

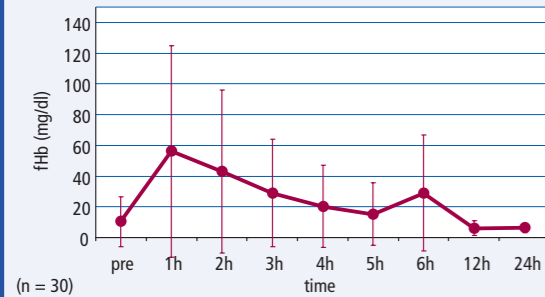
Complications

- No device related aortic valve injuries
- No reported infections
- Low incidence of thromboembolic events
- Transient reduction of thrombocytes was observed in some patients
- Low bleeding tendency
- Hemolysis (fHb) was transient
Depending on patient's pre-interventional status (prolonged shock, fever...) transient increase of fHb was observed, but went down while being on pump support

→ Overall low complication rate.

Impella® LP2.5

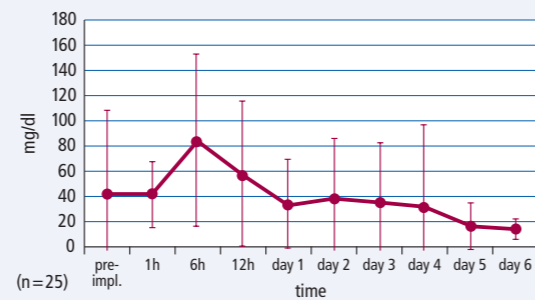
fHb (mean) High Risk interventions



Hemolysis (fHb) was transient and returned to baseline values within 24 hours.

Impella® LD/RD/LP5.0

fHb (mean) Post Cardiomy



Hemolysis (fHb) was transient, went down after 1st day on support and returned to baseline values within the following days.

Conclusion

- Safe and reliable platform technology for various indications
- Low anticoagulation required
- Reduction in myocardial workload
- Increase of coronary and end-organ perfusion
- Adequate hemodynamic support
- Unloading of the ventricle
- Reduction of inotropes
- Low complication rate
- Reduces risk of hemodynamic deterioration during High Risk interventions
- Impella® LP2.5: Fast, easy and safe percutaneous insertion

Some scientific publications that detail the experiences with the Impella® pump system are listed below

- Jurmann MJ, Siniawski H, Erb M, Drews T, Hetzer R. Initial experience with miniature axial flow ventricular assist devices for postcardiotomy heart failure. *Ann Thorac Surg* 2004; 77(5):1642-1647.
- Meyns B, Stolinski D, Leuneus V, Verbeken E, Flameng W. Left Ventricular Support by Catheter-Mounted Axial Flow Pump Reduces Infarct Size. *Journal of the American College of Cardiology*, Vol 41, No. 7, 2003.
- Siegenthaler MP, Brehm K, Strecker T, Hanke T, Nötzold A, Olschewski M, Weyand M, Sievers H, Beyersdorf F. The Impella-Recover microaxial left-ventricular-assist-device reduces mortality for postcardiotomy failure – A three center experience, *The Journal of Thoracic and Cardiovascular Surgery* 2004; 127: 812-822.
- Reesink K, Dekker A, van der Nagel T, van der Veen E, van Ommen V, Ganushak Y, Geskes G, Soemers C, Maessen J. New Impella Intracardiac Minipump Supports the Acutely Failing Left Heart Significantly More Effective Than Intra Aortic Balloon Pumping. Abstract STS, 2002.
- Colombo T, Garatti A, Bruschi G, Lanfranconi M, Russo C, Milazzo F, Catena E, Frigerio M, Vitali E. First Successful Bridge to Recovery with the Impella Recover 100 Left Ventricular Assist Device for Fulminant Acute Myocarditis. *Italian Heart Journal* 2003; 4(9): 642-645.
- Meyns B, Dens J, Verbeken E, Sergeant P, Herijgers P, Daenen W, Flameng W. Initial Experiences with the Impella Device in Patients with Cardiogenic Shock. *Thorac Cardiovasc Surg* 2003; 51:1-6.
- Christiansen S, Brose S, Demircan L, Autschbach R. Case report – A New Right Ventricular Assist Device for Right Ventricular Support, *European Journal of Cardio-Thoracic Surgery* 2003; 24: 834-836.
- Valgimigli M, Steendijk P, Sianos G, Onderwater E, Serruys PW. Left Ventricular Unloading and Concomitant Total Cardiac Output Increase by the Use of Percutaneous Impella Recover LP2.5 Assist Device During High-Risk Coronary Intervention, *Catheterization and Cardiovascular Interventions* 65: 263-267 (2005).
- Garatti A, Colombo T, Russo C, Lanfranconi M, Milazzo F, Catena E, Bruschi G, Frigerio M, Vitali E. Left Ventricular Mechanical Support With the Impella Recover Left Direct Microaxial Blood Pump: A Single-Center Experience. *Artificial Organs* 30(7):523-528 (2006).
- Henriques J, Rimmelink M, Baan J, van der Schaaf R, Vis M, Koch K, Scholten E, de Mol B, Tijssen J, Piek J, de Winter R. Safety and Feasibility of Elective High-Risk Percutaneous Coronary Intervention. Procedures With Left Ventricular Support of the Impella Recover LP 2.5. *Am J Cardiol* 2006;97:990-992

ABIOMED
Recovering hearts. Saving lives.™

Abiomed, Inc.
22 Cherry Hill Drive
Danvers, Massachusetts 01923 USA
Voice: 978-777-5410
Facsimile: 978-777-8411
Email: marketing@abiomed.com

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

Abiomed Europe Hotline: +49 (0) 1805 ABIOMED (2246633)

009053/11 July 2007

ABIOMED is a trademark of Abiomed, Inc., and is registered in the U.S.A. and certain foreign countries. The ABIOMED logo and Recovering hearts. Saving lives. are trademarks of Abiomed, Inc. IMPELLA and RECOVER are trademarks of Abiomed Europe GmbH, a subsidiary of Abiomed, Inc., and are registered in the U.S.A. and certain foreign countries.

©2006 ABIOMED, Inc. All rights reserved.

Not for Sale in the United States

Impella®

STATISTICAL ANALYSIS AND CLINICAL EXPERIENCE

Impella® LP2.5

Impella® LP5.0

Impella® RD

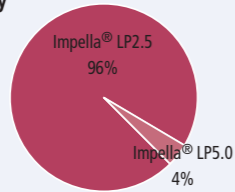
Impella® LD

ABIOMED
Recovering hearts. Saving lives.™

Ventricular Support

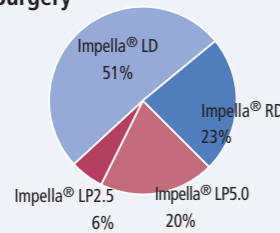
Cardiology

Impella® LP2.5	496
Impella® LP5.0	21
Total	517



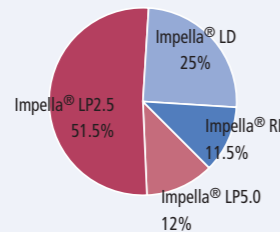
Cardiac Surgery

Impella® LD	254
Impella® RD	117
Impella® LP5.0	99
Impella® LP2.5	29
Total	499



In Total

Impella® LD	254
Impella® RD	117
Impella® LP5.0	120
Impella® LP2.5	525
Total	995



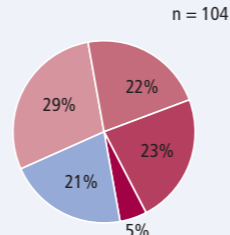
Number of centers: 179
Number of countries: 20

- Impella® LD (insertion via the ascending aorta)
- Impella® RD (surgically placed, inlet right atrium /outlet pulmonary artery)
- Impella® LP5.0 (inserted in the femoral artery via cut down)
- Impella® LP2.5 (percutaneously placed via the femoral artery)

995 reported patients supported by 1016 Impella® pumps through June 2007.

Impella® LP5.0

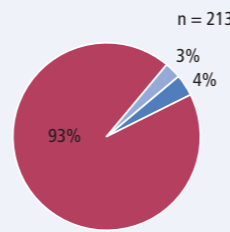
Cardiogenic Shock	30
LOS	23
AMI	24
CHF acute	5
Others	22



Treatment Goal

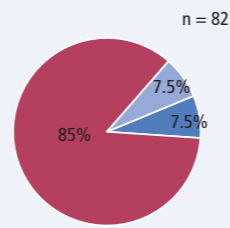
Impella® LD

Bridge to recovery	199
Bridge to transplant	6
Bridge to other assist	8



Impella® RD

Bridge to recovery	70
Bridge to transplant *	6
Bridge to other assist	6



Impella® LD and Impella® RD are predominately used in postcardiotomy (PCCS) cases.

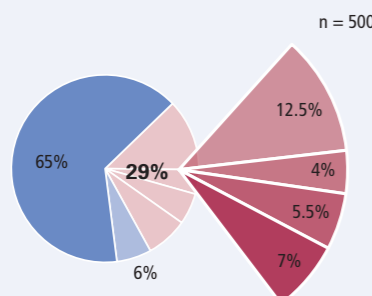
* most often in combination with long term LVAD

Indication

Impella® LP2.5

Elective (High Risk PCI)*	324
Prophylactic	30
Emergency	146
Cardiogenic Shock	62
LOS	21
AMI	27
Others	36

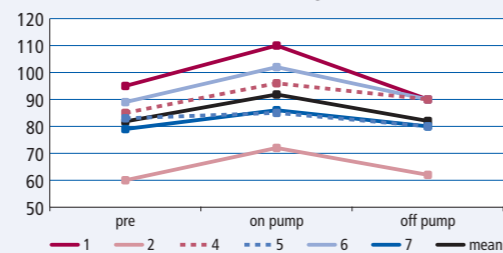
* High risk without additional pathology according to patient registry form



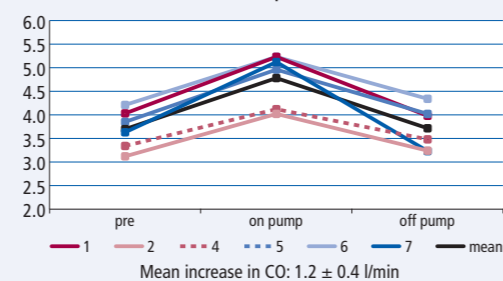
Hemodynamics

Impella® LP2.5

MAP [mmHg]

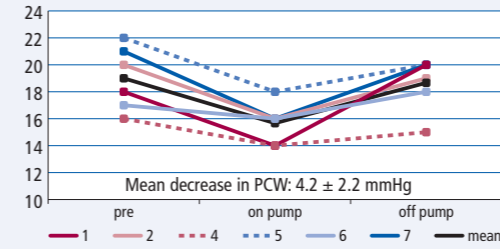


Cardiac output [l/min]



Mean increase in CO: 1.2 ± 0.4 l/min

PCWP [mmHg]



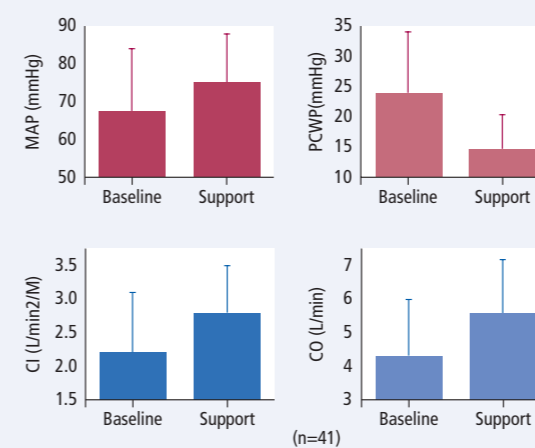
(Source: Paolo Danna, JIM 2005)

Patients (assisted High Risk PCI):

1. Old SVG to LAD/native RCA; LVEF 32; Unstable angina
2. Three vessel disease; LVEF 18, Chronic stable angina
3. Three vessel disease; LVEF 25, Unstable angina (no data available)
4. Ostial LM/RCA, LVEF 30, Crescendo angina
5. Three Vessel disease; LVEF 22, NSTEMI
6. Old SVG to LAD/RCA, LVEF 26, NSTEMI
7. Three vessel disease; LVEF 28, Chronic stable angina

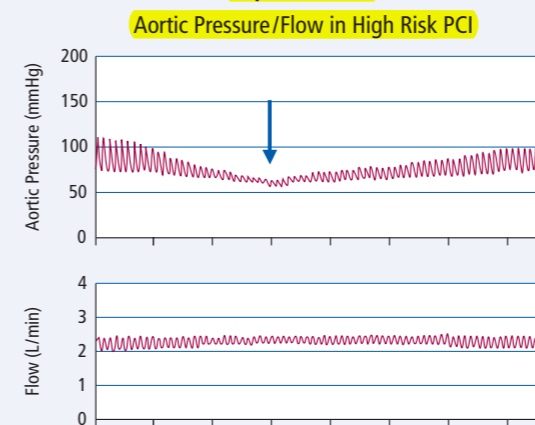
Impella® LD/LP5.0

Mean value of MAP, PCWP, CI and CO



- Impella catheters may be used to significantly augment MAP for patients that are hemodynamically compromised.
- The graph shows a major clinically relevant improvement over baseline in cardiac output during assistance via Impella® catheters.
- The PCWP is significantly reduced with the use of the Impella® catheter pumps.

Impella® LP2.5



A stable aortic pressure of ~ 60 mmHg is maintained, despite the marked decrease in aortic amplitude.

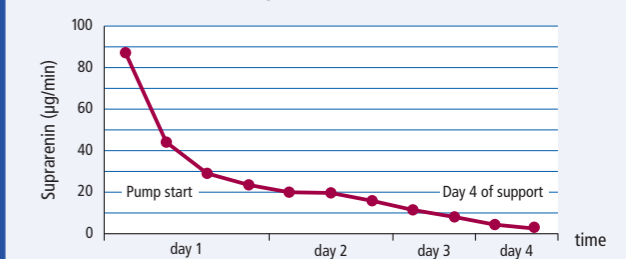
Anticoagulation Management

aPPT ~ 55s OR ACT ~ 160s

- In case of significant bleeding, quoted values can be reduced at the discretion of the physician.
- First clinical experience with the left ventricular pumps shows that even shorter coagulation times are well tolerated.
- Deviation from the aforementioned values is not recommended.

Reduction of Inotropes

Impella® LP2.5



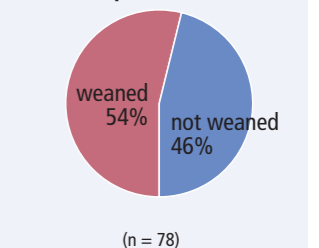
- Single case of a patient in deep cardiogenic shock:
- Hemodynamically stabilized and successfully weaned.
 - Reduction of Inotropes from lethal dose to zero within 4 days.

Weaning Success

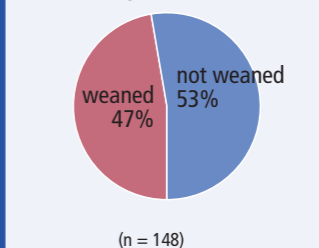
Impella® LP2.5



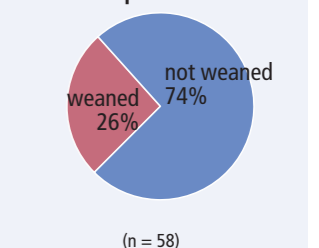
Impella® LP5.0



Impella® LD



Impella® RD



The statistical analysis is based on the informal, voluntarily reported patient data base of Abiomed Europe GmbH. No liability assumed.