

# What's New in MCS

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## Annual Review Report 2015



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Dear ladies and gentlemen,

The year 2015 has passed by and the field of mechanical circulatory support continues to go from strength to strength.

Continuous-flow left ventricular assist devices (LVAD) are still expanding rapidly worldwide in the treatment of refractory end-stage heart failure with ever improved outcomes, which was reported in the INTERMACS annual report:

- Kirklin JK, Naftel DC, Pagani FD, Kormos RL, Stevenson LW, Blume ED, Myers SL, Miller MA, Baldwin JT, Young JB. Seventh INTERMACS annual report: 15,000 patients and counting. J Heart Lung Transplant. 2015 Dec;34(12):1495-504.

As a result, the overall recognition as well as the reputation of mechanical circulatory support (MCS) within the cardiological and cardiac surgical community has also improved further. Moreover, the significance of the whole MCS field has gained both depth and width. This is exemplified by the following scientific, surgical, medical and technical developments, which were achieved in the field of MCS within the year 2015.

- 1) In 2015, minimally-invasive HVAD (Heartware Inc., Framingham, MA, USA) implantations are increasingly accepted as a standard-of-care for treatment worldwide. More than 50% of the HVAD implantations were being performed minimally-invasively in Germany. In USA, 18% of the HVAD implantations are performed minimally-invasively, too, even though this remains “off-label-use”.

Importantly, the “lateral-thoracotomy-study” to investigate the minimally-invasive LVAD-implantation technique and to achieve “on-label-use” for implantations of the HVAD through a thoracotomy approach was started.

- Hanke JS, Rojas SV, Avsar M, Bara C, Ismail I, Haverich A, Schmitto JD HeartWare left ventricular assist device for the treatment of advanced heart failure. *Future Cardiol.* 2016 Jan;12(1):17-26.
- Hanke JS, Rojas SV, Martens A, Schmitto JD. Minimally invasive left ventricular assist device implantation with outflow graft anastomosis to the innominate artery. *J Thorac Cardiovasc Surg.* 2015 Apr;149(4):e69-70.
- Hanke JS, Rojas SV, Avsar M, Haverich A, Schmitto JD. Minimally-invasive LVAD Implantation: State of the Art. *Curr Cardiol Rev.* 2015;11(3):246-51.
- Rojas SV, Avsar M, Hanke JS, Khalpey Z, Maltais S, Haverich A, Schmitto JD. Minimally invasive ventricular assist device surgery. *Artif Organs.* 2015 Jun;39(6):473-9.
- Rojas SV, Avsar M, Uribarri A, Hanke JS, Haverich A, Schmitto JD. A new era of ventricular assist device surgery: less invasive procedures. *Minerva Chir.* 2015 Feb;70(1):63-8.

2) The year 2015 has also seen the first implantation in man of another next generation VAD pump: the Heartmate 3 (St. Jude Medical Inc., Pleasanton, California).

- Schmitto JD, Hanke JS, Rojas SV, Avsar M, Haverich A. First implantation in man of a new magnetically levitated left ventricular assist device (HeartMate III). *J Heart Lung Transplant.* 2015; June 34(6):858-9.

This miniaturized, magnetically-levitated centrifugal-flow pump enhances hemocompatibility by minimizing hemodynamic shear forces and a sophisticated blood–biomaterial interface. These features are intended to lower adverse event rates and improve minimally invasive surgical implantation through a compact size. Moreover, the 6 months follow-up of the Heartmate 3 CE mark trial was successfully accomplished and its data have led to the official CE mark approval. These data were published in December in *JACC*.

- Netuka I, Sood P, Pya Y, Zimpfer D, Krabatsch T, Garbade J, Rao V, Morshuis M, Marasco S, Beyersdorf F, Damme L, Schmitto JD. Fully Magnetically Levitated Left Ventricular Assist System for Treating Advanced HF: A Multicenter Study. *J Am Coll Cardiol.* 2015 Dec 15;66(23):2579-89.

This trial was a prospective, non-randomized study with 50 patients enrolled at ten hospitals in six countries. Enrollment included both bridge-to-transplant and destination therapy patients in NYHA Class IIIb or IV heart failure. From the first implantation at Hannover Medical School in Hannover, Germany until completion of the study, 88% of patients continued on support, 4% received transplants, and 8% died. Thirty-day mortality was 2% and 6-month survival was 92%. This represented the highest six month survival reported in a LVAD CE Mark clinical trial. Thus, support with

the HeartMate 3 significantly reduced mortality risk by 66% compared with the Seattle Heart Failure Model-predicted survival of 78% ( $p = 0.0093$ ). Moreover, New York Heart Association classification, 6-min walk test, and quality-of-life scores showed progressive and sustained improvement. Key adverse events included reoperation for bleeding (14%), driveline infection (10%), gastrointestinal bleeding (8%), and debilitating stroke (modified Rankin Score  $>3$ ) (8%). There were no pump exchanges, pump malfunctions, pump thrombosis, or hemolysis events.

Thus, HeartMate 3 is a very promising LVAD technology based on the improvements in clinical outcomes demonstrated in this trial. Patient follow-up will continue during the first two years of ongoing support, while enrollment in the HeartMate 3 U.S. IDE trial remains ongoing.

- 3) A third player in the field of MCS, ReliantHeart Inc., came up within another milestone for their product HeartAssist5: In July 2015, the worldwide first less-invasive HeartAssist5 (ReliantHeart Inc; Houston, USA) took place. [personal communication ReliantHeart Inc.]. With its unique technical features, including direct flow measurement instead of flow estimation, and the potential to perform remote monitoring, etc. the novel HeartAssist5 pump might also play a prominent role within the field of MCS in the near future.

The following articles contributed pivotal knowledge within the MCS field in 2015 and are cited according to the order of the journals they were published in:

#### **Circulation:**

- Zalawadiya SK, Lindenfeld J, DiSalvo T. Rapid diagnosis of cardiac tamponade using pulsatility index variability in a patient with a HeartWare ventricular assist device. *Circulation*. 2015 Mar 31;131(13):e387-8.
- Mody KP, Lyons JJ, Jorde UP, Uriel N. A cold taken to heart. *Circulation*. 2015 May 12;131(19):1703-11.
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- Zwadlo C, Schmidtman E, Szaroszyk M, Kattih B, Froese N, Hinz H, Schmitto JD, Widder J, Batkai S, Bähre H, Kaefer V, Thum T, Bauersachs J, Heineke J. Antiandrogenic therapy with finasteride attenuates cardiac hypertrophy and left ventricular dysfunction. *Circulation*. 2015 Mar 24;131(12):1071-81.
- Cornwell WK 3rd, Tarumi T, Stickford A, et al. Restoration of Pulsatile Flow Reduces Sympathetic Nerve Activity Among Individuals With Continuous-Flow Left Ventricular Assist Devices. *Circulation*. 2015 Dec 15;132(24):2316-22.

### **European Heart Journal:**

- Thiele H, Ohman EM, Desch S, Eitel I, de Waha S. Management of cardiogenic shock. *Eur Heart J*. 2015 May 21;36(20):1223-30.
- Schmidt M, Burrell A, Roberts L, Bailey M, Sheldrake J, Rycus PT, Hodgson C, Scheinkestel C, Cooper DJ, Thiagarajan RR, Brodie D, Pellegrino V, Pilcher D. Predicting survival after ECMO for refractory cardiogenic shock: the survival after veno-arterial-ECMO (SAVE)-score. *Eur Heart J*. 2015 Sep 1;36(33):2246-56.
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- Bouabdallaoui N, Lebreton G, Demondion P, Charfeddine A, Leprince P. Monitoring of left ventricular assist device implantation and set-up with miniaturized transoesophageal echocardiography: Initial experience at La Pitié-Salpêtrière Hospital and possible application fields. *Eur Heart J Acute Cardiovasc Care*. 2015 Dec 10.

### **Journal of Heart and Lung Transplantation:**

- Schmitto JD, Hanke JS, Rojas SV, Avsar M, Haverich A. First implantation in man of a new magnetically levitated left ventricular assist device (HeartMate III). *J Heart Lung Transplant*. 2015; June 34(6):858-9.
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