Interactive CardioVascular and Thoracic Surgery 27 (2018) 938–942
doi:10.1093/icvts/ivy228 Advance Access publication 2 August 2018

ORIGINAL ARTICLE

Cite this article as: Eulert-Grehn J-J, Lanmüller P, Schönrath F, Solowjowa N, Müller M, Mulzer J *et al.* Two implantable continuous-flow ventricular assist devices in a biventricular configuration: technique and results. Interact CardioVasc Thorac Surg 2018;27:938–42.

Two implantable continuous-flow ventricular assist devices in a biventricular configuration: technique and results†

Jaime-Jürgen Eulert-Grehn[a,b,*], Pia Lanmüller[a], Felix Schönrath[a,b], Natalia Solowjowa[a], Marcus Müller[a], Johanna Mulzer[a], Friedrich Kaufmann[a], Christoph Starck[a,b], Thomas Krabatsch[a,b], Volkmar Falk[a,b,c] and Evgenij Potapov[a,b]

[a] Department of Cardiothoracic and Vascular Surgery, German Heart Center Berlin, Berlin, Germany
[b] DZHK (German Center for Cardiovascular Research), Partner Site Berlin, Berlin, Germany
[c] Department of Cardiothoracic Surgery, Charité—Universitätsmedizin Berlin, Corporate Member of Freie Universität Berlin, Humboldt-Universität zu Berlin, and Berlin Institute of Health, Berlin, Germany

* Corresponding author. Department of Cardiothoracic and Vascular Surgery, German Heart Center Berlin/Klinik für Herz-, Thorax-und Gefäßchirurgie, Deutsches Herzzentrum, Berlin, 13353 Berlin, Germany. Tel: +49-30-45932247; e-mail: jeulert@dhzb.de (J.-J. Eulert-Grehn).

Received 26 January 2018; received in revised form 7 May 2018; accepted 12 June 2018

Key question

How can one modify a left ventricular assist device for right ventricular support and how are the results?

Key findings

The 3 main modifications used resulted in a 30-day survival rate of 72.7% and a 1-year survival rate of 45% for primary continuous flow left ventricular assist device support.

Take-home message

Continuous flow left ventricular assist device support is a valuable option for long-term mechanical support and increases the treatment options for severe heart failure.

Abstract

OBJECTIVES: No continuous-flow right ventricular assist device for long-term support is available at the moment. Two continuous-flow ventricular assist devices used in a continuous-flow biventricular assist device configuration is an emerging option which has proven its feasibility but still is not approved for routine use. We present our technique and results of modifying the left ventricular assist device and making it suitable for right ventricular support.

METHODS: Between September 2009 and October 2017, 39 patients received implantation of a continuous-flow ventricular assist device for right ventricular support in a continuous-flow biventricular assist device configuration. For implantation of the HeartWare® manufacturers name of the pump HeartWare HVAD pump (HVAD)® centrifugal ventricular assist device, we performed 2 major modifications:

†Presented at the 12th European Mechanical Circulatory Support Summit (EUMS), Bad Oeynhausen, Germany, 29 November–2 December 2017.

banding of the outflow graft and reducing the intracaval length of the inflow cannula. The HVAD® could be safely implanted into the right atrium or ventricle. The HeartMate 3® left ventricular assist device needed no banding, but we increased the extraventricular part of the inflow cannula.

RESULTS: The overall 30-day survival for the group receiving primarily a continuous-flow biventricular assist device was 72.7% (9.5% standard error of the mean (SEM)), and the 1-year survival was 45.0% (10.7% SEM). The overall 30-day survival for the group receiving a subsequent pump for right ventricular support in a continuous-flow biventricular assist device configuration after temporary right ventricular support was 71.4% (12.1% SEM), and 1-year survival was 40.8% (13.6% SEM).

CONCLUSIONS: At the moment, there is a lack of a continuous-flow right ventricular assist device especially designed and approved for right ventricular support. Therefore, modifications in continuous-flow ventricular assist devices designed for the left ventricle are done to make them suitable for right ventricular support. However, more information is needed regarding the optimal surgical technique, patient selection and the optimal time point of implantation.

Keywords: LVAD • RVAD • Right heart failure • BVAD • HeartMate 3 • HVAD • Biventricular failure • Biventricular assist device

INTRODUCTION

Today, continuous-flow left ventricular assist devices (cfLVADs) are a well-established treatment option for end-stage heart failure. Nevertheless, 5–10% of all patients develop right heart failure (RHF) after left ventricular assist device (LVAD) implantation, which requires a right ventricular assist device (RVAD). Risk factors for postoperative RHF are an INTERMACS 1–2 profile, the need for extracorporeal membrane oxygenation or renal replacement therapy preimplant, along with severe tricuspid regurgitation, history of cardiac surgery or simultaneous procedures other than tricuspid valve repair at the time of LVAD implantation. Unfortunately, previously developed predictors and risk scores for post-LVAD RHF lack sensitivity and specificity [1]. RHF is one of the leading causes of early death post-cfLVAD implantation, which is why immediate and durable therapy is crucial [2, 3].

METHODS

Patients

After a detailed preoperative discussion, especially regarding the possible risks of the off-label device use as an RVAD, each patient gave permission for the operation to be conducted. Between September 2009 and October 2017, 39 patients received implantation of a continuous-flow ventricular assist device (cfVAD) for right ventricular support in a continuous-flow biventricular assist device (cfBVAD) configuration. So far, there are no clear-cut signs and cut-off values to exactly predict right ventricular failure after LVAD implantation. In patients at high risk for right ventricular failure or with intraoperative post-LVAD RHF, the implantation of either a permanent or a temporary cfVAD for right ventricular support was left to the surgeon's discretion.

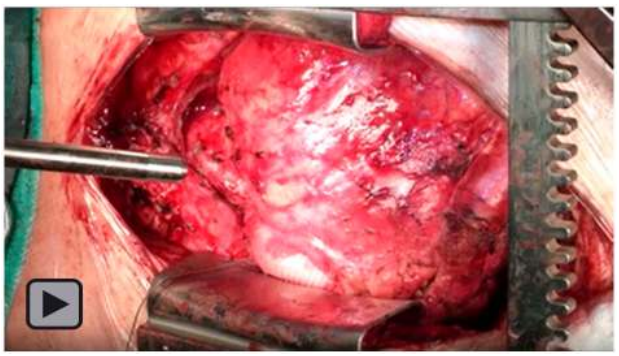
Devices

As of October 2017, we have implanted 4 HeartMate 3® (Abbott Corp., Abbott Park, IL, USA) and 35 HeartWare® HVAD® (HeartWare International Inc., Framingham, MA, USA) for right ventricular support in a biventricular assist device configuration. Four of 5 patients with HeartMate 3 for left ventricular support received a HeartMate 3 device for right ventricular support. One patient supported with HeartMate 3 in the left ventricular position had temporary RVAD support with Levitronix and then implantation of HeartWare manufacturers name of the pump HeartWare HVAD pump (HVAD) as a cfRVAD. The smaller HeartWare was used because of limited space around the right atrium which prohibited the implantation of a HeartMate 3 device for right ventricular support.

Implantation technique

The HVAD and HeartMate 3 as LVADs were implanted as described elsewhere [4, 5]. We perform some technical modifications while implanting the HVAD as an RVAD (see Video 1):

1. Banding: the HVAD runs with an optimal pump speed of 2200–3500 rpm as recommended by the manufacturer. This could lead to suction events and an overflow of volume to the pulmonary vascular bed and, therefore, to pulmonary oedema. We artificially increase the afterload of the HVAD by reducing the inner graft diameter to 5–7 mm depending on the degree of pulmonary vascular resistance at the moment of implantation. We decrease the diameter of the graft with surgical tweezers or with a clamp and aim for equalization of the left and right side pump flow with a pump speed of between 2600 and 2900 rpm. After achieving a constant flow on both sides, we perform side clamping of the graft and narrowing of the graft with a suture (6 × 0 Prolene) or by placing surgical clips. The length of the narrowed section is approximately 35 mm. To avoid any possible direct injury to the vascular graft, we now place a second piece of vascular graft around the first one and then place the clips. Nowadays, we have changed our policy and only place clips to narrow the graft.



Video 1: Implantation of an HVAD as an RVAD.

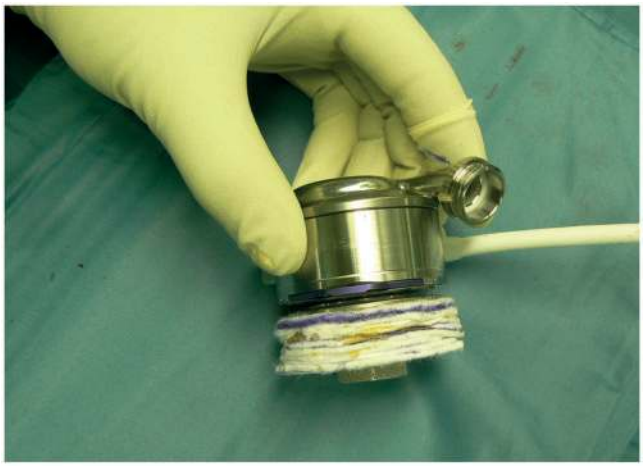


Figure 1: Ring augmentation.

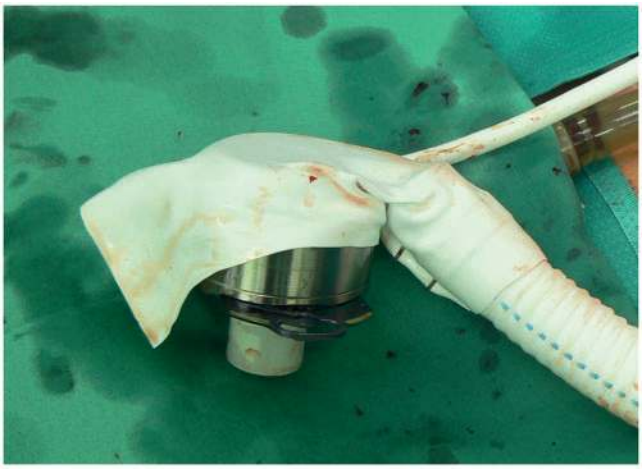


Figure 2: Gore-Tex membrane to protect the lung.

2. Ring augmentation: the inflow cannula of the HVAD (∼32 mm) is too long for the right ventricle with a right ventricular end diastolic dimension (RVEDD) of 36 ± 6.8 mm or the right atrium. Bearing in mind the height of the implantation ring (5 mm) and the right ventricular wall thickness (∼4 mm), 26 mm of the cannula would extend into the right ventricular cavity. Therefore, we add some layers of Teflon plates (between 6 and 8) to reduce the effective length of the inflow cannula (Fig. 1). This modification reduces the intracavitary length of the pump but requires more space between the right ventricle and chest wall. Nowadays, our preferred implantation site is the wall of the right atrium, with the optimal point selected under echocardiographic monitoring.
3. Pump placement: the pump body is placed into the right pleural cavity through incision of the pericardium. The pericardium should be used to augment the pump in the right position. The pump should be covered with a Gore-Tex membrane, to avoid damage to the lung (Fig. 2).

Alternative implantation sites in slimmer patients are the anterior or inferior right ventricular wall. In patients needing a second HeartMate 3 as the right ventricular cfVAD, the approach is similar but with the major difference that we reduce the outflow graft to only 10 mm if the graft was primarily used for Levitronix implantation because of the intrinsic stable rotor position of the HeartMate 3 pump. In the case of primary implantation of a HeartMate 3 as an RVAD, no banding was performed. The HeartMate 3 pump may operate in the low rotation range without limitations as described above. Therefore, no narrowing of the outflow graft of the HeartMate 3 pump is necessary.

Until now, the HeartMate 3 pump has been implanted in the right atrium [6, 7]. The driveline of the RVAD is placed opposite to the left ventricular driveline with the driveline exit mostly at the right anterior abdominal wall.

RESULTS

Between September 2009 and October 2017, 39 patients received implantation of a cfVAD for right ventricular support in a cfBVAD configuration. The implantation was performed as a primary biventricular assist device (BVAD) implantation, as a subsequent cfRVAD after temporary right ventricular support or as a subsequent cfRVAD for late right ventricular failure after cfLVAD implantation. There were no patients with predominant RHF due to right ventricular pathology such as Uhl's disease with a primary indication for right ventricular support and secondary left ventricular support. No patients experienced intractable ventricular arrhythmias at implantation.

During this time period, 1007 patients received a continuous-flow LVAD in our institution. Fourteen patients received an INCOR device, 5 patients received a Heart-Assist 5, 116 patients received a HeartMate 2 device, 124 patients received a HeartMate 3 device and 728 patients an HVAD. Only 3.9% of the patients received a cfVAD for right ventricular support.

In 22 patients, we implanted 2 cfLVADs as a primary biventricular assist device. Ten (45%) had dilative cardiomyopathy and 8 (36%) had ischaemic cardiomyopathy. Their age ranged from 21 to 73 (mean age 52) years. Eleven patients were in INTERMACS profile 1 and profile 2 and 11 patients in INTERMACS profile 3 and profile 4. In 21 cases, we implanted an HVAD and in 1 case a HeartMate 3. The implantation site was the right atrium in 5 cases and right ventricle in 17 cases.

Fourteen patients received subsequent implantation of a cfVAD for right ventricular support in a cfBVAD configuration after temporary right ventricular support. Seven (50%) had dilatative cardiomyopathy and 5 (36%) had ischaemic cardiomyopathy. In 12 cases, we implanted an HVAD, and in 2 cases, we implanted a HeartMate 3 device. The implantation site was the right atrium in 12 cases and the right ventricle in 2. Patient age ranged from 32 to 74 (mean age 51) years. The pump was implanted in the right atrium, right ventricular anterior free wall or right ventricular inferior wall. In our series, only a few patients were theoretically suited for heart transplantation.

In 3 cases, a long-term VAD (1 HeartMate 3, and 2 HVAD) for right ventricular support was implanted for late right ventricular failure after 76 days, after 3 years and 9 months and 2 years and 10 months after primary LVAD surgery with 1 death after 25 days and 2 patients an assist device 9 and 8 months after VAD implantation for right ventricular support, respectively.

The overall 30-day survival for the group receiving primarily a cfBVAD was 72.7% (9.5% SEM), the 6-month survival was 54.5% (10.6% SEM) and the 1-year survival was 45.0% (10.7% SEM). The

overall 30-day survival for the group subsequently receiving an LVAD for right ventricular support in a cfBVAD configuration after temporary right ventricular support was 71.4% (12.1% SEM), the 6-month survival was 57.1% (13.2% SEM) and the 1-year survival was 40.8% (13.6% SEM). In our series, only 1 patient underwent heart transplantation after 8 months on a cfBVAD.

Pump thrombosis

We observed 12 cases of RVAD pump thrombosis in 39 RVAD patients. Cumulated RVAD-support time was 106 years leading to 0.11EPPY (RVAD only), which in fact is slightly lower than our observed LVAD pump thrombosis rate. In 5 cases, rTPA lysis was successful, 1 pump exchange was performed, 2 patients were weaned from RVAD (with the LVAD still running) and 4 patients died due to pump thrombosis.

DISCUSSION

Patients with right ventricular failure after cfLVAD have markedly higher morbidity and mortality than patients with a cfLVAD only [8]. This is difficult to predict preimplant and challenging to treat conservatively [1]. Before, during and after every LVAD implantation, the question remains as to whether univentricular left ventricular support is sufficient for the patient.

Nowadays, this problem can be addressed with 3 options suitable for long-term support: implantation of a total artificial heart, extracorporeal displacement pumps and continuous-flow assist devices in a biventricular configuration. With the introduction of continuous-flow LVAD, which has resulted in a reduction in mortality and marked increase in quality of life compared to implantable pulsatile or even paracorporeal devices, there is the desire to offer patients with biventricular failure the advantages of cfVADs [4]. Now there is growing but still limited experience with the use of cfVADs for biventricular support [1].

Three key points have to be addressed: adapting the cfVAD to right heart anatomy and right heart physiology and adjusting the controller to the different setting. An ideal cfRVAD would have:

1. a range of nominal flow of 2–6 l/min with a range of nominal pump differential pressures of 20–60 mmHg,
2. versatility of device insertion (the right atrium and right ventricle) with a shorter inflow cannula and an adjustable sewing ring height and
3. a single controller for automatic control in a biventricular assist device configuration would be desirable [8].

At the moment, no cfVAD has been designed and/or approved for support of the right ventricle. We report our experience on how to address the first 2 points with some modifications on the cfVADs designed for support of the left ventricle and discuss alternative approaches.

We implant the HeartWare HVAD (HW) LVAD device and the HeartMate 3 LVAD as the cfRVAD pump depending on the first pump implanted as an LVAD, although the implantation and successful long-term treatment with simultaneous use of 2 non-identical continuous-flow pumps have recently been reported [10]. However, in 1 case due to massive adhesion around the right atrium, the HeartMate 3 was deemed unsuitable as it would cause massive damage to the right lung or atria. Therefore, a smaller HeartWare HVAD was implanted into the right atrium, although the LVAD was a HeartMate 3. In the second case, we implanted the HeartWare HVAD into the right atrium while the LVAD was a HeartMate 2.

We started in 2009 with the first implantation of an HVAD as an RVAD in a biventricular assist device configuration. The modifications are based on our work in an *in vitro* model [6]. We performed a banding procedure on the outflow graft and ring augmentation. The goal of the banding procedure is to guarantee an appropriate flow within the recommended lowest pump settings to ensure a stable rotor position. This is achieved by side clamping the graft and narrowing the graft with a suture (6 × 0 Prolene) or by placing surgical clips. To minimize bleeding complications, we now prefer placing clips. A higher flow compared to that of the left-sided LVAD would lead to pulmonary oedema. Continuous-flow VADs have low preload sensitivity and pump flow pulsatility and high afterload sensitivity [11]. Other centres have reported the implantation of cfLVAD for right ventricular support without the banding procedure, by running the HVAD at a lower pump setting [12]. In our opinion, a lower speed increases the risk for pump thrombosis because of the poor washout of the pump and exposing the surfaces to speeds below the recommended pump settings. A recently published analysis based on the INTERMACS database showed a high rate of suspected thrombosis in the BVAD configuration for the pump implanted on the right side [1]. In a case series with cfLVADs implanted for right ventricular support in a cfBVAD configuration, RVAD pump thrombosis occurred in 3 of 6 cases if the pump was implanted in the right ventricle and in 1 of 7 patients in the right atrial configuration. In this study with 13 patients with cfBVAD support, the 1-year survival rate was 62% [13].

Because of the stable rotor position even at lower speed settings, the HeartMate 3 device can be run at a lower speed than recommended, and this makes the banding procedure unnecessary. Another point is adapting the cfLVAD to the right ventricular anatomy with the highly trabeculated right ventricle, the adjacency of the chordae tendinae and the close proximity to the interventricular septum than on the left side [9]. Surgeon preference has changed with the experience gained, and the often-enlarged right atrium is the implantation site of choice. Herein, the pump position can be easily stabilized with the pericardium. To reduce the risk of suction, we perform ring augmentation, whereas other centres implant the cfLVAD on the right side without any augmentation [12, 14]. A recent single-centre case series with 11 patients applying ring augmentation and using only the right atrium as implantation site reported 1 death during a total of 4314 BVAD support days with a rate of pump thrombosis of 36% [15]. The EUROMACS database shows a 6-month survival for LVAD patients without any form of RHF of 79%. Patients with any degree of RHF have an overall survival after 6 months of only 61% [16]. In the largest analysis reported to date of patients with 2 LVADs in a cfBVAD configuration, the 1-month survival and 12-month survival were 89% and 62%, respectively, with approximately 25% of patients receiving a heart transplant after 6 months compared to the 1-month survival and 12-month survival observed in this series of 72.7% and 54.5%, respectively [1]. In our series, only 1 patient underwent heart transplantation after 8 months on cfBVAD. The 7th INTERMACS report with data from 2012 to 2014 reported 1-year survival for BVAD of 56% and for total artificial heart of 59%. Overall comparisons in this heterogeneous patient group are difficult. We did not attempt a statistical analysis between the groups because of the heterogeneity of the patient cohorts and surgical bias

regarding the implantation performed. Because of our institutional policy, the rate of subsequently implanted permanent cfVAD for right ventricular support has increased in the past years.

CONCLUSIONS

Patients with biventricular failure needing biventricular support have higher mortality than patients needing an LVAD alone. At the moment, there is a lack of a cfRVAD designed and approved for right ventricular support. Therefore, modifications of cfVAD devices designed for the left ventricle can have certain advantages by making them more suitable for right ventricular support. Our data show that, despite high mortality in this patient cohort considering the critical preimplant condition, 2 LVADs in a BVAD configuration are a valuable option for long-term mechanical support in biventricular failure. The cfLVAD for right ventricular support can be implanted primarily in a cfBVAD configuration or secondarily for RHF after LVAD implantation. However, more information is needed regarding the optimal surgical technique, patient selection and time point of implantation.

ACKNOWLEDGEMENTS

The authors thank Anne Gale for editorial assistance and Julia Stein for statistical assistance.

Conflict of interest: none declared.

REFERENCES

[1] Arabía FA, Milano CA, Mahr C, McGee EC Jr, Mokadam NA, Rame JE *et al*. Biventricular support with intracorporeal, continuous flow, centrifugal ventricular assist devices. Ann Thorac Surg 2018;105:548–55.

[2] Kirklin JK, Naftel DC, Pagani FD, Kormos RL, Stevenson LW, Blume ED *et al*. Seventh INTERMACS annual report: 15,000 patients and counting. J Heart Lung Transplant 2015;34:1495–504.

[3] Kirklin JK, Pagani FD, Kormos RL, Stevenson LW, Blume ED, Myers SL *et al*. Eighth annual INTERMACS report: special focus on framing the impact of adverse events. J Heart Lung Transplant 2017;36:1080–6.

[4] Slaughter MS, Rogers JG, Milano CA, Russell SD, Conte JV, Feldman D *et al*. HeartMate II Investigators. Advanced heart failure treated with continuous-flow left ventricular assist device. N Engl J Med 2009;361:2241–51.

[5] Netuka I, Sood P, Pya Y, Zimpfer D, Krabatsch T, Garbade J *et al*. Fully magnetically levitated left ventricular assist system for treating advanced HF: a multicenter study. J Am Coll Cardiol 2015;66:2579–89.

[6] Krabatsch T, Potapov E, Stepanenko A, Schweiger M, Kukucka M, Huebler M *et al*. Biventricular circulatory support with two miniaturized implantable assist devices. Circulation 2011;124(11 Suppl):S179–86.

[7] Potapov EV, Kukucka M, Falk V, Krabatsch T. Biventricular support using 2 HeartMate 3 pumps. J Heart Lung Transplant 2016;35:1268–70.

[8] de By TMMH, Mohacsi P, Gahl B, Zittermann A, Krabatsch T, Gustafsson F *et al*. EUROMACS members. The European Registry for Patients with Mechanical Circulatory Support (EUROMACS) of the European Association for Cardio-Thoracic Surgery (EACTS): second report. Eur J Cardiothorac Surg 2018;53:309–16.

[9] Karimov JH, Sunagawa G, Horvath D, Fukamachi K, Starling RC, Moazami N. Limitations to chronic right ventricular assist device support. Ann Thorac Surg 2016;102:651–8.

[10] Baldwin ACW, Sandoval E, Cohn WE, Mallidi HR, Morgan JA, Frazier OH. Nonidentical continuous-flow devices for biventricular support. Tex Heart Inst J 2017;44:141–3.

[11] Fukamachi K, Shiose A, Massiello AL, Horvath DJ, Golding LA, Lee S *et al*. Implantable continuous-flow right ventricular assist device: lessons learned in the development of a cleveland clinic device. Ann Thorac Surg 2012;93:1746–52.

[12] Strueber M, Meyer AL, Malehsa D, Haverich A. Successful use of the HeartWare HVAD rotary blood pump for biventricular support. J Thorac Cardiovasc Surg 2010;140:936–7.

[13] Shehab S, Macdonald PS, Keogh AM, Kotlyar E, Jabbour A, Robson D *et al*. Long-term biventricular HeartWare ventricular assist device support—case series of right atrial and right ventricular implantation outcomes. J Heart Lung Transplant 2016;35:466–73.

[14] Bernhardt AM, De By TM, Reichenspurner H, Deuse T. Isolated permanent right ventricular assist device implantation with the HeartWare continuous-flow ventricular assist device: first results from the European Registry for Patients with Mechanical Circulatory Support. Eur J Cardiothorac Surg 2015;48:158–62.

[15] Tran HA, Pollema TL, Silva Enciso J, Greenberg BH, Barnard DD, Adler ED *et al*. Durable biventricular support using right atrial placement of the HeartWare HVAD. ASAIO J 2018;64:323–7.

[16] Soliman OI, Akin S, Muslem R, Boersma E, Manintveld OC, Krabatsch T *et al*. EUROMACS investigators. Derivation and validation of a novel right-sided heart failure model after implantation of continuous flow left ventricular assist devices: the EUROMACS (European Registry for Patients with Mechanical Circulatory Support) Right-Sided Heart Failure Risk Score. Circulation 2018;137:891–906.