European Journal of Cardio-Thoracic Surgery 0 (2017) 1–8
doi:10.1093/ejcts/ezx320

REPORT

Cite this article as: de By TMMH, Mohacsi P, Gahl B, Zittermann A, Krabatsch T, Gustafsson F *et al.*. 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 2017; doi:10.1093/ejcts/ezx320.

The European Registry for Patients with Mechanical Circulatory Support (EUROMACS) of the European Association for Cardio-Thoracic Surgery (EACTS): second report

Theo M.M.H. de By[a,*†], Paul Mohacsi[b,*†], Brigitta Gahl[b], Armin Zittermann[c], Thomas Krabatsch[d], Finn Gustafsson[e], Pascal Leprince[f], Bart Meyns[g], Ivan Netuka[h], Kadir Caliskan[i], Evaristo Castedo[j], Francesco Musumeci[k], André Vincentelli[l], Roland Hetzer[m] and Jan Gummert[c], on behalf of the EUROMACS members

[a] EACTS House, Windsor, UK
[b] Swiss Cardiovascular Center, University Hospital Bern (Inselspital), Bern, Switzerland
[c] Herz- und Diabeteszentrum NRW, Bad Oeynhausen, Germany
[d] Deutsches Herzzentrum Berlin, Berlin, Germany
[e] Rigshospitalet, Copenhagen, Denmark
[f] Université Pierre et Marie Curie, Hôpital La-Pitié Salpetrière, Paris, France
[g] Katholieke Universiteit Leuven, Leuven, Belgium
[h] Institute for Clinical and Experimental Medicine (IKEM), Prague, Czech Republic
[i] Erasmus Medisch Centrum, Rotterdam, Netherlands
[j] Hospital Universitario Puerta de Hierro Majadahonda, Madrid, Spain
[k] Azienda Ospedaliera San Camillo-Forlanini, Rome, Italy
[l] Centre Hospitalier Régional Universitaire de Lille, France, Lille, France
[m] Cardio Centrum Berlin, Berlin, Germany

* Corresponding authors. Swiss Cardiovascular Center, University Hospital Bern (Inselspital), Bern, Switzerland. Tel: +41-31-6322375; fax: +41-31-6324443; e-mail: paul.mohacsi@insel.ch (P. Mohacsi) and EUROMACS, EACTS House, Madeira Walk, Windsor Berks SL1 4EU, UK. Tel: +44-1753-832166; e-mail: theo.deby@eacts.co.uk (T.M.M.H. de By).

Received 14 February 2017; received in revised form 8 August 2017; accepted 13 August 2017

Abstract

OBJECTIVES: The European Registry for Patients with Mechanical Circulatory Support (EUROMACS) was founded in Berlin, Germany. EUROMACS is supported fully by the European Association for Cardio-Thoracic Surgery (EACTS) and, since 2014, has functioned as a committee of the EACTS. The purpose of having the EUROMACS as a part of the EACTS is to accumulate clinical data related to long-term mechanical circulatory support for scientific purposes and to publish annual reports.

METHODS: Participating hospitals contributed surgical and cardiological pre-, peri- and long-term postoperative data of mechanical circulatory support implants to the registry. Data for all implants performed from 1 January 2011 to 31 December 2016 were analysed. Several auditing methods were used to monitor the quality of the data. Data could be provided for in-depth studies, and custom data could be provided at the request of clinicians and scientists. This report includes updates of patient characteristics, implant frequency, mortality rates and adverse events.

RESULTS: Fifty-two hospitals participated in the registry. This report is based on 2947 registered implants in 2681 patients. Survival of adult patients (>17 years of age) with continuous-flow left ventricular assist devices with a mean follow-up of 391 days was 69% (95% confidence interval 66–71%) 1 year after implantation. On average, patients were observed for 12 months (median 7 months, range 0–70 months). When we investigated for adverse events, we found an overall event rate per 100 patient-months of 3.56 for device malfunction, 6.45 for major bleeding, 6.18 for major infection and 3.03 for neurological events within the first 3 months after implantation.

CONCLUSIONS: Compared to the first EUROMACS report, the number of participating hospitals increased from 21 to 52 (+148%), whereas the number of registered implants more than tripled from 825 to 2947 (+257%). The increase in the number of participating hospitals led us to increase the quality control measures through data input control, on-site audits and statistical analyses.

Keywords: Mechanical circulatory support • Ventricular assist device • Registry • End-stage heart failure

†The first two authors contributed equally to this study.

INTRODUCTION

The purpose of the European Registry for Patients with Mechanical Circulatory Support (EUROMACS) registry of the European Association for Cardio-Thoracic Surgery (EACTS) is to accumulate clinical data on long-term mechanical circulatory support (MCS) and to enable scientific research to improve this method of treatment for patients with end-stage heart failure. The registry permits the retrieval of data on survival and morbidity rates so that clinicians and industry representatives can identify and learn from the factors that influence the results of MCS therapy. Various measures were taken to safeguard the completeness and correctness of the data that have been submitted by the participating centres to improve data quality. These methods include data input control, on-site audits and statistical analyses.

Data have been made available for several studies that resulted in publications [1, 2] or abstracts [3]. Upon the request of the participating centres, custom analyses of data could be provided. Of special interest, a paediatric study group has been established among the EUROMACS members to carry out studies on the treatment of children with MCS. The first article containing paediatric data from the EUROMACS will be submitted in 2017 to the *European Journal of Cardio-Thoracic Surgery* (*EJCTS*). Several joint projects with other national and international registries to exchange or to accumulate data were initiated. Finally, a course for ventricular assist device (VAD) coordinators, including the EUROMACS registration modalities, has been conducted annually since 2015 [4].

The EUROMACS and the International Society for Heart and Lung Transplantation (ISHLT) have an agreement whereby the ISHLT participates in the Interagency Registry for Mechanically Assisted Circulatory Support (IMACS). IMACS enrols and follows patients receiving durable MCS devices on a global basis. The first IMACS annual report, including data from EUROMACS, was published in the spring of 2016 [5].

METHODS

Hospitals that contribute baseline and follow-up clinical data from their consenting patients to EUROMACS agree to do so within 6 weeks after the patient receives an MCS device. Similarly, events are to be registered within 6 weeks after their occurrence. Hospitals register their patients with MCS online via a secured Internet connection, using an individual password, in an ongoing prospective manner, but also retrospectively to 1 January 2011. Although some centres have chosen to submit earlier records, only implants from 1 January 2011 are included in this analysis, which is consistent with the data included in the first annual report [6].

All paediatric and adult patients who received a long-term MCS device, designed for ≥6 months support, were eligible for registration in the EUROMACS database (Table 1). A provision has been made for devices that were implanted concomitantly (as a temporary right ventricular assist device) with a long-term device (see Table 1, 'Short-term devices').

Table 1: Present CE-marked MCS systems registered in the EUROMACS database

MCS type	
Long-term devices	
Continuous flow	Berlin Heart INCOR CircuLite SYNERGY[a] HeartAssist 5 HeartWare HVAD Jarvik 2000 MicroMed DeBakey Thoratec HeartMate II Thoratec HeartMate 3
Pulsatile extracorporeal	Berlin Heart EXCOR Thoratec PVAD Abiomed AB5000
Total artificial heart	SynCardia Cardiowest
Short-term devices	Medos DeltaStream[b] Levitronix CentriMag[b] Maquet CARDIOHELP[b]

[a]Withdrawn from the market in 2014.
[b]These short-term devices can be used with an oxygenator for ECLS/ECMO. A provision has been made for devices that were implanted concomitantly (as a temporary right ventricular assist device) with a long-term device.
CE: European conformity; ECLS/ECMO: extracorporeal life support/extracorporeal membrane oxygenation; EUROMACS: European Registry for Patients with Mechanical Circulatory Support; HVAD: HeartWare ventricular assist device; MCS: mechanical circulatory support; PVAD: paracorporeal ventricular assist device; VAD: ventricular assist device.

QUALITY CONTROL

To safeguard the correctness and completeness of the data submitted by the contributing hospitals, a set of tools and protocols has been developed. Primarily, the hospitals sign an agreement in which they consent to submit data from every patient who receives MCS on a long-term basis (support duration ≥6 months), unless the patient refuses consent to participate. The procedure to obtain consent is based on national legislation, which varies in the different nations in which hospitals submitting data are situated. The hospitals agree to communicate data records to the registry in accordance with the structure of the EUROMACS database and ensure that all data have been correctly acquired, in accordance with the state of the art of medical procedures.

In addition, checks on data completeness and data consistency are carried out on a structural basis. Data managers are approached directly in case of specific issues. The participating hospitals are requested to confirm the completeness of their data on 30 June and 31 December each year. Thus, the consolidated data can be used for analyses and the annual report. For more details, see Supplementary Material.

On-site audits are conducted by the EUROMACS management team and comprise an overview of possible non-compliance reports using a random selection of patient files that are compared with the respective data files from the local hospitals.

Statistical analysis

In preparing the analysis for this report, we involved on-site data managers to achieve complete data with respect to the most important variables. Our goal was to increase the completeness of the survival data by assuming a patient's death if a date of death or a cause of death had been entered or if the patient's death

was mentioned as an adverse event or as a type of discharge. We used the brand of the device to derive the type of pump in case this information was missing. No multiple data imputations were done. We checked for the chronological plausibility of the follow-up records and eliminated or corrected implausible records by queries to on-site data managers.

The Kaplan–Meier estimates of cumulative probabilities were calculated for mortality, including 95% confidence intervals (CIs) as a measure of certainty, where we did not truncate the curves. A patient is considered at risk up to the date of his or her individual last follow-up information saying that the patient has received a transplant, has been weaned from the device, has died or is alive. For major adverse events other than death, we calculated event rates per 100 patient-months and constructed corresponding CIs that accounted for the Poisson distribution of event counts. Competing outcomes (ongoing device support or death or heart transplant or weaning) are presented for the first 6 months after device implant. Percentages are calculated as the ratio of the number of subjects who experienced the mentioned outcomes divided by the total number of subjects in the data set multiplied by 100. To avoid any censored individuals, only patients with a follow-up period of at least 6 months were considered for the competing outcome analysis. All CIs and *P*-values were 2-sided. All calculations were made using Stata 12 (Stata Corporation LLC, College Station, TX, USA).

RESULTS

Since the publication of the first EUROMACS annual report, the enrolment of hospitals increased by 148%, from 21 to 52, and patients in the registry more than tripled from 741 to 2681 (262%) [6].

Centres

Table 2 presents the 52 hospitals in 18 countries (in 2013, 21 hospitals in 12 countries) [6] contributing data to the EUROMACS as of 31 December 2016. On the same date, the agreement in which the rules of engagement were defined was under consideration in 4 hospitals in 2 additional countries. In addition, the Spanish Registry for Mechanical Circulatory Support (ESPAMACS), which includes the collective data from almost all Spanish hospitals that implant MCS devices, agreed to provide data to EUROMACS on a regular basis, whereas 1 hospital contributes its data separately [7]. At the end of 2015, an agreement was reached with the Societé Francaise de Chirurgie Thoracique et Cardio-Vasculaire (SFCTCV) [8] whereby the 18 hospitals in France that implant MSC devices will start contributing data in 2017.

EUROMACS, in turn, has come to an understanding with the ISHLT concerning its participation in IMACS.

Table 2: Participating institutions as of 31 December 2016

Country	City, Hospital
Austria	Innsbruck, Universitätskliniken
Azerbaijan	Baku, Central Clinic Hospital
Belarus	Minsk, National Institute 'Cardiology'
Belgium	Aalst, Onze Lieve Vrouwenziekenhuis
	Gent, Universitair Ziekenhuis Gent
	Leuven, Katholieke Universiteit Leuven
Czech Republic	Prague, Institute for Experimental Cardiac Surgery (IKEM)
	Brno, Center for Cardiovascular and Transplant Surgery
Denmark	Århus, Århus University Hospital Skejby
	Copenhagen, Rigshospitalet
France	Le Plessis-Robinson, Centre Chirurgical Marie Lannelongue
Germany	Berlin, Deutsches Herzzentrum Berlin
	Lübeck, Universitätsklinikum Schleswig Holstein
	Bad Oeynhausen, Herz- und Diabeteszentrum Nordrhein-Westfalen
	Hamburg, Universitätsklinikum Eppendorf
	Freiburg, Universitäts Herzzentrum Freiburg - Bad Krozingen
	Jena, Universitäts-Herzzentrum Thüringen
	Karlsburg, Klinikum Karlsburg
	Köln, Universitätsklinikum Köln, AöR
Greece	Athens, Onassis Cardiac Surgery Center
	Thessaloniki, Aristotle University of Thessaloniki
Hungary	Budapest, Heart Center of the Semmelweis University
	Budapest, Gottsegen György Hungarian Institute of Cardiology
Italy	Bologna, Ospedale S. Orsola
	Rome, Ospedale San Camillo
	Milan, Ospedale Niguarda Ca'Granda
	Bergamo, Ospedale Papa Giovanni XXIII
	Naples, Ospedale dei Colli
	Palermo, ISMETT
	Rome, Ospedale Pediatrico Bambino Gesù
	Torino, Regina Margherita Children's Hospital
Kazakhstan	Astana, National Research Cardiac Surgery Center
Netherlands	Groningen, Universitair Medisch Centrum Groningen
	Rotterdam, Erasmus Medisch Centrum
	Utrecht, Universitair Medisch Centrum Utrecht
Norway	Oslo, Rikshospitalet
Poland	Warsaw, Childrens Memorial Hospital
	Zabrze, Silesian Heart Center
Spain	Pamplona, Clínica Universidad de Navarra
	ESPAMACS, Madrid, collective of 7 hospitals
Switzerland	Bern, University Hospital Bern (Inselspital)
	Zürich, Kinderspital Zürich
Turkey	Izmir, Ege University School of Medicine
	Istanbul, Florence Nightingale Hospital
	Ankara, Bashkent University Hospital
	Ankara, Yüksek Ihtisas Hospital

Update per 31 December 2016

The analyses in this annual report are based on the data for implantation of MCS devices beginning 1 January 2011. Between 1 January 2011 and 31 December 2016, 2681 patients (mean age 51.7 years, median 55 years, range 0–86 years) were registered in the EUROMACS database (Table 3). The increase in the number of devices implanted, compared with the number in the first annual report, is 1856 (+225%).

The aetiology of heart failure was primarily ischaemic cardiomyopathy ($n = 1091$, 40.7%) and idiopathic cardiomyopathy ($n = 926$, 34.5%) (Table 3). The distribution by ABO blood group type and gender is given in Table 4.

Table 5 presents the types of VADs implanted stratified according to age in 2681 patients for whom exact data were available.

An isolated left ventricular assist device (LVAD) was implanted in 2366 (88.3%) patients as a first implant. An LVAD with a temporary right ventricular assist device was implanted in 126 (4.7%)

Table 3: Demographic profile of 2681 patients

Patient characteristics	
Age (years), mean ± SD (median, range)	51.7 ± 15.3 (55, 0–86)
Gender (male/female)	2200/481
Ethnic origin	
Asian	217
White	2117
Other or unknown	347
Primary diagnosis	
Idiopathic cardiomyopathy	926
Ischaemic cardiomyopathy	1091
Restrictive cardiomyopathy	17
Hypertrophic cardiomyopathy	22
Toxin-induced cardiomyopathy	40
Postpartal cardiomyopathy	16
Myocarditis	136
End-stage valvular heart disease	45
Congenital heart disease	56
Neoplasia	7
Unknown	325

Table 4: Patient characteristics according to gender and blood groups

Blood group	Male	Female	Total, *n* (%)
A	985	196	1181 (44.05)
AB	119	30	149 (5.56)
B	292	56	348 (12.98)
O	803	199	1002 (37.37)
Unspecified	1	0	1 (0.04)
Total, *n* (%)	2200	481	2681 (100)

Table 5: Types of ventricular assist devices per age group in the 2695 implants for which data were available

Age group (years)	<17	17–65	>65	Total
LVAD alone				
Continuous	37	1897	324	2258
Pulsatile	48	29	3	80
Unspecified	1	120	24	145
LVAD + RVAD				
Continuous	1	102	18	121
Continuous LVAD, pulsatile RVAD	0	4	0	4
Pulsatile LVAD, continuous RVAD	2	0	0	2
Continuous LVAD, unspecified RVAD	0	3	0	3
Unspecified LVAD, unspecified RVAD	0	1	0	1
BiVAD				
Continuous	2	20	4	26
Continuous LVAD, pulsatile RVAD	0	1	0	1
Continuous LVAD, unspecified RVAD	0	6	1	7
Pulsatile LVAD, continuous RVAD	0	1	0	1
Pulsatile	16	16	1	33
Pulsatile LVAD, unspecified RVAD	2	9	0	11
Unspecified LVAD, unspecified RVAD	0	2	0	2
All implants	109	2211	375	2695

BiVAD: biventricular assist device; LVAD: left ventricular assist device; RVAD: right ventricular assist device.

patients. Isolated right ventricular assist device s were implanted in 28 (1.0%) patients and total artificial hearts in 27 (1.0%) patients. Table 6 presents that, after the first implantation of MCS, 218 patients underwent a second device implantation and 37 patients received a third implantation, 9 patients a fourth implantation and 2 patients a fifth implantation.

Strategy for ventricular assist device implantations

Table 7 presents the strategy for VAD implantations in 2947 implantations. VADs were implanted primarily as bridge to candidacy (possible bridge to transplant, $n = 1052$, 36%) or bridge to transplant ($n = 813$, 28%). VADs as a destination or a permanent therapy were implanted in 458 (16%) patients. We expected that, given the large numbers of patients on the heart transplant waiting lists in several countries, a relative increase would be seen in the number of patients older than 65 years on destination therapy compared to the numbers in other age categories [9].

INTERMACS LEVELS

VAD implantation was performed primarily in Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) Levels 2 and 3 as presented in Table 8.

Table 6: Primary and subsequently implanted devices ($n = 2947$)

	Sequence of operations					
	1st	2nd	3rd	4th	5th	Total
BiVAD	80	1	0	0	0	81
LVAD	2366	122	22	5	0	2515
LVAD, RVAD	126	4	1	0	0	131
RVAD	28	72	10	3	1	114
SVAD	3	0	1	0	0	4
Total artificial heart	27	4	0	0	0	31
Unknown	51	15	3	1	1	71
Total	2681	218	37	9	2	2947

BiVAD: biventricular assist device; LVAD: left ventricular assist device; RVAD: right ventricular assist device; SVAD: ventricular assist device placement in a single ventricle; VAD: ventricular assist device.

Table 7: Device strategy at the time of implantation, stratified by age categories, *n* (%)

Strategy	<50 years	50–64 years	65–70 years	>70 years	Total
Bridge to recovery	24 (2)	28 (2)	3 (1)	2 (1)	57 (2)
Bridge to candidacy	402 (42)	568 (39)	60 (18)	22 (12)	1052 (36)
Bridge to transplant	332 (34)	414 (28)	48 (14)	19 (10)	813 (28)
Destination therapy	22 (2)	170 (12)	157 (47)	109 (60)	458 (16)
Rescue therapy	68 (7)	105 (7)	19 (6)	18 (10)	210 (7)
Other	4 (0)	5 (0)	2 (1)	0 (0)	11 (0)
Unknown	112 (12)	176 (12)	45 (13)	13 (7)	346 (12)
Total	964	1466	334	183	2947

Table 8: INTERMACS levels of 2947 ventricular assist device implantations in 2681 patients

INTERMACS patient profile	*n* (%)
Level 1: Critical cardiogenic shock	424 (14)
Level 2: Progressive decline	896 (30)
Level 3: Stable but inotrope dependent	733 (25)
Level 4: Resting symptoms	472 (16)
Level 5: Exertion intolerant	104 (4)
Level 6: Exertion limited	49 (2)
Level 7: Advanced NYHA Class 3	43 (1)
Unknown	226 (8)
Total	2947

INTERMACS: Interagency Registry for Mechanically Assisted Circulatory Support; NYHA: New York Heart Association.

OUTCOME OF VENTRICULAR ASSIST DEVICE IMPLANTATION

Types of ventricular assist devices implanted

Figure 1 shows the types of VADs implanted in both paediatric and adult patients from 1 January 2011 to 31 December 2016, entered into the EUROMACS database.

Survival

The overall survival of 2268 adult patients (aged >17 years) with a continuous LVAD or a biventricular assist device (BiVAD) and a mean follow-up period of 379 days (median 236 days, range 1–2098 days) was 86% (CI 85–88), 66% (CI 64–68), 53% (CI 51–56) and 42% (CI 39–45) at 30 days, 1 year, 2 years and 3 years, respectively (Fig. 2).

Stratified according to the site of VAD implantation, the survival rate of 2113 patients with continuous-flow LVAD, either as a destination therapy or as a bridge to transplant, was 88% (CI 87–90), 69% (CI 66–71), 55% (CI 52–58) and 44% (CI 40–47) at 30 days, 1 year, 2 years and 3 years, respectively (Fig. 3). The survival rate of 141 patients with BiVAD was 61% (CI 52–68), 32% (CI 23–40), 27% (CI 19–35) and 21% (CI 13–30) at 30 days, 1 year, 2 years and 3 years, respectively (Fig. 3).

Figure 4 shows the age group-based survival rates of patients with primary LVAD and BiVAD support. At 2 years, the survival rate was 64% (CI 59–68), 53% (CI 49–56), 42% (CI 35–49) and 27% (CI 18–37) in patients aged <50, 50–64, 65–70 and >70 years, respectively.

Figure 5 depicts the actuarial survival depending on device strategy. Bridge-to-transplant strategy revealed the best survival.

Table 9 shows the causes of death of 1027 patients with VAD who were registered as deceased. The 2 main causes of death were multiorgan failure in 186 (18%) patients and infections and sepsis in 208 (20%) patients.

Adverse events (morbidity)

Major adverse events (Table 10) related to device malfunctions, such as accidental disconnection, wear or breaking of the driveline and pump thrombosis, were observed 454 times within the entire follow-up period, which corresponds to 0.037 malfunctions per patient year. For definitions of adverse events, we refer the reader to the corresponding INTERMACS definitions [10]. As other groups have reported, patients with continuous-flow assist devices had a higher risk for major bleeding [11]. In the EUROMACS database, major bleeding (requesting at least 1 unit of blood for transfusion) was reported 433 times, whereas 845 major infections caused by either the driveline or the assist device were observed. Neurological dysfunction (stroke) occurred in 319 of the adverse events, whereas 52 of the adverse events were a combination of one or more events. All major adverse events occurred more frequently within the first 3 months after implantation than later during the patients' course. The rate of device malfunctions and infections reached a stable state 1 year after implantation, whereas the rates of bleeding and neurological events decreased for the entire follow-up period.

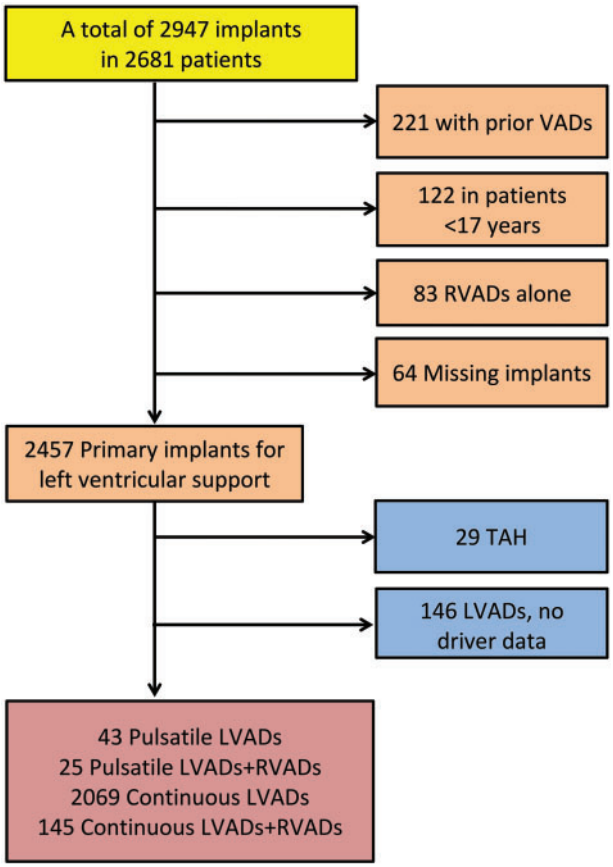

Figure 1: Types of mechanical circulatory support systems implanted from 1 January 2011 to 31 December 2016. LVAD: left ventricular assist device; RVAD: right ventricular assist device; TAH: total artificial heart; VAD: ventricular assist device.

Competing outcomes

Within 6 months after device implantation, 5.4% of the patients received a heart transplant and 27.9% died. Only 1.5% could be weaned from the device, and 65.2% had ongoing device support during this period (Fig. 6).

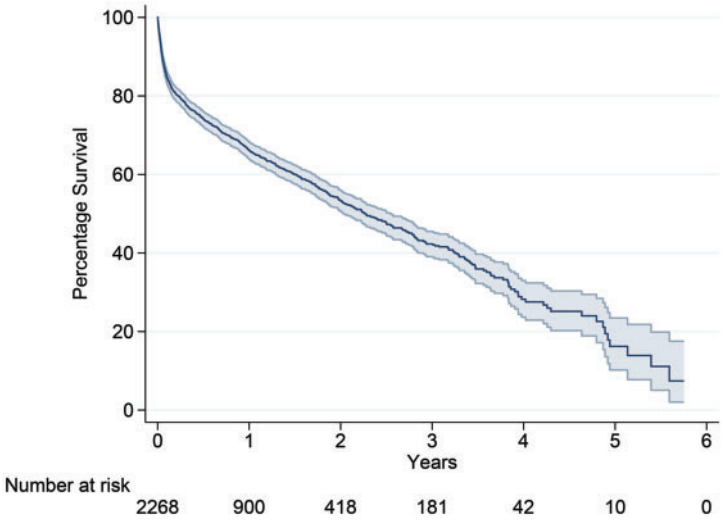

Figure 2: Survival of adult patients after primary LVAD or BiVAD implantation with continuous-flow LVAD. In adult patients after primary LVAD or BiVAD implantation with continuous-flow LVAD, mean follow-up was 392 (median 270, range 1–1795) days. BiVAD: biventricular assist device; LVAD: left ventricular assist device.

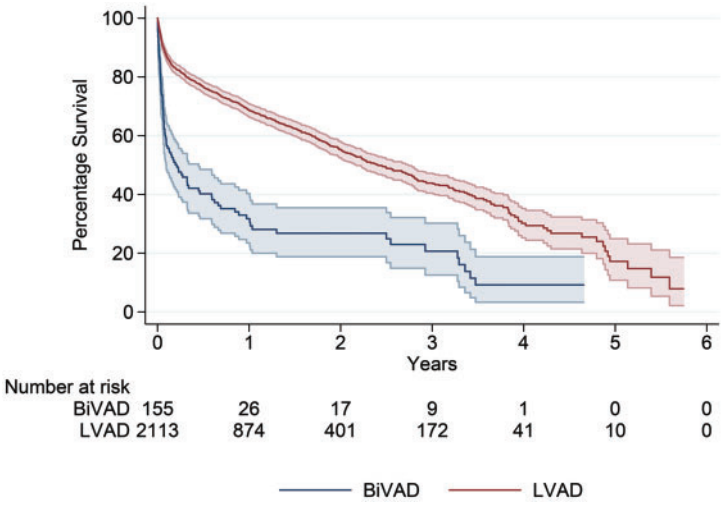

Figure 3: Survival of adult patients with a continuous-flow LVAD stratified by primary LVAD or a primary BiVAD implant. BiVAD: biventricular assist device; LVAD: left ventricular assist device.

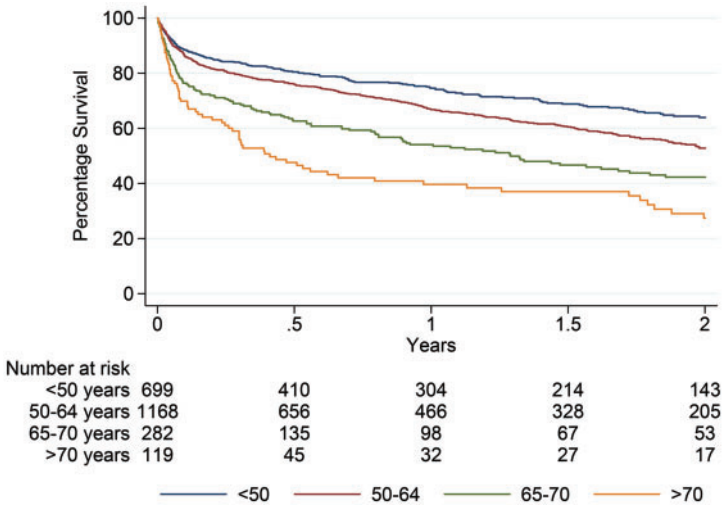

Figure 4: Survival of adult patients after primary implantation of a continuous-flow left ventricular assist device or a continuous-flow biventricular assist device, stratified by age category.

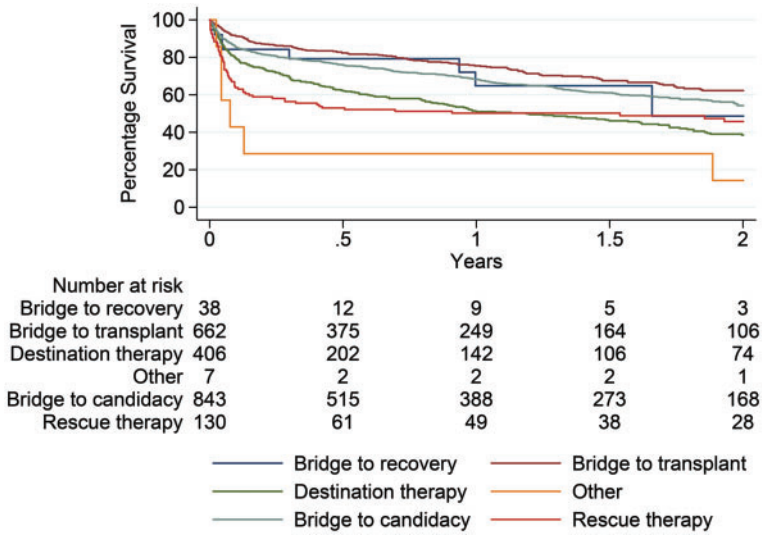

Figure 5: Survival of adult patients after primary implantation of a continuous-flow left ventricular or biventricular assist device, stratified by the device implant strategy used.

Table 9: Causes of death

Causes of death	*n* (%)
Infection	208 (20)
Cerebrovascular accident	132 (13)
Cardiopulmonary failure	48 (5)
Multiorgan failure	186 (18)
Bleeding	50 (5)
Other cause of death	403 (39)
Total	1027

Table 10: Major adverse event rates

	Within 3 months after implant		More than 3 months after implant	
	Event counts	Events per 100 patient-months (CI)	Event counts	Events per 100 patient-months (CI)
Device malfunction	120	3.56 (2.96–4.26)	334	2.88 (2.58–3.21)
Major bleeding	217	6.45 (5.62–7.36)	216	1.86 (1.62–2.13)
Major infection	208	6.18 (5.37–7.08)	637	5.49 (5.08–5.94)
Neurological event	102	3.03 (2.47–3.68)	217	1.87 (1.63–2.14)

CI: confidence interval.

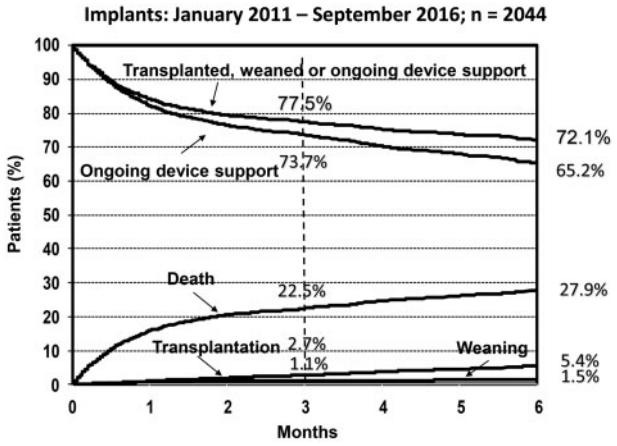

Figure 6: Competing risks of patients after assist device implants who have been followed for at least 6 months.

DISCUSSION

Compared to the first EUROMACS report, the number of participating hospitals has increased from 21 to 52 (+148%), whereas the number of registered implantations more than tripled from 825 to 2947 (+257%). The 3-year survival rate of patients with continuous-flow LVAD and BiVAD implants, 44% and 21%, respectively, was far less favourable than the results of the seventh INTERMACS annual report (fig. 6 of that report), which was 58% and 40%, respectively [12].

There are major differences between the rate of morbidity in our current EUROMACS report and recent INTERMACS results, such as the occurrence of major infections, which is far higher in the INTERMACS cohort within the first 3 months after implantation (15.19 vs 6.18 events per 100 patient-months) but lower during the later course (4.03 vs 5.49) [6]. The same pattern can be seen with respect to neurological events (4.18 vs 3.03 events per 100 patient-months within 3 months after implant, 1.21 vs 1.87 in the later course).

What are the possible explanations for differences? (i) One reason might be differences in the quality of the data with respect to the completeness of reported events. INTERMACS has a high level of completeness of collected data, mandated by the National Institutes of Health, though, similar to EUROMACS, INTERMACS has also periodic site visits, confirmation of case counts and frequent contact with sites to review adverse events

(J.K. Kirklin, personal communication). On the other hand, EUROMACS, being an EACTS Committee, follows the same strategy of quality control as INTERMACS (see section 'Quality Control'). (ii) There might be some differences in definitions of events and different periods of observation times. (iii) There may be some real differences in outcomes related to different devices and management strategies or patient selection practices. These differences were discussed with IMACS before the 2 registries agreed to analyse aggregated anonymous EUROMACS data. An incoming study proposal intends to investigate the details of these differences.

The growth in the number of participating hospitals precipitated the increase in quality control by means of statistical analyses.

Limitations

The registry continues recruiting to increase the numbers of contributing centres, the goal being to include as many European centres as possible. In contrast to the situation in the USA, participation in EUROMACS is not mandatory in Europe. Therefore, surveillance and improvement of data quality are ongoing efforts.

CONCLUSION

Because EUROMACS became an official committee of EACTS, the registry experienced an increase in the number of participating hospitals (+148%) and more than tripled the number of implants, representing European MCS data at the best achievable level and reached a unique comprehensive representation of European MCS baseline and follow-up data. In addition, the productive cooperation with IMACS permits the inclusion of worldwide data and important comparisons. Mortality and morbidity outcome data differ between the registries. It is of high importance to investigate the reasons for these differences.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *EJCTS* online.

ACKNOWLEDGEMENTS

We are grateful to James K. Kirklin for his cooperation and advice. We very much appreciate the generous initial funds provided by the Friede-Springer-Herz-Stiftung, as well as the support from various manufacturers (Berlin Heart, CircuLite, Inc., HeartWare, Inc., Micro-Med, Syncardia Systems, Inc. and Thoratec Corporation).

Conflict of interest: Pascal Leprince is Proctor for Syncardia, HeartMate II (Abbott) and HVAD (Medtronic) and is a board member of Medtronic. Finn Gustafsson received speaker's fee from Abbott. Ivan Netuka is consultant and Advisory Board Member of Abbott. The other authors have nothing to disclose.

REFERENCES

[1] Zuk K, Gahl B, Susac M, Vierecke J, de By TMMM, Windecker S *et al.* Mid-term mechanical circulatory support: comparison of single-centre data with the EUROMACS registry. Eur J Cardiothorac Surg 2017;51:127–34.
[2] Bernhardt AM, De By TMMH, 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.
[3] Schweiger MHM, Berger F, Miera O, Loforte A, Gargiulo A, De By T *et al.* Incidence of thrombo-embolic events of intra-corporeal ventricular assist devices in pediatrics–EUROMACS analyses. J Heart Lung Transplant 2016;35:S350–1.
[4] EACTS. Raising Standards Through Education and Training 2017. http://www.eacts.org/educational-events/programme/vad/ (5 September 2017, date last accessed).
[5] Kirklin JK, Cantor R, Mohacsi P, Gummert J, De By TMMH, Hannan MM *et al.* First annual IMACS report: a global International Society for Heart and Lung Transplantation Registry for Mechanical Circulatory Support. J Heart Lung Transplant 2016;35:407–12.
[6] de By TMMH, Mohacsi P, Gummert J, Bushnaq H, Krabatsch T, Gustafsson F *et al.* The European Registry for Patients with Mechanical Circulatory Support (EUROMACS): first annual report. Eur J Cardiothorac Surg 2015;47:770–6; discussion 6–7.
[7] de By TMMH, Castedo E, Krabatsch T, Mohacsi P, Meyns B, Netuka I *et al.* The EUROMACS Registry of patients who receive mechanical circulatory support: role and perspectives. Cir Cardiov 2016;23:22–5.
[8] Mazzucotelli JP, Leprince P, Litzler PY, Vincentelli A, Le Guyader A, Kirsch M *et al.* Résultats de l'assistance circulatoire mécanique en France. Chir Thorac Cardiovasc 2011;15:17–22.
[9] Kirklin JK, Myers SL, Clark ML, Collum C, Hollifield K, Cleggett M. INTERMACS Quarterly Statistical Report 2016 Q2: JHLT Online 2016. http://www.uab.edu/medicine/intermacs/images/Federal_Quarterly_Report/Federal_Partners_Report_2016_Q2.pdf (5 September 2017, date last accessed).
[10] INTERMACS Executive Committee. INTERMACS Adverse Event Definitions: Adult and Pediatric patients 2013. https://www.uab.edu/medicine/intermacs/images/protocol_4.0/protocol_4.0_MoP/Appendix_A_INTERMACS_AE_Definitions__05152013.docx (5 September 2017, date last accessed).
[11] Shrode CW, Draper KV, Huang RJ, Kennedy JL, Godsey AC, Morrison CC *et al.* Significantly higher rates of gastrointestinal bleeding and thromboembolic events with left ventricular assist devices. Clin Gastroenterol Hepatol 2014;12:1461–7.
[12] 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.