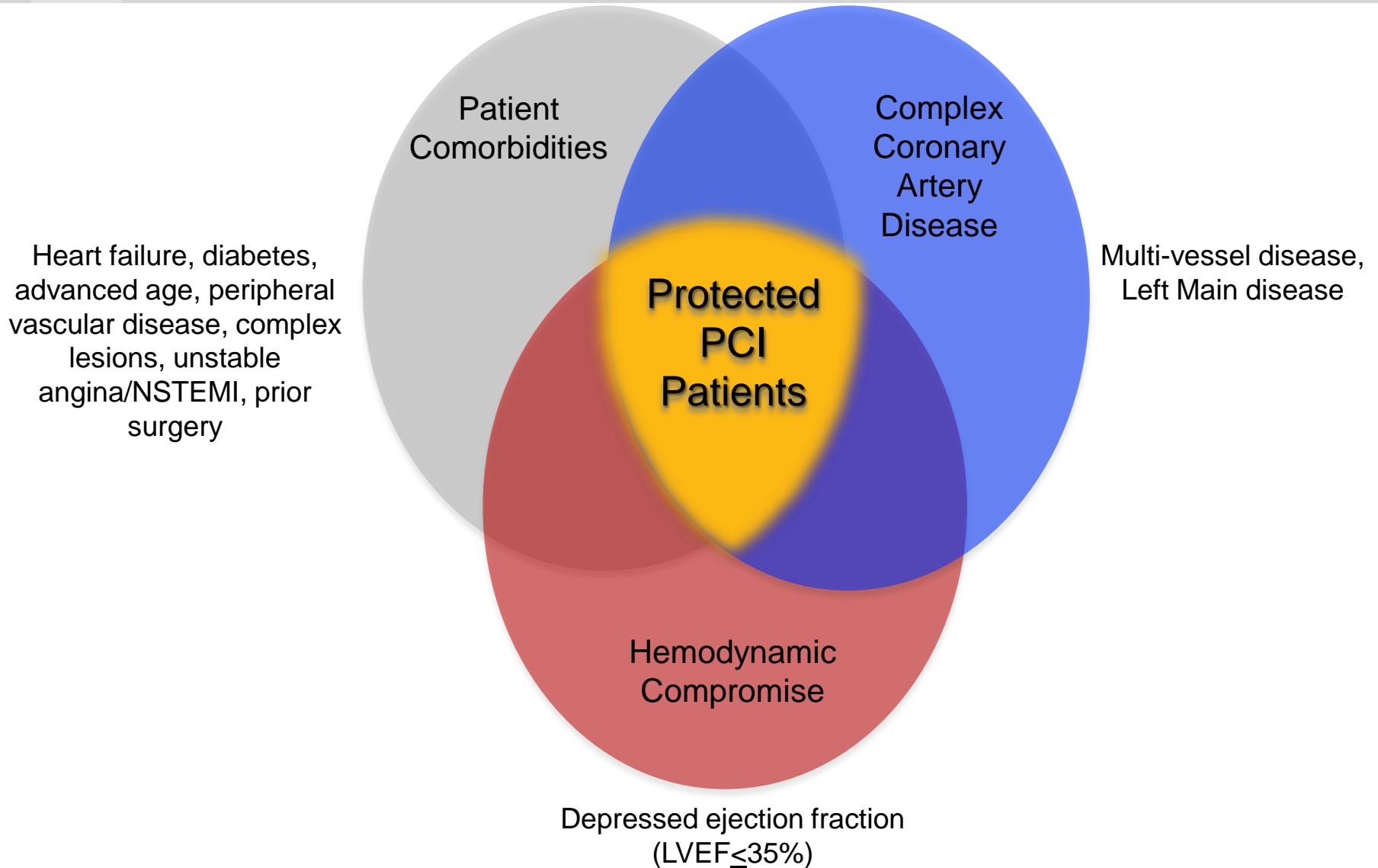
The patient population enrolled consisted of patients undergoing elective or urgent hemodynamically-supported high risk PCI on an unprotected left main or last patent conduit, with an LVEF \leq 35%, or patients who had three-vessel disease and an LVEF \leq 30%. Investigators were to identify the target lesions prior to randomization and then aim for the most complete revascularization of the myocardium at jeopardy in a single procedure. The randomization was 1:1 between the two study arms (Impella vs. IABP).

High-Risk-PCI

Prolonged time of intervention

- Multi-vessel PCI or LM
 - Complex lesion treatment
(e.g. additional therapy options like Rotablation therapy)
- Hypotensiv and ischemic episodes during intervention
- higher EDV + EDP → higher O_2 demand and reduced O_2 Supply
 - Lower aortic pressure → reduced O_2 Supply + reduced cardiac output

High-Risk-PCI

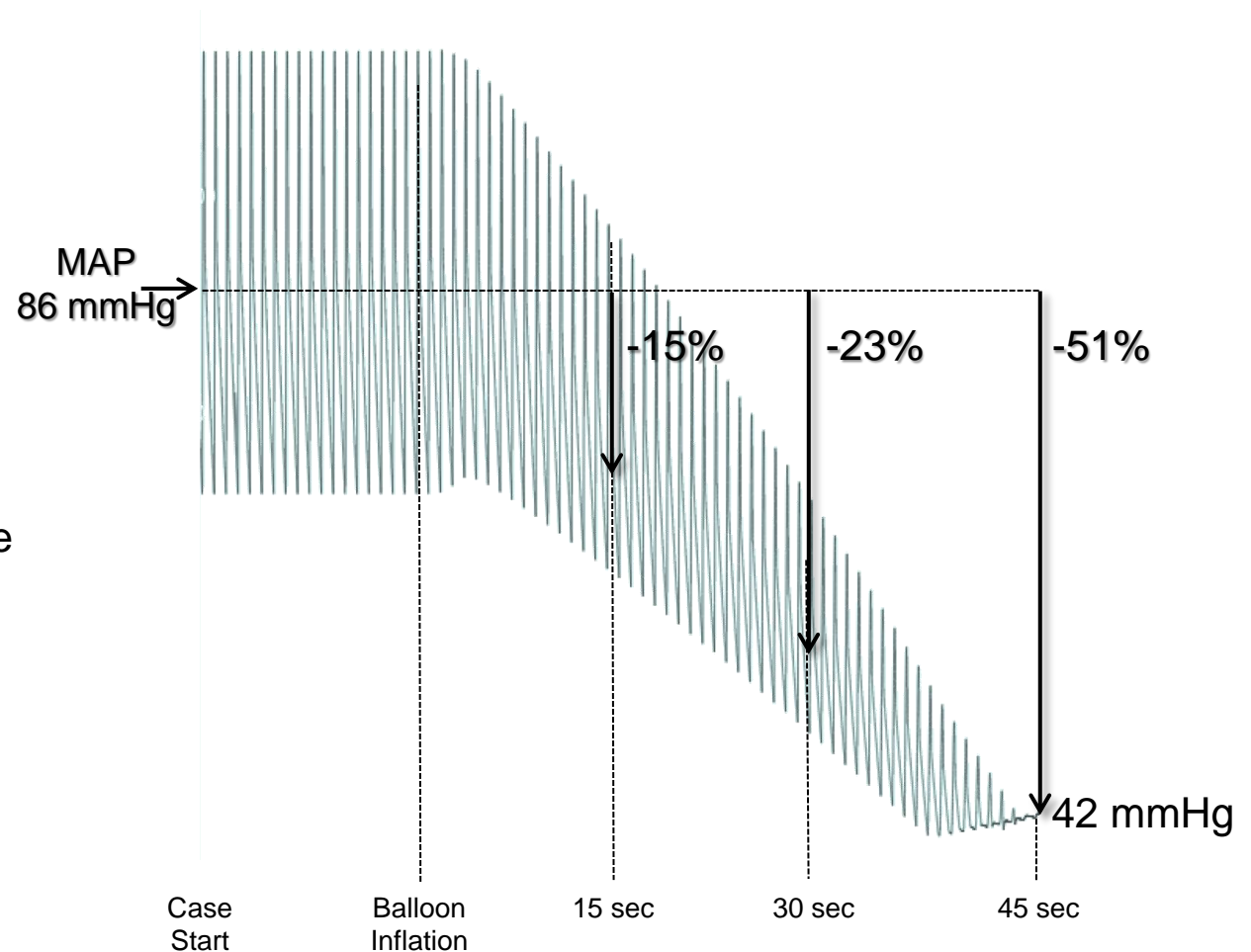


HEMODYNAMICS OF PROTECTED PCI

Simulated Arterial Pressure Tracings¹

Case Example

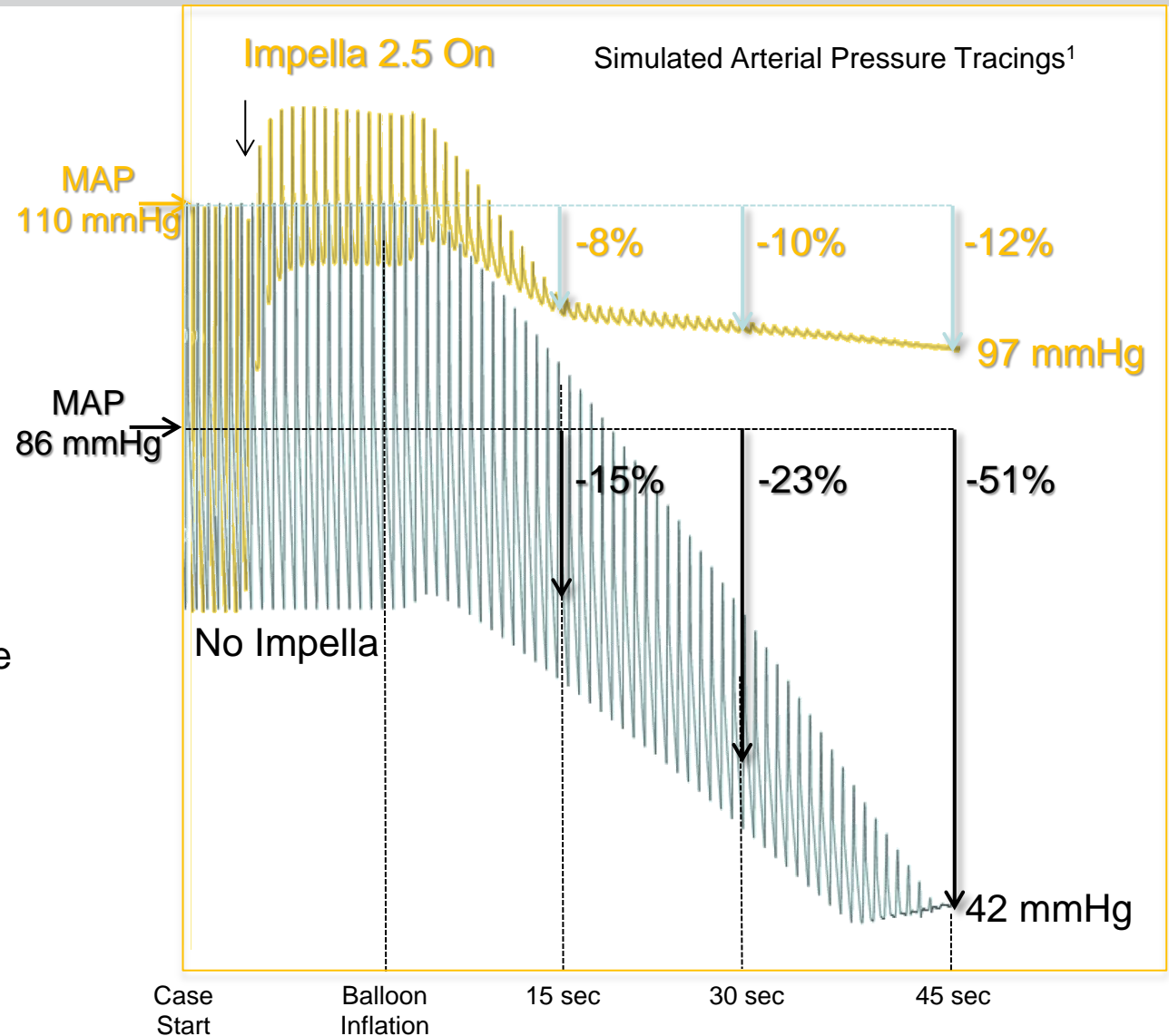
- 66 yo male
- 85% SVG
- Last patent conduit
- EF = 30%
- NYHA Class IV
- Prior CABG
- Prior PCI
- Not Surgical Candidate



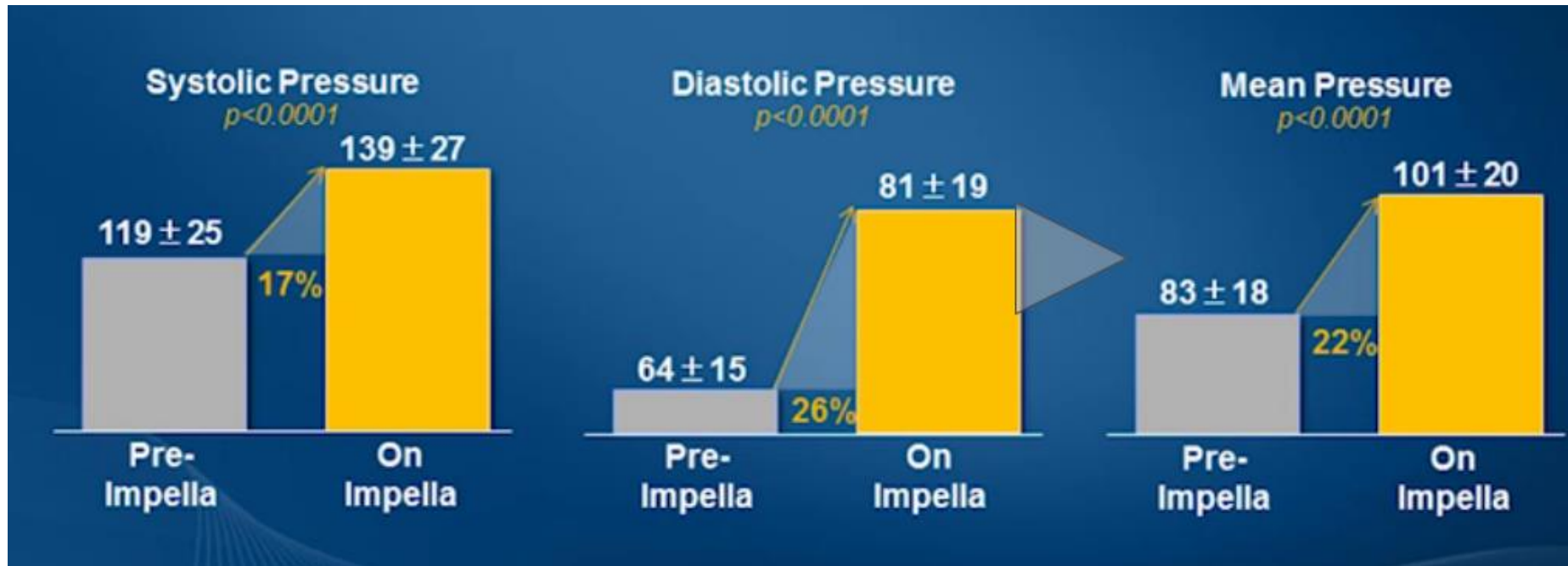
HEMODYNAMICS OF PROTECTED PCI

Case Example

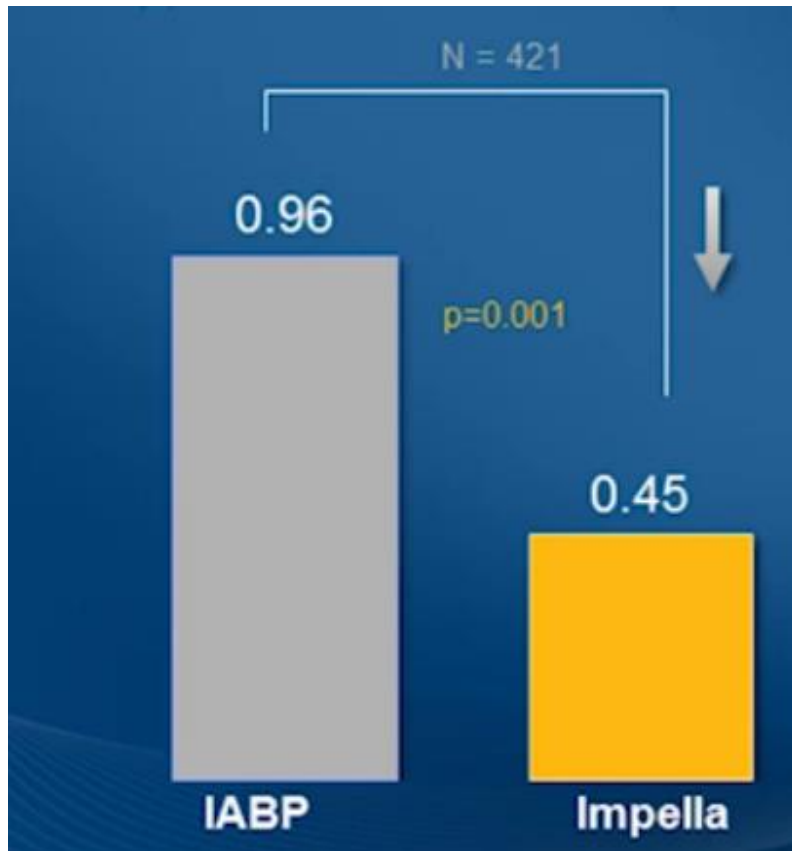
- 66 yo male
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IMPELLA REGISTRIES (N= 148)



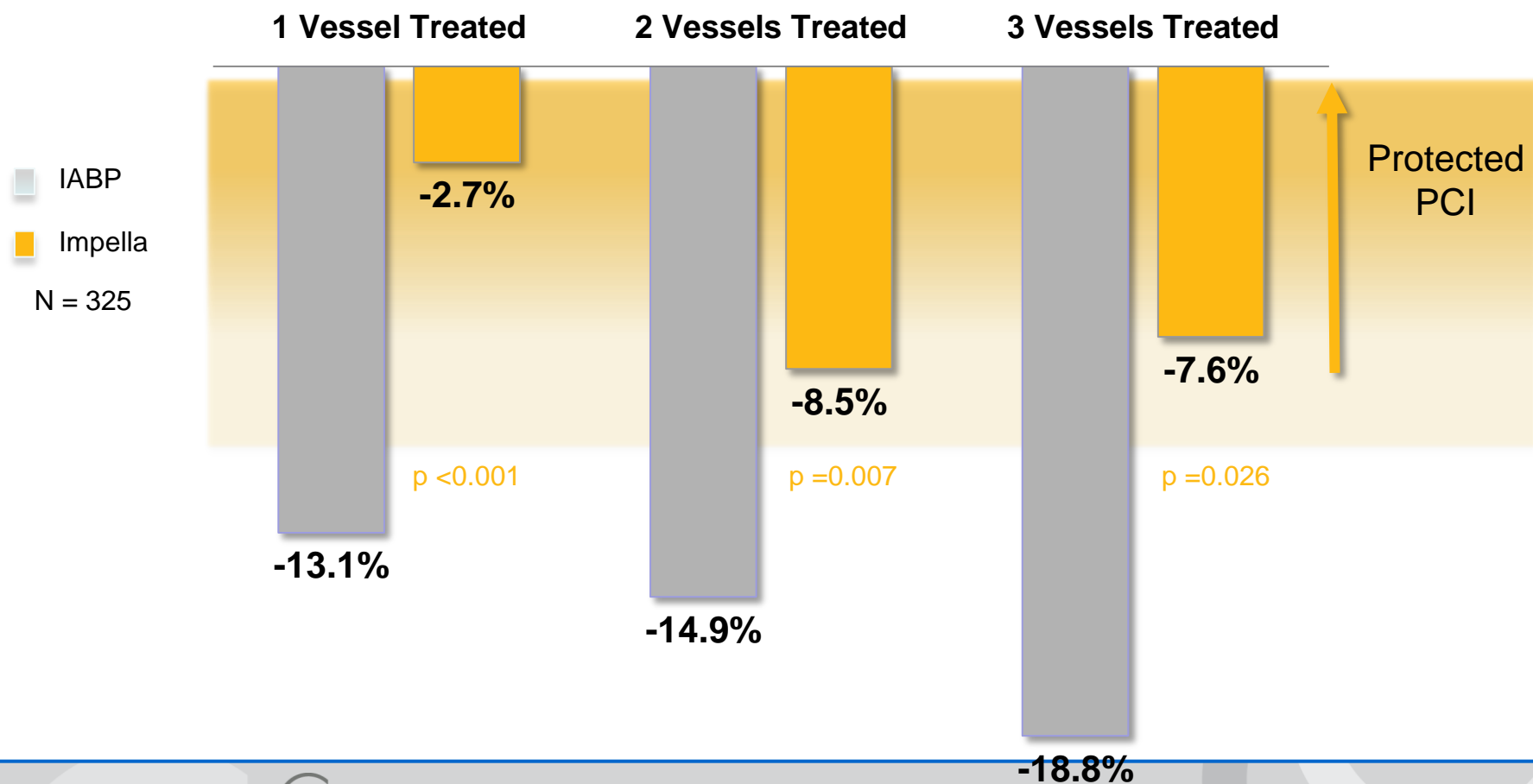
HYPOTENSIVE EVENTS PRO PATIENT



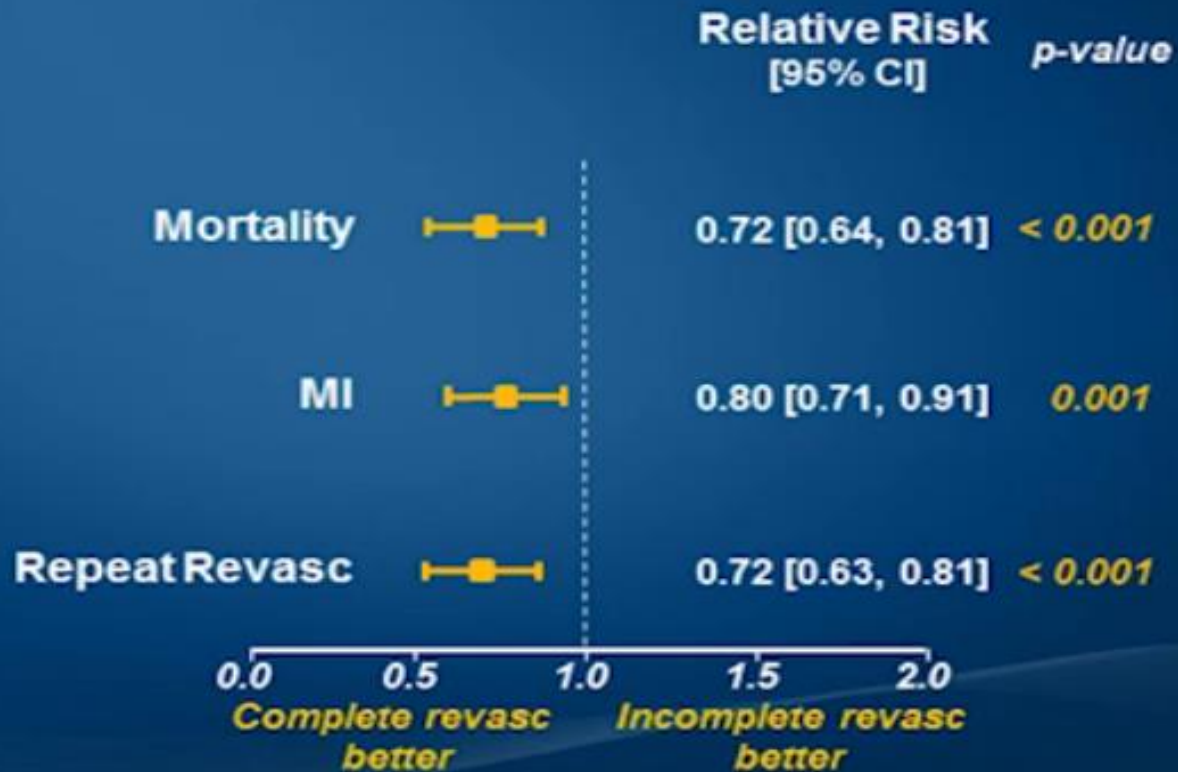
53% Reduktion

IMPELLA MAINTAINS PATIENT HEMODYNAMICS ALLOWING FOR MORE COMPLETE REVASCULARIZATION

Procedural Decrease in Arterial Pressure from Baseline

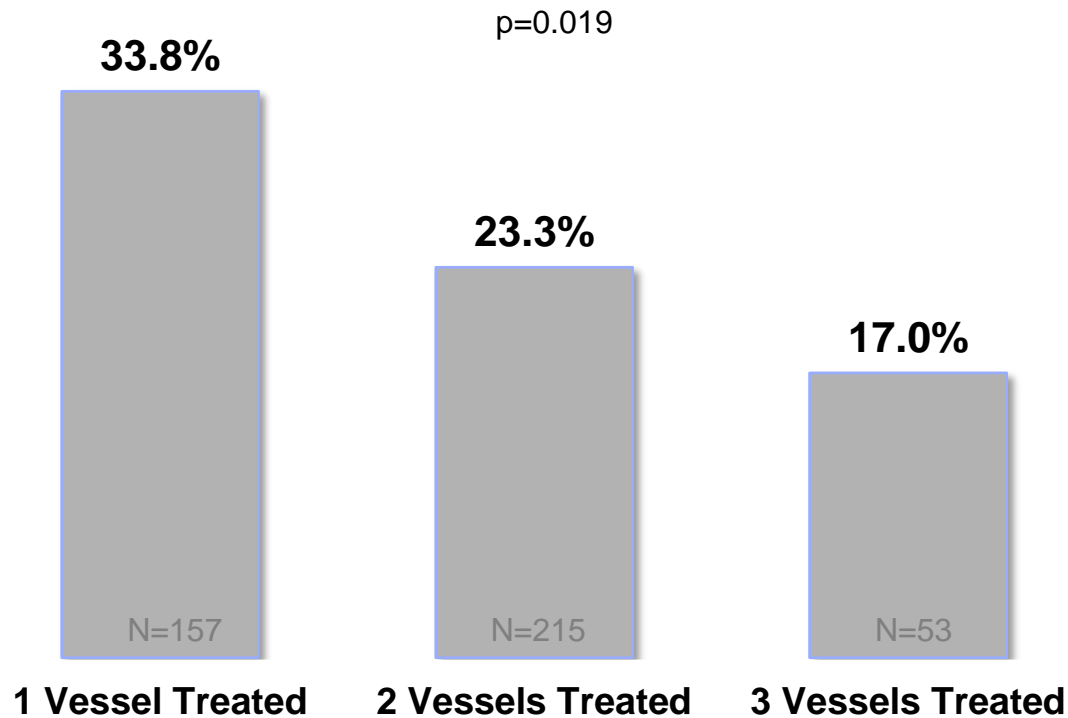


Pooled PCI Studies



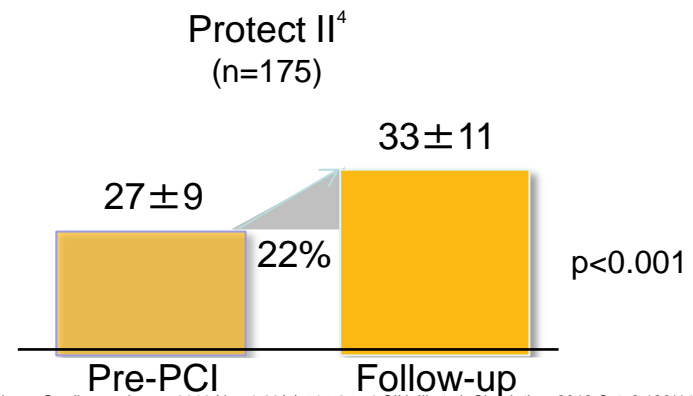
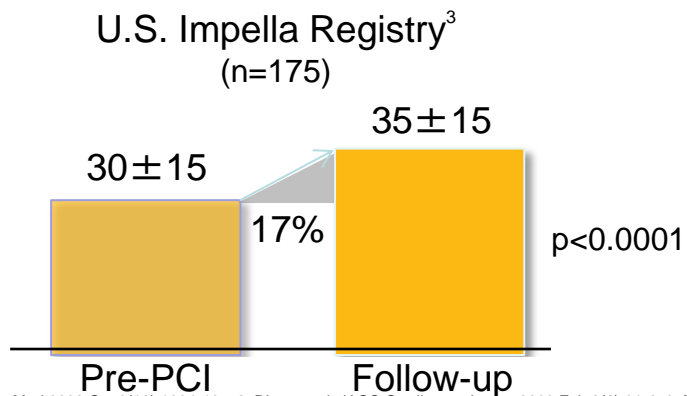
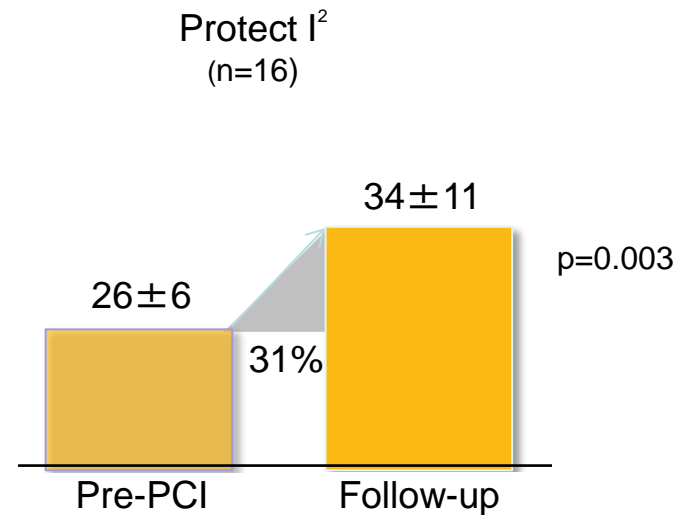
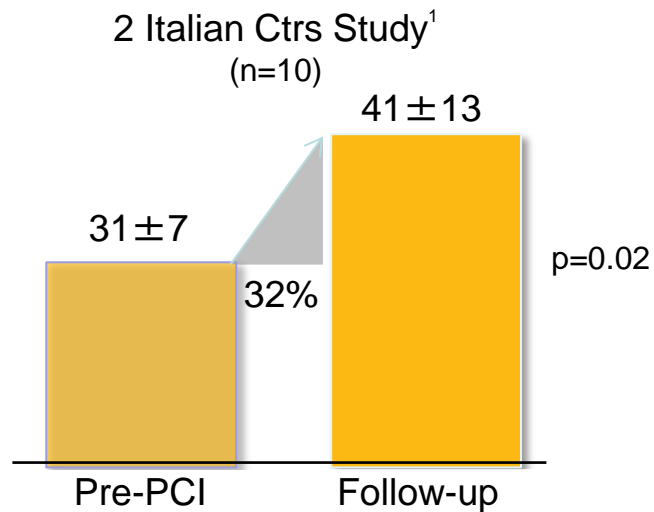
MORE COMPLETE REVASCUARIZATION LEADS TO REDUCED ADVERSE EVENTS

MACCE at 90 Days
Protect II Both Arms, All Patients



HIGH RISK PATIENTS BENEFIT FROM PROTECTED PCI

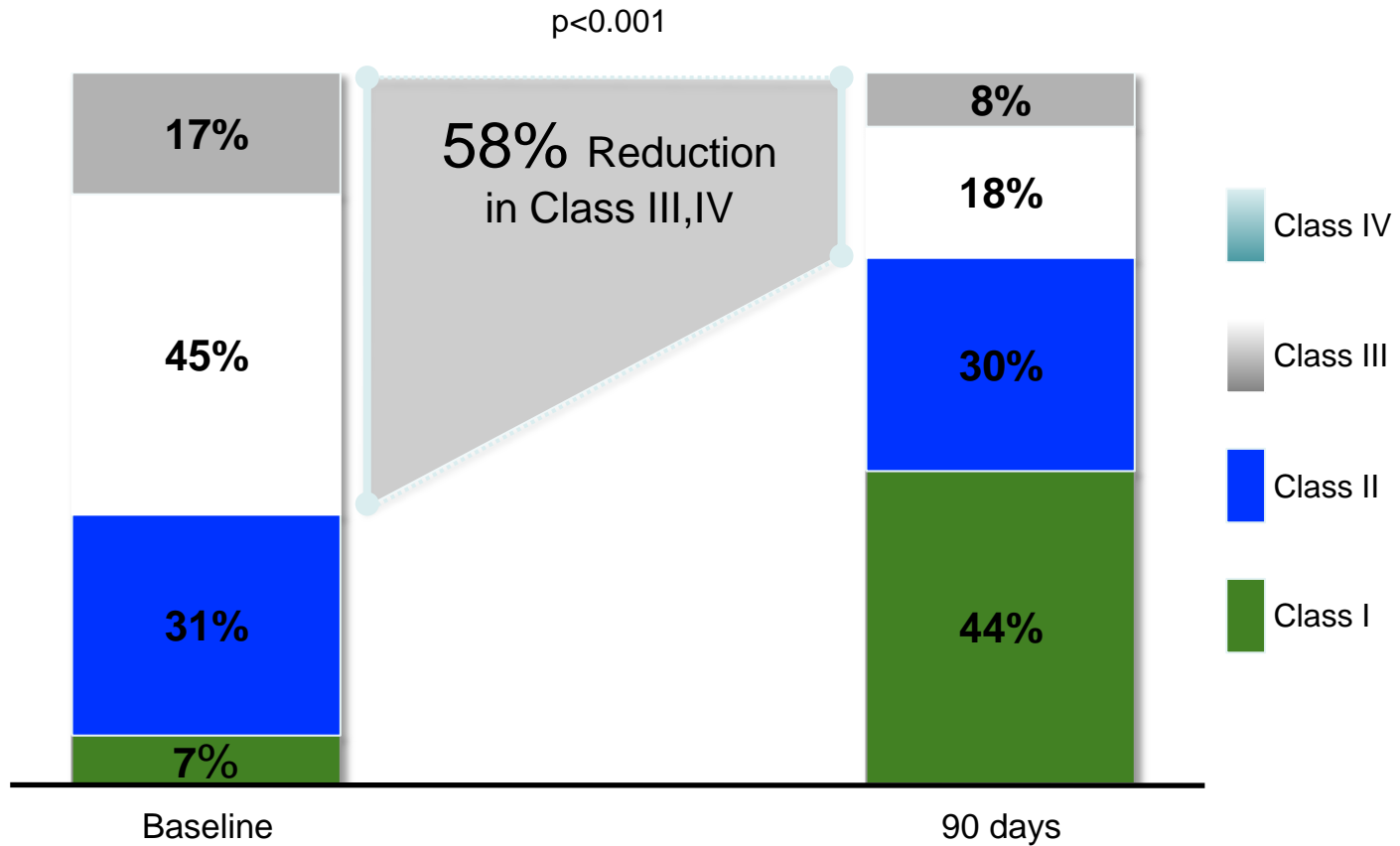
LVEF Improvement Post Protected PCI



1. Burzotta et al. Cardiovasc Med 2008 Oct;9(10):1004-10.; 2. Dixon et al. JACC Cardiovasc Interv. 2009 Feb;2(2):91-6; 3. Maini et al. Catheter Cardiovasc Interv. 2012 Nov 1;80(5):717-25.; 4. O'Neill et al. Circulation. 2012 Oct 2;126(14):1717-27

IMPROVEMENT IN QUALITY OF LIFE POST PCI

NYHA Class Improvement Post Procedure



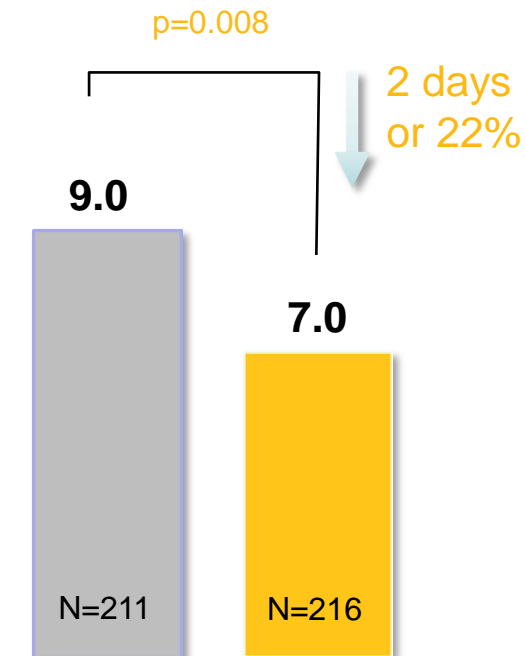
N=223 patients with NYHA measurements available at baseline and 90 days¹

FDA Approved
Randomized

REDUCED LENGTH OF STAY WITH PROTECTED PCI

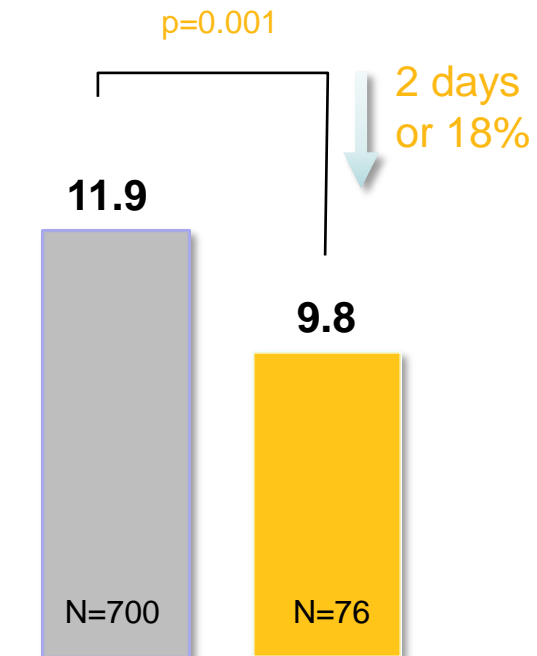
Protect II RCT

Total Days in Hospital^{1,3}



Population Study, Optum

Total Days in Hospital^{2,3}



1. Gregory , O'Neill, et al. American Health & Drug Benefits 2013 Mar;6(2):88-99
2. Gregory, et al. Managed Care Medicine, Feb 2013; OptumInsight division of United Healthcare
3. Maini, et al. Expert Rev Pharmacoecon Outcomes Res. 2014 Jun;14(3):403-16

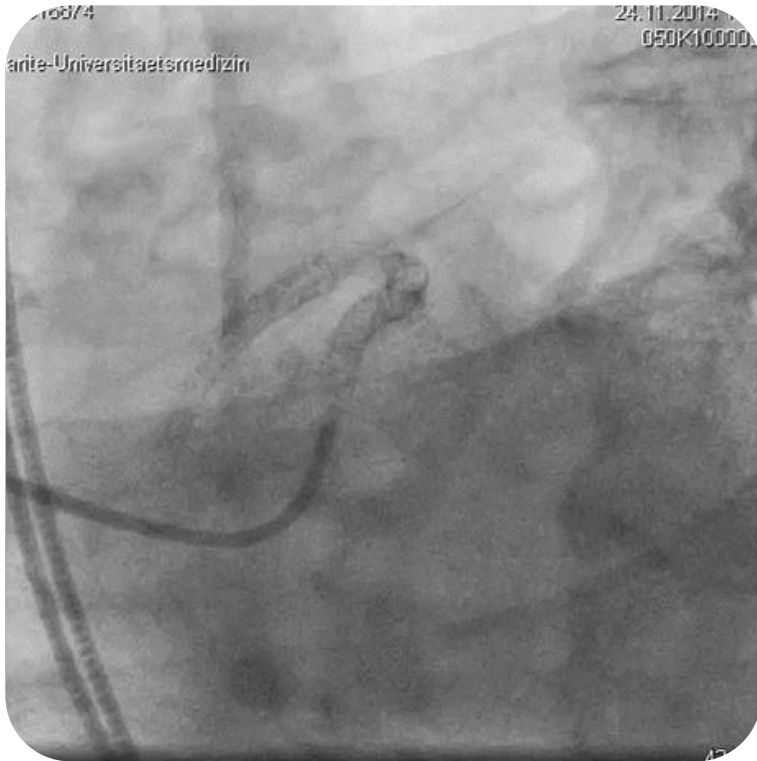
80- years old patient

Angina CCS III-IV for several days

- Known coronary heart disease
- Myocardial infarction and stent-implantation LAD
- PM-Implantation 2014 (AV-Block II. und III)
- Moderate reduced LV-function (LVEF 40%)

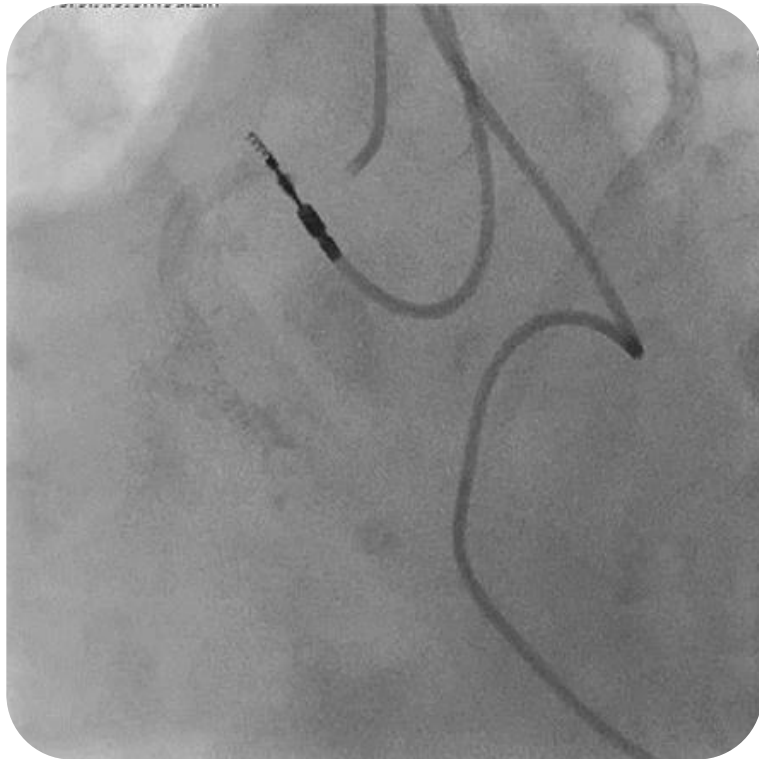
- Stroke with Aphasia und Hemiparesis 06/2014.
- Hypertension
- Diabetes mellitus, Typ II
- Hyperlipoproteinämie
- Hypothyreose (substituted)
- Chronic Renal Impairment

Coronary angiography



LAO 45° CAU 19°

Coronary angiography



LAO 38° CRA 22°

Coronary Angiography

3 vessel disease

- Distal left main, calcificated?
- High-graded LAD Stenose, ostial
- High-graded LCX Stenose, ostial
- CTO of RCA with bridging collaterales

SYNTAX Score von 35

CABG is not option for this patient

Log EuroScore 50,84%

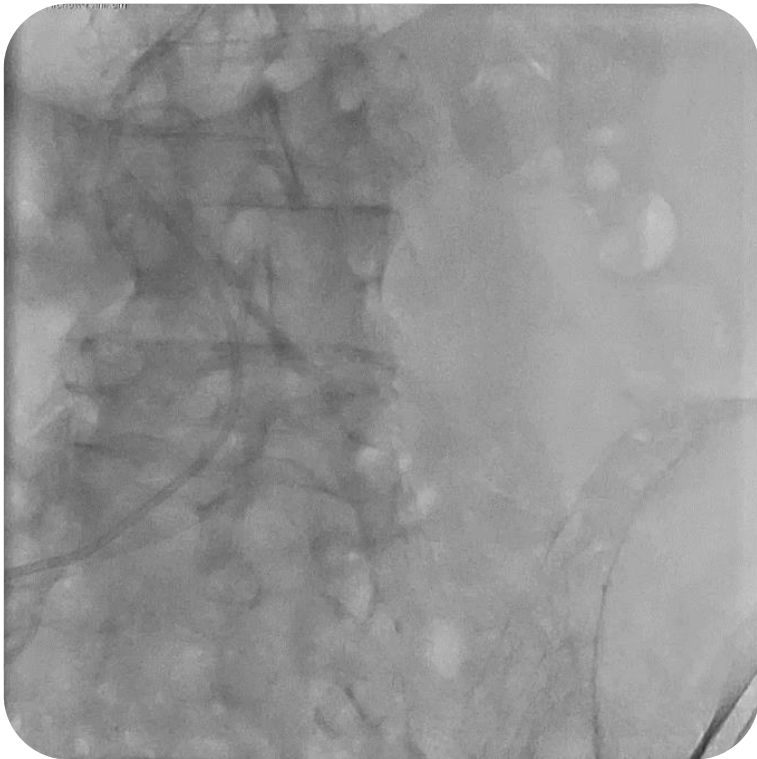
| Patient-related factors | | | Cardiac-related factors | | |
|--|---------------------------------|---------|-------------------------------------|-----------------------------------|---------|
| Age (years) | 80 | 0 | Unstable angina ⁵ | Yes <input type="checkbox"/> | 5677075 |
| Gender | Female <input type="checkbox"/> | 3304052 | LV function | Moderate <input type="checkbox"/> | 4191643 |
| Chronic pulmonary disease ¹ | No <input type="checkbox"/> | 0 | Recent MI ⁷ | Yes <input type="checkbox"/> | 5460218 |
| Extracardiac arteriopathy ² | No <input type="checkbox"/> | 0 | Pulmonary hypertension ⁸ | No <input type="checkbox"/> | 0 |
| Neurological dysfunction ³ | Yes <input type="checkbox"/> | 841626 | Operation-related factors | | |
| Previous Cardiac Surgery | No <input type="checkbox"/> | 0 | Emergency ⁹ | No <input type="checkbox"/> | 0 |
| Creatinine > 200 µmol/L | Yes <input type="checkbox"/> | 6521653 | Other than isolated CABG | No <input type="checkbox"/> | 0 |
| Active endocarditis ⁴ | No <input type="checkbox"/> | 0 | Surgery on thoracic aorta | No <input type="checkbox"/> | 0 |
| Critical preoperative state ⁶ | No <input type="checkbox"/> | 0 | Post infarct septal rupture | No <input type="checkbox"/> | 0 |

Logistic EuroSCORE 50,84%

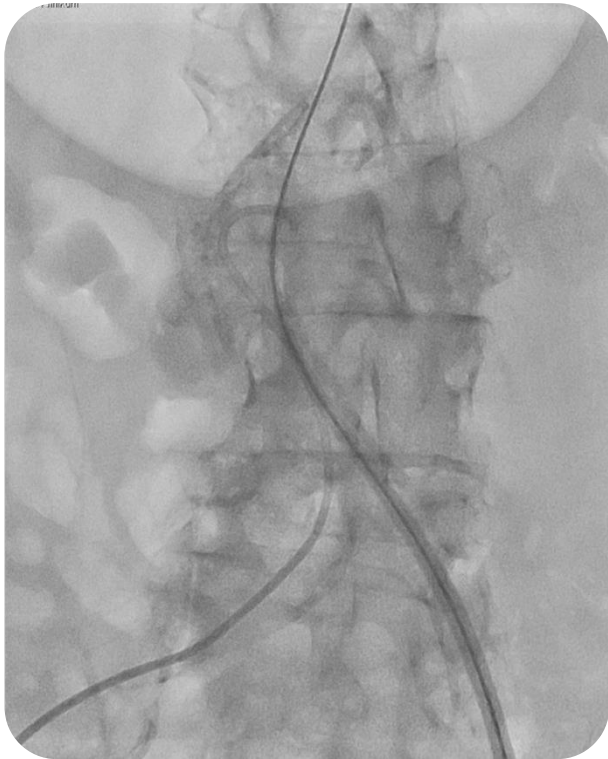
PCI Approach

- PCI mit hemodynamic support with a Impella 2.5
- PCI LM/LAD und LCX
- If necessary with rotablation therapy

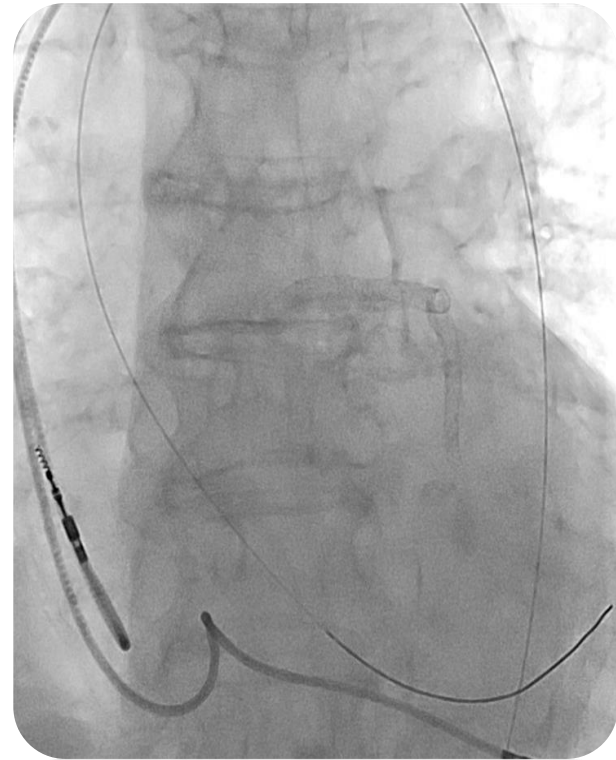
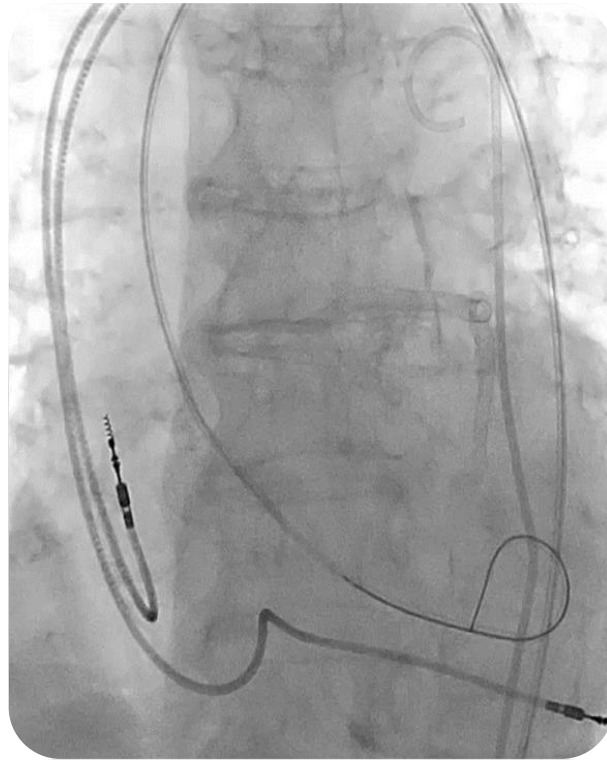
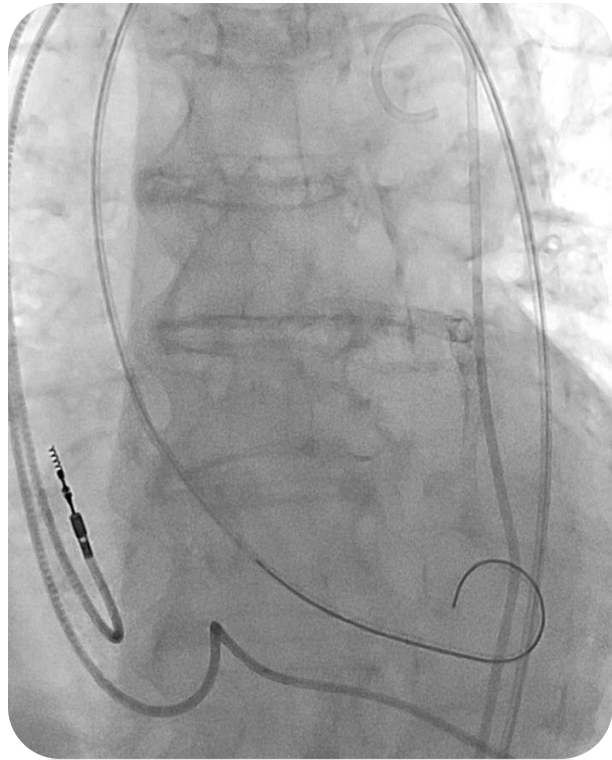
Angiography



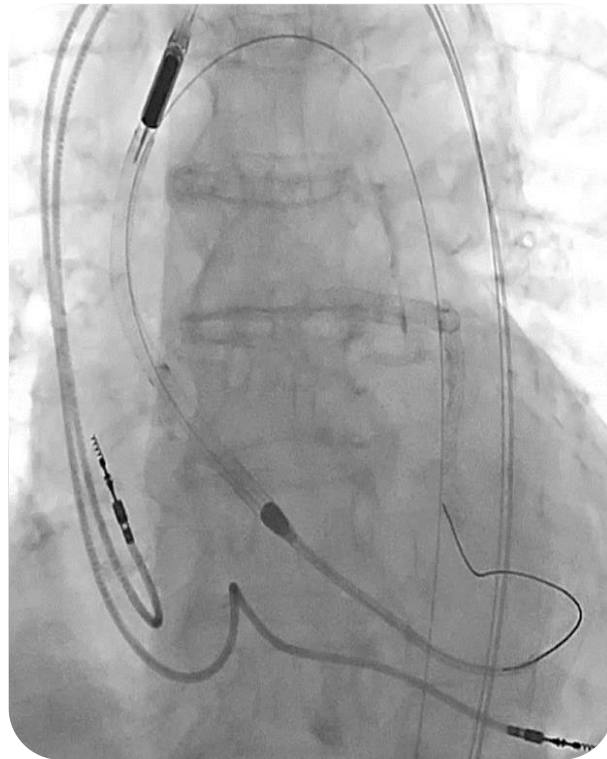
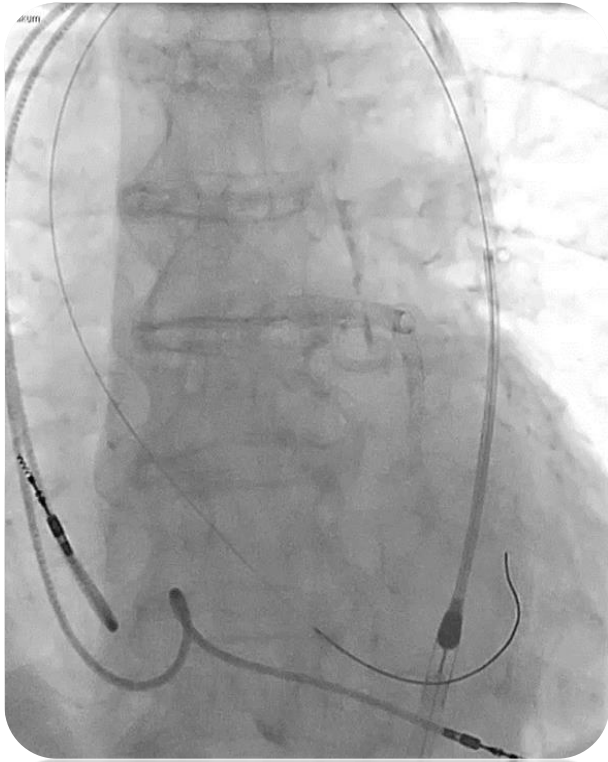
Impella-Implantation



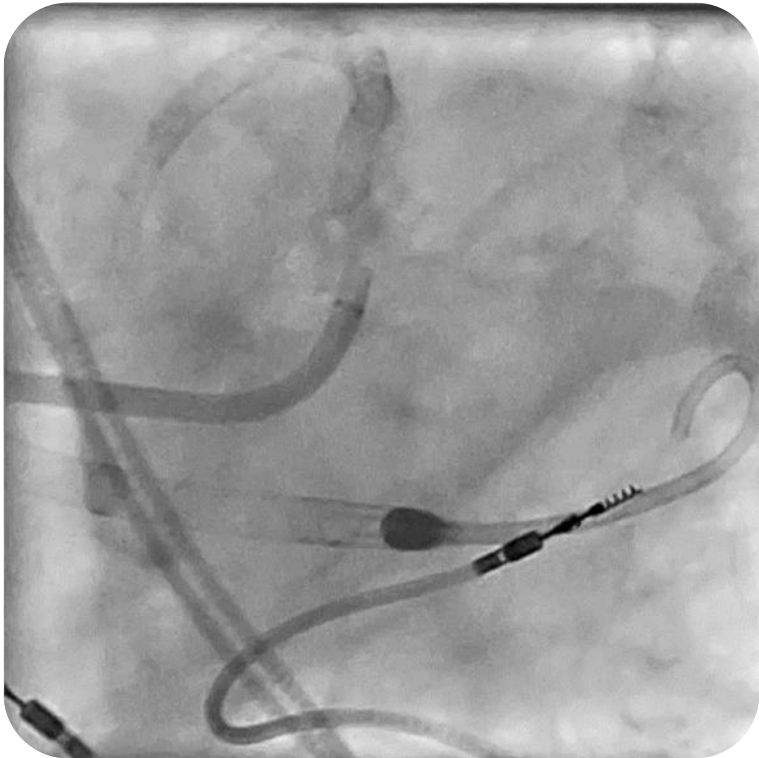
Impella-Implantation



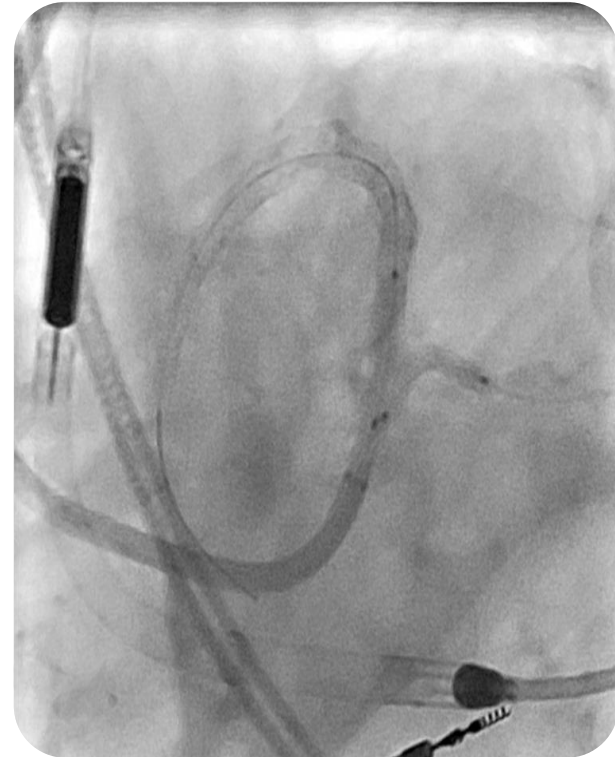
Impella-Implantation



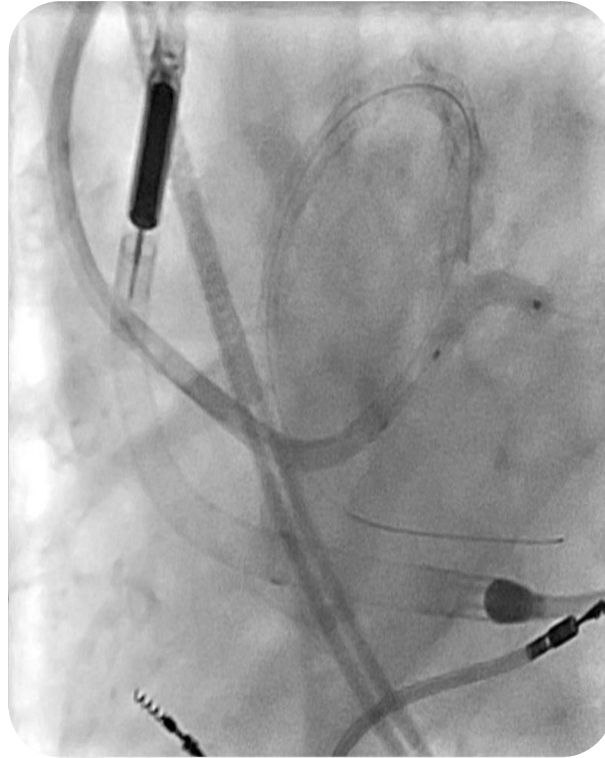
Coronary angiography



LAO 47° CAU 28°



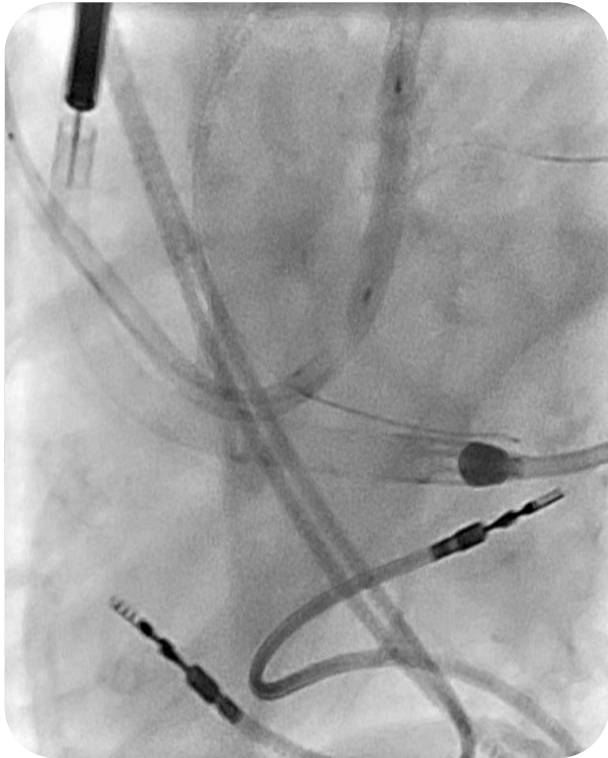
2x Maverick 2.5 x15 mm, 16 bar, 15 Sec



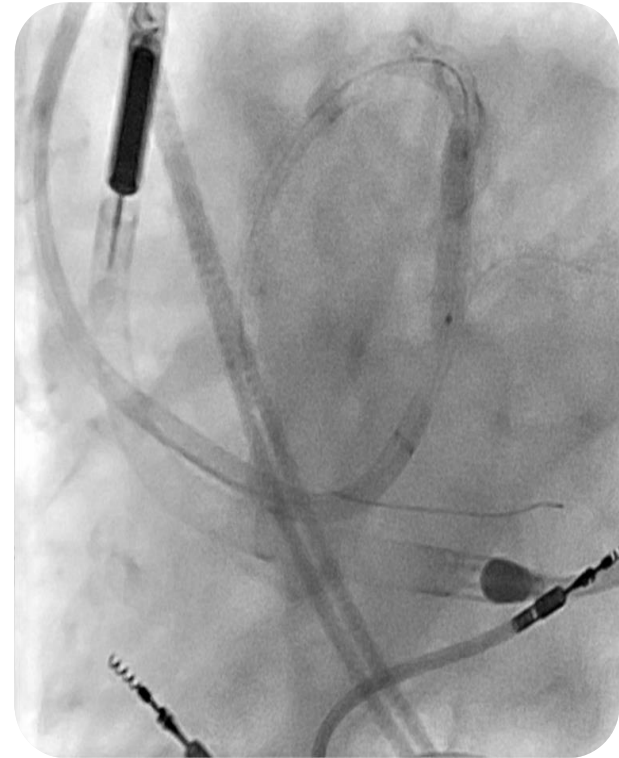
Maverick 3.0 x 15 mm, 16 bar, 40 Sec



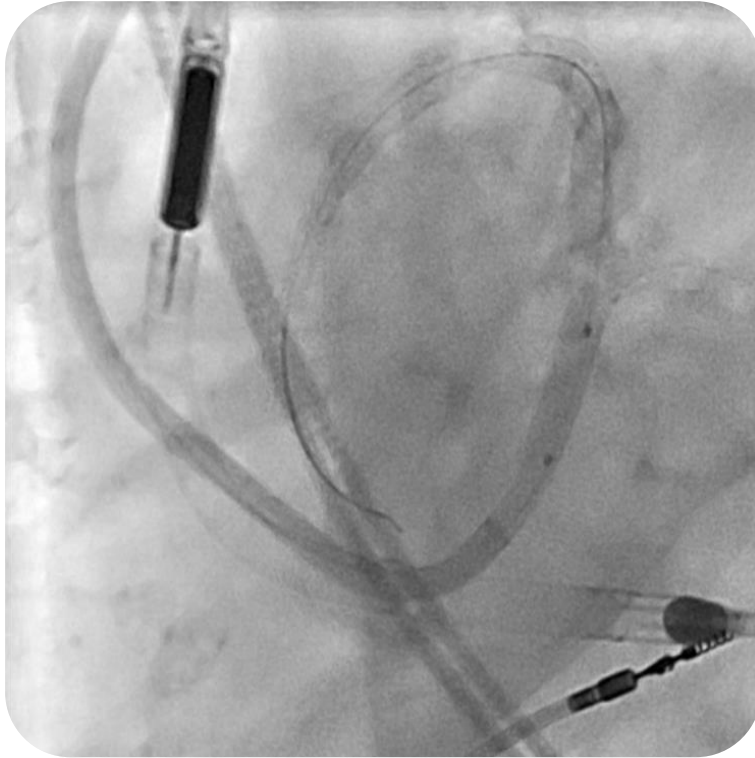
Biomatrix 3.0 x 14 mm



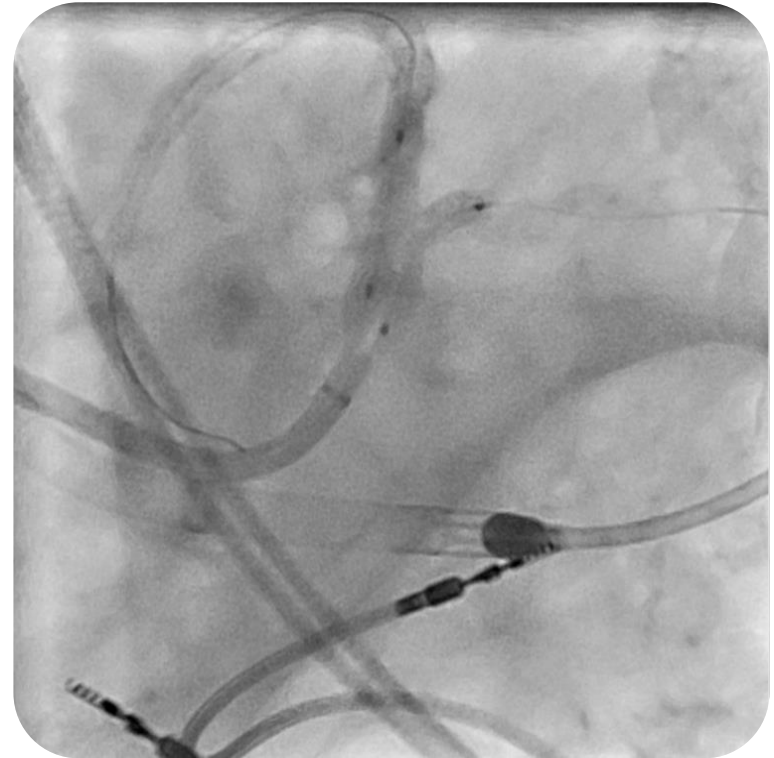
Maverick 3.5 x 20 mm



Biomatrix 3.5 x 18 mm

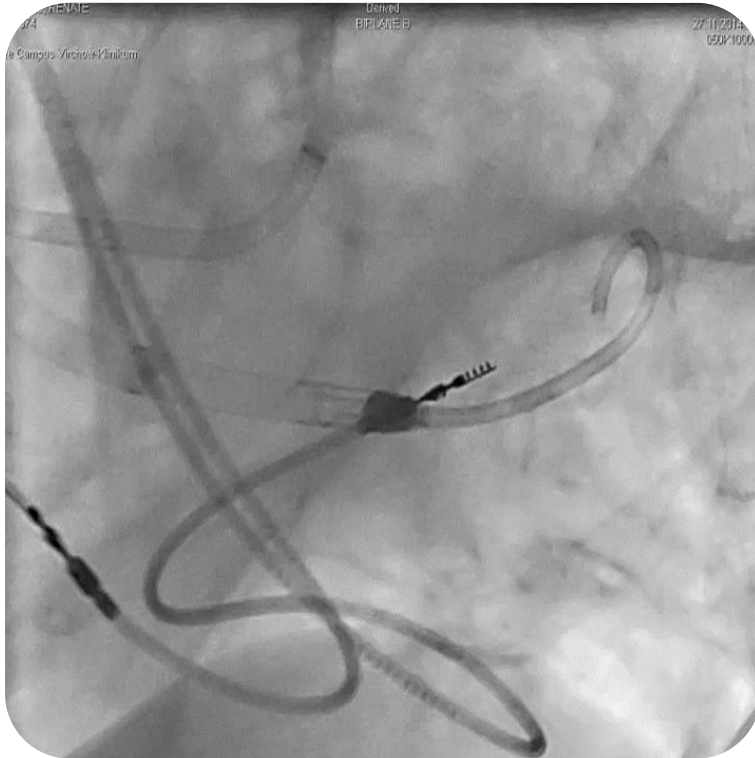


NC Ballon 4.0 x 12 mm



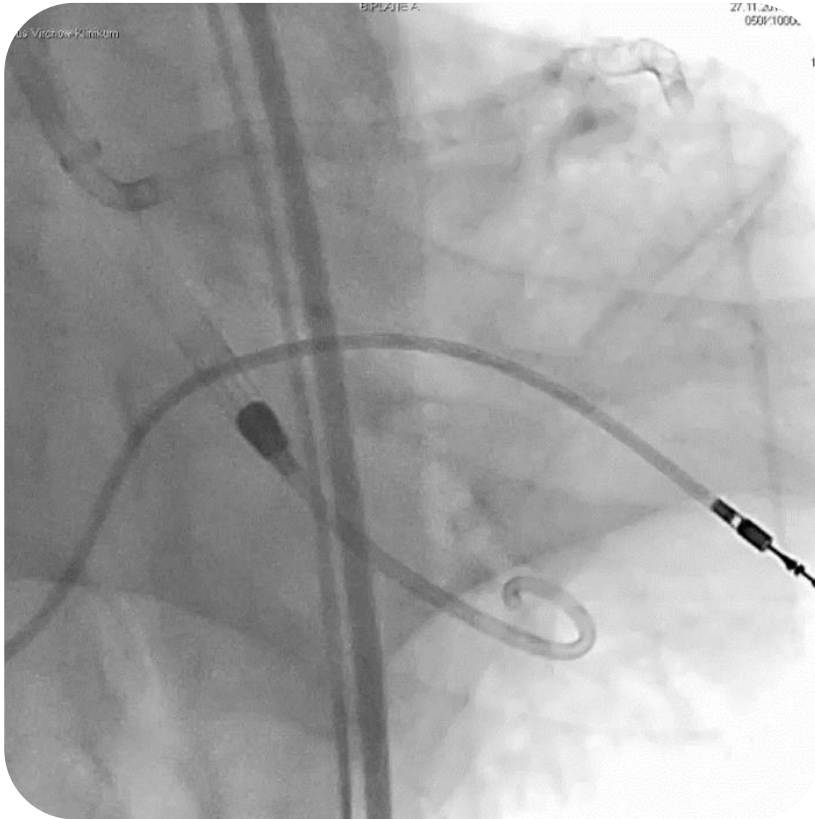
Kissing Ballon: 3.5 x 15 / 3.0 x 15 mm

Final Result



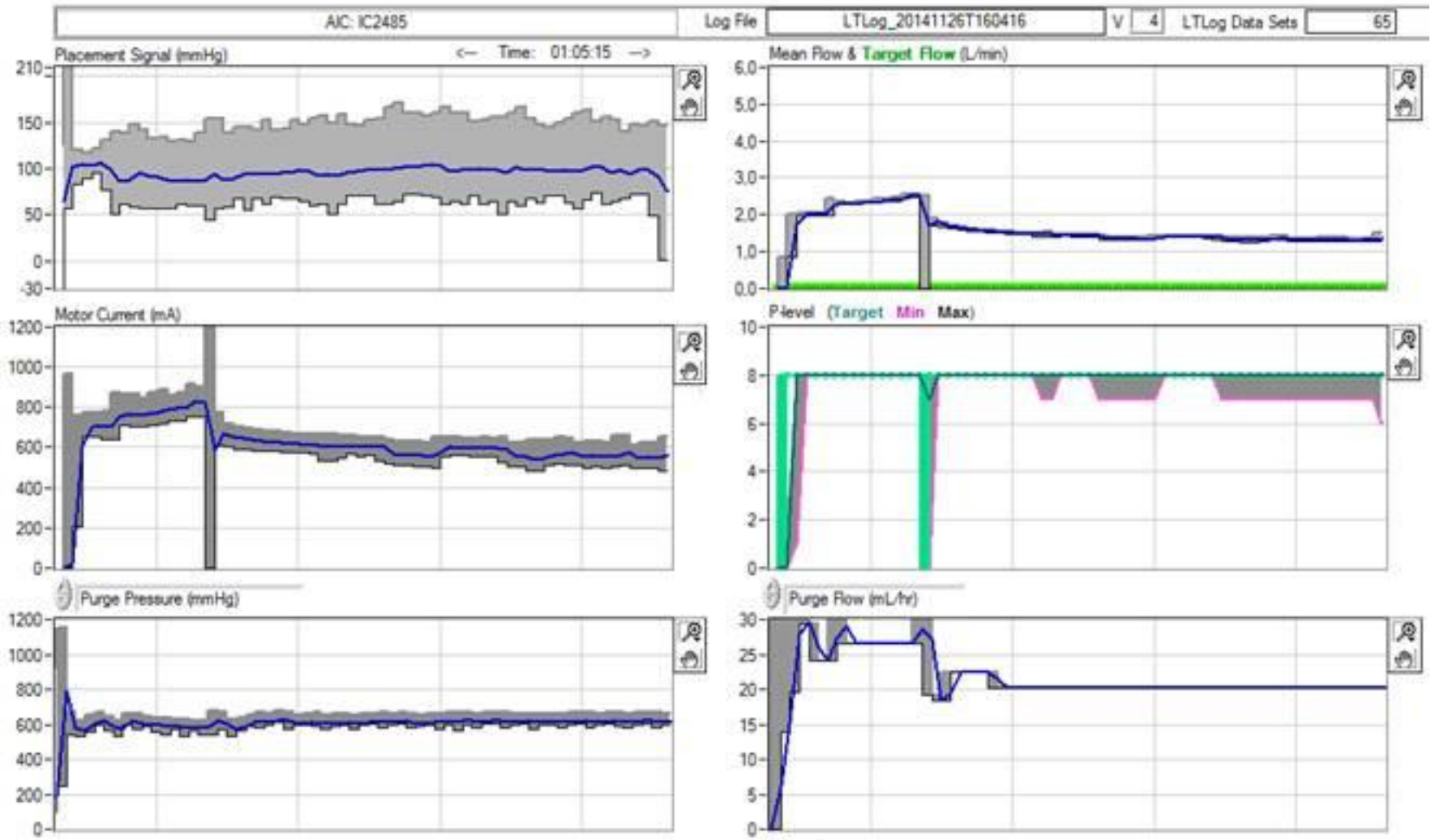
LAO 48° CAU 28°

Final Result

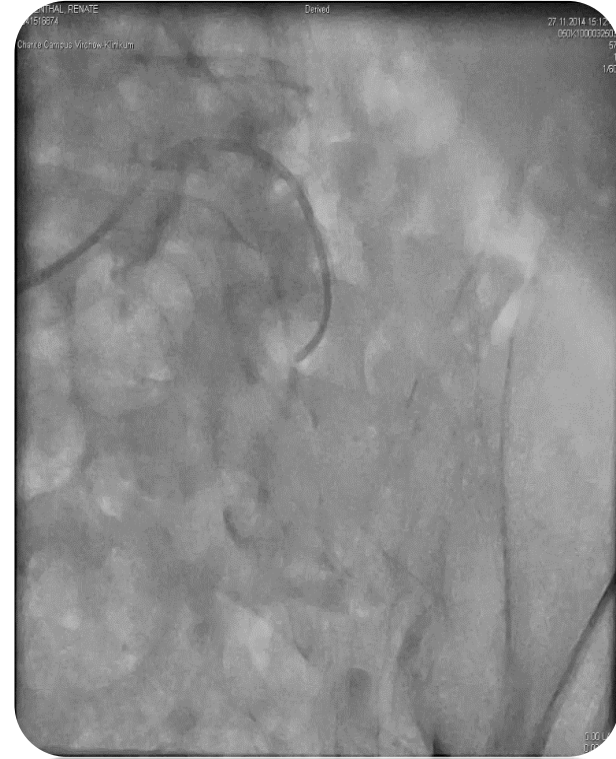
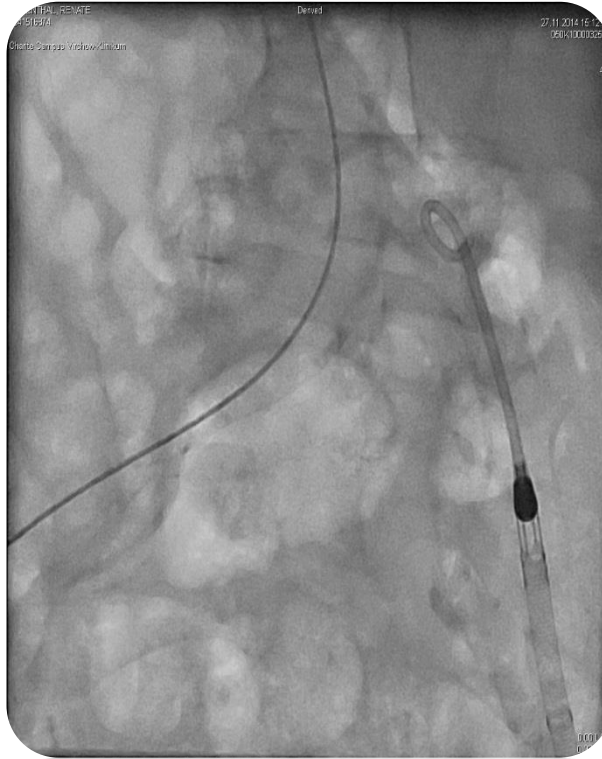
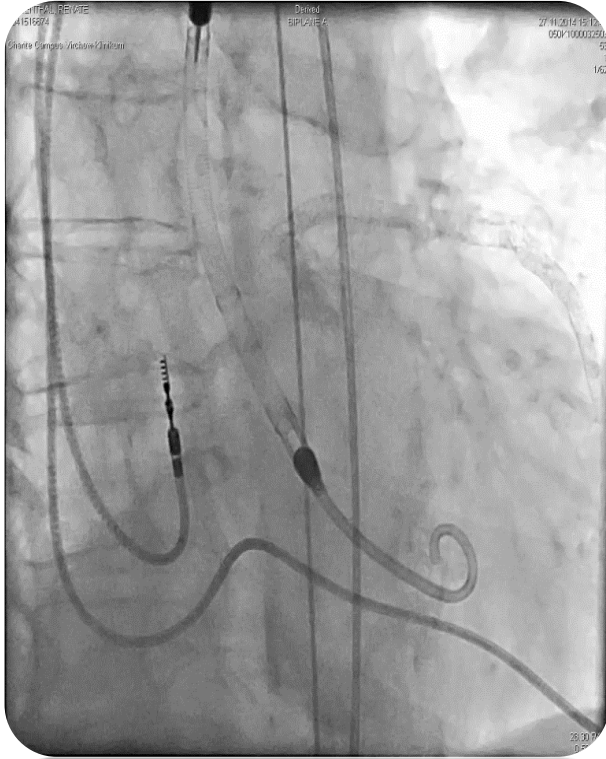


RAO 22° CAU 37°

Hemodynamic results



Impella Explantation



Proglide-Device

Follow up

- Intermediate care station for one night
 - No periprocedural complications
- Demission two days later
- 6 months FU
 - no AE
 - Dypnoe NYHA II
 - No angina

Conclusion

- Impella blood pump is safe and effective in elective and urgent high-risk PCI patients by reducing peri-and post-procedural adverse events.
- High risk PCI can be defined as the combination of complex coronary artery disease, hemodynamic compromise and patient's comorbidities.
- High risk PCI is not only limited to reduced LV function or urgent interventions.
- For these patients protected PCI with prophylatic Impella support offer safe hemodynamic conditions during complex intervention.



Thank you very much !