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REPORT

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The European Registry for Patients with Mechanical Circulatory Support (EUROMACS): first annual report[†]

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Abstract

The European Registry for Patients with Mechanical Circulatory Support (EUROMACS) was founded on 10 December 2009 with the initiative of Roland Hetzer (Deutsches Herzzentrum Berlin, Berlin, Germany) and Jan Gummert (Herz- und Diabeteszentrum Nordrhein-Westfalen, Bad Oeynhausen, Germany) with 15 other founding international members. It aims to promote scientific research to improve care of end-stage heart failure patients with ventricular assist device or a total artificial heart as long-term mechanical circulatory support. Likewise, the organization aims to provide and maintain a registry of device implantation data and long-term follow-up of patients with mechanical circulatory support. Hence, EUROMACS affiliated itself with Dendrite Clinical Systems Ltd to offer its members a software tool that allows input and analysis of patient clinical data on a daily basis. EUROMACS facilitates further scientific studies by offering research groups access to any available data wherein patients and centres are anonymized. Furthermore, EUROMACS aims to stimulate cooperation with clinical and research institutions and with peer associations involved to further its aims. EUROMACS is the only European-based Registry for Patients with Mechanical Circulatory Support with rapid increase in institutional and individual membership. Because of the expeditious data input, the European Association for Cardiothoracic Surgeons saw the need to optimize the data availability and the significance of the registry to improve care of patients with mechanical circulatory support and its potential contribution to scientific intents; hence, the beginning of their alliance in 2012. This first annual report is designed to provide an overview of EUROMACS' structure, its activities, a first data collection and an insight to its scientific contributions.

Keywords: End-stage heart failure • Registry • Mechanical circulatory support • Left ventricular assist device • Right ventricular assist device • Biventricular assist device • Total artificial heart • Bridge to transplant

HISTORY AND BACKGROUND

The increasing routine use of ventricular assist devices (VADs) to keep patients alive until heart transplantation paved the way to their clinical use as an established treatment for end-stage heart failure by themselves. This has become essential in the face of the increasing organ shortage. Moreover, the use of VADs also has increasing relevance as the possible bridge to transplant (bridge to candidacy), such as in the setting of pulmonary hypertension or curable neoplasia having a follow-up of at least 5 years after successful treatment [1, 2] and tumour-free for at least 1 year in highly selected cases [3].

These issues and the lack of a European registry have prompted the creation of EUROMACS (European Registry for Patients with Mechanical Circulatory Support e.V.) (e.V., German abbreviation meaning 'eingetragener Verein': registered association, formally registered at the Berlin Charlottenburg Court), by 15 international members, registered in Berlin on 10 December 2009. Initial funds were provided by the Friede-Springer-Herz-Stiftung and support from various manufacturers (CircuLite, Inc., HeartWare, Inc., MicroMed, Syncardia Systems, Inc., Thoratec Corporation). Promotion

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of scientific research to improve care of end-stage heart failure patients with VADs or a total artificial heart (TAH) as long-term mechanical circulatory support (MCS) is its primary objective. In 2010, EUROMACS affiliated itself with Dendrite Clinical Systems Ltd, a specialist supplier of clinical database and analysis, to offer its members a secure software tool for the input and analysis of patients' clinical data on a daily basis. From then on, the database was developed, and the registry became accessible in April 2012. The contributing centres were advised to submit their data retrospectively as of 1 January 2011. The registry facilitates further scientific studies by offering research groups access to anonymized data. EUROMACS is the only existing European-based MCS registry for all devices implanted in children and adults, which is in contrary to other registries such as INTERMACS, which registers only Food and Drug Administration (FDA)-approved devices and no paediatric patients.

In 2012, EUROMACS became an official committee of the European Association for Cardiothoracic Surgery (EACTS), and hereby fulfils all by-laws of the association. The EACTS has taken over the costs of EUROMACS. Likewise, EUROMACS affiliates with the policies and quality programme of the EACTS.

This first annual report aims to provide an overview of EUROMACS' activities, a first data collection of the EUROMACS registry and an insight to its scientific contributions.

STRUCTURE OF EUROMACS

In 2013, the legally registered constitution of EUROMACS officially declared itself as a Committee of the EACTS.

Figure 1 shows the organizational structure of EUROMACS. It functions as an EACTS Committee, and as such, it follows the EACTS policies and regulations. This allows any EACTS member to join EUROMACS freely.

DATABASE DESIGN AND FUNCTION

The EUROMACS database has been designed in such a way that the patient and device outcomes will be comparable with that of the INTERMACS database. The software, developed by Dendrite Clinical Systems Ltd is user-friendly, and can be accessed by either MS Windows or Apple OS. It was made possible that security of data according to German and European legislation is assured. The centres can enter their data any time, using a unique password, and for safety reasons by using hypertext transfer protocol secure (https) communication.

The database consists of two major parts, as follows:

(i) Implant data
  (a) Basic patient data.
  (b) Examinations and assessment prior to implant (e.g. echocardiogram, haemodynamics, laboratory values and medications).
  (c) Surgical procedures.
  (d) Clinical investigations and status at discharge.

(ii) Follow-up data
  (a) Routine follow-up, e.g. out-patient visits.
  (b) Events (major/minor bleeding, thromboembolism, infection, pump failure and/or exchange, problems with the driveline, controller or the batteries, weaning, myocardial recovery, transplantation, death).

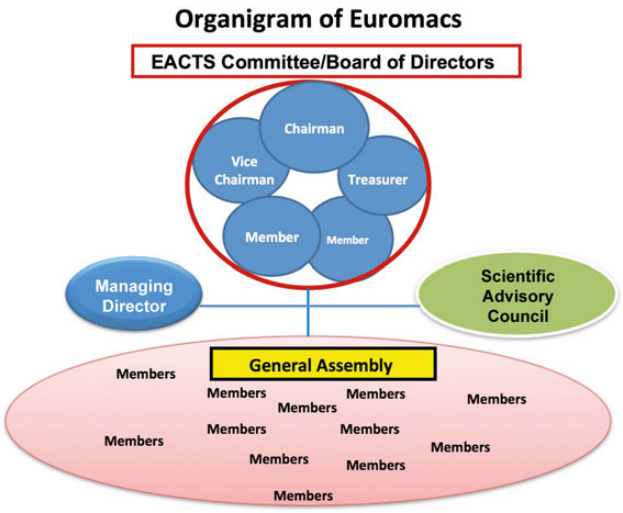

Figure 1: The EUROMACS organizational structure.

Requirements for site participation and working area

Any hospital/centre/institution, contributing to EUROMACS is offered a contract between their local institution and EUROMACS. The agreement regulates that patients are informed according to the national or local regulations. Furthermore, hospitals agree to the complete and timely data entry of all patients who consent to participate. In return, EUROMACS agrees to keep the data secured and confidential for other centres, provides data availability for clinical analysis and addresses quality control.

The working area of EUROMACS is in those countries, which are either entirely or partially located on the European continent. However, if any centre outside this working area decides to participate voluntarily in EUROMACS, such a centre would be free to join the registry.

Since one of the primary objectives of EUROMACS is to promote scientific research to improve care of end-stage heart failure patients with long-term MCS, any centre or scientist who wants to use available data in the database, research proposals must be submitted to the Executive Board. If for some reasons that the proposal is rendered unsuitable, it is referred to the scientific advisory committee for further assessment. All approved research proposals are monitored to ensure that the data are used appropriately. In July 2013, the first scientific proposal to use EUROMACS data was granted; hence, data were made available for analysis and publication [4].

Patient selection

All patients (adults and children) who receive long-term MCS are eligible for registration in the EUROMACS database. However, a provision has been made to register devices used for temporary or short-term (≤30 days) support, which are implanted concomitantly (as a temporary RVAD) with a long-term device and which are designed to function for ≥6 months (Table 1).

Statistical analyses

Categorical variables are reported as number and percentage of observations. Continuous variables are expressed as mean, median and range. We generated Kaplan–Meier estimates to investigate

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

MCS type	Device
Long-term devices	
Continuous flow	Berlin Heart Incor
	Circulite Synergy
	Heart Assist 5
	HeartWare HVAD
	Jarvik 2000
	MicroMed DeBakey
	Thoratec HeartMate II
Pulsatile extracorporeal	Berlin Heart Excor
	Thoratec pVAD
Total artificial heart	SynCardia Cardiowest
Short-term devices	Abiomed AB5000
	Deltastream Medos
	Levitronix Centrimag
	Maquet CardioHelp

CE: European conformity; MCS: mechanical circulatory support.

the probability of survival or event-free survival as a function of time after VAD implantation. Results are presented for adults with primary LVAD or BiVAD implants, and indicate mean values with 95% confidence intervals. Patients were censored at the time of transplantation, weaning or second VAD implantation.

APPROVED DEVICES

Table 1 lists the current devices with a European conformity (CE) mark, which are approved for clinical use.

STATUS OF EUROMACS DATABASE

As previously mentioned, EUROMACS aims to create and operate a European registry to assemble baseline and follow-up data of patients receiving long-term MCS for the treatment of advanced heart failure, to determine the factors influencing the clinical results.

Table 2 shows the 12 participating countries and 21 hospitals contributing data to the EUROMACS database as of 31 December 2013. During the same date, the content of the contract with EUROMACS was still being evaluated by the legal advisers in 27 centres (in 6 additional countries), for conformation with their local or national regulatory requirements.

Participating hospitals register the implant data of newly enlisted patients who consent to their enrolment in the EUROMACS database. Follow-up data that include routine examinations and occurrence of events, are likewise registered. Provisions are made to register patients with MCS from 1 January 2011 retrospectively.

Between 1 January 2011 and 31 December 2013, 741 patients (mean age: 53.3, median: 56, range: 0–83 years) were registered in the EUROMACS database. Most patients are Caucasians ($n = 672$, 90.7%) and males ($n = 610$, 82.3%). The aetiology of end-stage heart failure was mostly idiopathic dilated cardiomyopathy ($n = 348$, 47%) and ischaemic cardiomyopathy ($n = 294$, 39.7%) (Table 3). The distribution by AB0 blood group type is given in Table 4. These data are deemed important for comparison with the patients on organ transplant waiting lists.

Table 2: Participating countries/institutions as of 31 December 2013

Country	City, hospital
Belarus	Minsk, Republican Scientific Practical Center 'Cardiology'
Belgium	Aalst, Onze Lieve Vrouwen Ziekenhuis
	Gent, Academisch Ziekenhuis Gent
Czech Republic	Prague, Institute for Clinical and Experimental Medicine (IKEM)
	Brno, Center for Cardiovascular and Transplant Surgery
Denmark	Copenhagen, Rigshospitalet
Germany	Bad Oeynhausen, Herz- und Diabeteszentrum Nordrhein-Westfalen
	Berlin, Deutsches Herzzentrum Berlin (DHZB)
	Freiburg, Universitäts-Herzzentrum Freiburg – Bad Krozingen
	Hamburg, Universitäres Herzzentrum Hamburg
Greece	Thessaloniki, AHEPA University Hospital
Hungary	Budapest, Heart Center of the Semmelweis University
	Budapest, Gottsegen Hungarian Institute of Cardiology
Italy	Bologna, San Orsola Hospital
	Milan, Niguarda Ca Granda Hospital
	Rome, San Camillo Hospital
Kazakhstan	Astana, National Research Cardiac Surgery Center
Netherlands	Rotterdam, Erasmus MC
Switzerland	Bern, Inselspital
	Zurich, Kinderspital
Turkey	Izmir, Ege University Hospital

Table 3: Demographic profile of 741 VAD patients

Characteristics	*n*
Mean age (median, range), years	53.3 (56, 0–83)
Gender (male/female)	610/131
Race	
African-American	2
Asian	65
Caucasian	672
Hawaiian/Pacific	1
Others	1
Aetiology of end-stage heart failure	
Idiopathic dilated cardiomyopathy	348
Ischaemic cardiomyopathy	294
Restrictive cardiomyopathy	8
Hypertrophic obstructive cardiomyopathy	2
Toxin-induced cardiomyopathy	13
Post-partal cardiomyopathy	5
Myocarditis	38
End-stage valvular heart disease	15
Congenital heart disease	13
Neoplasia	5

Table 5 shows the types of VADs implanted stratified according to age in the 713 patients of whom exact data were available.

Table 6 details primary and subsequently implanted devices ($n = 825$) in 741 patients. An isolated LVAD was implanted in 636 (85.8%) patients. LVAD with a temporary RVAD was implanted in 45 (6.1%) patients. Isolated RVADs were implanted in 53 (7.1%), and TAH in 9 (1.2%). Additionally, Table 6 shows that, after the first implantation of MCS, 70 patients underwent a second device

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implantation, and 8 patients received a third, 4 patients a fourth and 2 patients a fifth implantation, respectively.

Table 7 shows the indications for VAD implantation (n = 825) in 741 patients. VADs were implanted mostly to possible bridge patients to transplant (n = 312, 37.8%) or bridge to transplantation (n = 202, 24.5%). VAD as destination or permanent therapy was implanted in 130 (15.8%) patients.

INTERMACS LEVELS

The EUROMACS database shows that VAD implantation was performed mostly in patients on INTERMACS levels 2 and 3, as shown in ref. [5] Table 8.

OUTCOME OF VAD IMPLANTATION

Types of ventricular assist device implanted

Figure 2 shows the types of VADs implanted on both paediatric and adult patients from 1 January 2011 to 31 December 2013, entered into the EUROMACS database.

Table 4: Patient characteristics according to gender and blood groups

Blood group	Male	Female	Total	Percentage
A	277	48	325	43.9
B	75	20	95	12.8
AB	36	13	49	6.6
0	221	50	271	36.6
Unspecified	1	0	1	0.1
Total	610	131	741	
Percentage	82.3	17.7		

Survival

The overall actuarial survival of 650 adult patients (aged ≥17 years) with LVAD and BiVAD at a mean follow-up of 264.6 (median: 180, range: 0–1363) days, is 88.7, 68.4, 59.1 and 57.3% at 30 days, 1, 2 and 3 years, respectively (Fig. 3).

Stratified according to site of VAD implantation, the actuarial survival rate of 583 adult patients with a continuous flow LVAD implanted either as destination therapy or bridge to transplant is 92.2, 72.5, 62.8 and 60.9%, at 30 days, 1, 2 and 3 years, respectively (Fig. 4). In comparison with a similar cohort in INTERMACS, the 1- and 3-year actuarial survival rate is 80 and 59%, respectively [6].

The actuarial survival rate of 67 patients with BiVAD (mostly pulsatile extracorporeal systems) is 52.5, 26.4 and 17.6% at 30 days, 1 and 2 years, respectively (Fig. 4).

Figure 5 shows the age group-based actuarial survival of patients with primary LVAD and BiVAD support. At 3 years, the actuarial survival is 79, 56, 40 and 39% in patients <50, 50–64, 65–70 and >70 years of age, respectively.

The major adverse events (Table 9), which can be found in problems with the device, malfunctions, such as loosening, wear or breaking of the drive line and pump thrombosis, were reported in 87 (20.1%) of the cases. As other groups have reported [7], patients with continuous flow assist devices have a higher risk for major bleeding. In the EUROMACS database, major bleeding (requesting at least one unit of blood transfusion) was reported 113 times (26.1%), whereas 153 (35.3%) major infections (to be defined), caused by the drive line, which is an entry port for bacteria, were observed. Neurological dysfunction (stroke) occurred in 71 (16.4%) of the adverse events, whereas 9 (2.1%) of the adverse events were a combination of one or more.

The reasons for decease, and of multiorgan failure, in patients receiving MCS is that the progress of end-stage cardiac disease, expressed in INTERMACS levels, is in most instances on level 1 through 3 (607 patients, 70.1%).

In Table 10, the causes of death of 293 VAD patients are broken down. A total of 89 (30.4%) died of MOF, 69 (23.5%) of infection or

Table 5: Types of VADs implanted stratified according to age

Implant and type of flow	Age at implant/years				
	<17	17–65	>65	Unspecified	All
LVAD alone					
Continuous	6	497	88	1	592
Pulsatile	4	6	0	3	13
Unspecified	0	6	2	0	8
LVAD + RVAD					
Continuous	0	37	4	0	41
Continuous LVAD and pulsatile RVAD	0	1	0	0	1
Continuous LVAD and unspecified RVAD	0	1	0	0	1
BiVAD alone					
Continuous	0	16	2	0	18
Continuous LVAD and pulsatile RVAD	0	1	0	0	1
Continuous LVAD and unspecified RVAD	0	4	1	0	5
Pulsatile LVAD and continuous RVAD	0	1	0	0	1
Pulsatile	5	16	1	4	26
Pulsatile LVAD and unspecified RVAD	0	0	0	1	1
Unspecified LVAD and unspecified RVAD	0	4	0	1	5
All implants	15	590	98	10	713

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

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Table 6: Number of implantations of mechanical circulatory support (MCS) according to type of VADs

	Operation sequence						Percentage
	1	2	3	4	5	All	
LVAD alone							
No secundary device	608	26	1	1	0	636	77.10
LVAD + RVAD							
Long-term device	1	0	0	0	0	1	0.10
Short-term device	45	0	0	0	0	45	5.50
Other	2	0	0	0	0	2	0.20
Total	48	0	0	0	0	48	
RVAD alone							
No secundary device	8	0	2	0	0	10	1.20
With short-term device	2	34	2	2	1	41	5.00
Other	0	0	1	0	0	1	0.10
None recorded	0	1	0	0	0	1	0.10
Total	10	35	5	2	1	53	
BiVAD alone							
No secundary device	34	0	0	0	0	34	4.10
Short-term device	9	0	0	0	0	9	1.10
Other	7	0	0	0	0	7	0.80
None recorded	7	1	0	0	0	8	1.00
Total	57	1	0	0	0	58	
TAH	7	1	0	0	1	9	1.20
Unspecified	11	7	2	1	0	21	2.50
All	741	70	8	4	2	825	100.00
Percentage	90%	8.4%	1%	0.40%	0.20%	100%	

Table 7: Indications for VAD implantation

Purpose of implantation	*n*	%
Rescue	46	5.6
Bridge to recovery	7	0.8
Possible bridge to transplant	312	37.8
Bridge to transplant, on waiting list	202	24.5
Destination therapy	130	15.8
Other	128	15.5
Total	**825**	**100.0**

Table 8: INTERMACS levels of 825 VAD implantations in 741 patients

INTERMACS level	*n*	%
Critical cardiogenic shock	100	12.1
Progressive decline	251	30.4
Stable but inotrope dependent	236	28.6
Resting symptoms	102	12.4
Exertion intolerant	22	2.7
Exertion limited	2	0.2
Advanced NYHA class 3	3	0.4
Unspecified	109	13.2
Total (%)	**825**	**100.0**

NYHA: New York Heart Association.

sepsis, 37 (12.6%) of cardiopulmonary failure, 20 (6.8%) of cerebro-vascular accidents, 18 (6.1%) of a major bleeding and 60 (20.5%%) of other causes. Other causes are cancer: 2, suicide 2, technical problems 1 and unknown 55.

Adverse events

Based on the EUROMACS database, 433 major adverse events included VAD malfunction (i.e. pump thrombosis, driveline breaks, cable wear and pump stops) bleeding, infection and stroke (Table 9). The 3-year freedom from VAD malfunction was 85.2%, while freedom from bleeding, infection and stroke were 89, 82 and 93.5%, respectively (Fig. 6).

COMMENTS

True to its objectives, the EUROMACS database, the first European-based MCS registry, has evolved into becoming an important database, for improvements in VAD-patient care and research. The EUROMACS database shows that 59% of patients with MCS were in INTERMACS levels 2 and 3, whereas the fifth INTERMACS report showed a total of 62.9% of patients on these two levels [6].

Likewise, in comparison with the fifth INTERMACS report, wherein 19.7% of patients were in critical cardiogenic shock at the time of implantation, the EUROMACS database showed only 12.1% of patients in this category.

In the first 19 months of its establishment, the EUROMACS registry has evolved into an EACTS-database in which European hospitals and those from other member countries can upload their MCS patient data. The accumulated data of 825 implanted MCS devices could now be analysed, and compared with international data from registries in other parts of the world.

The strengths of the EUROMACS registry are the quality management, the affiliation with the EACTS as an official committee, as well

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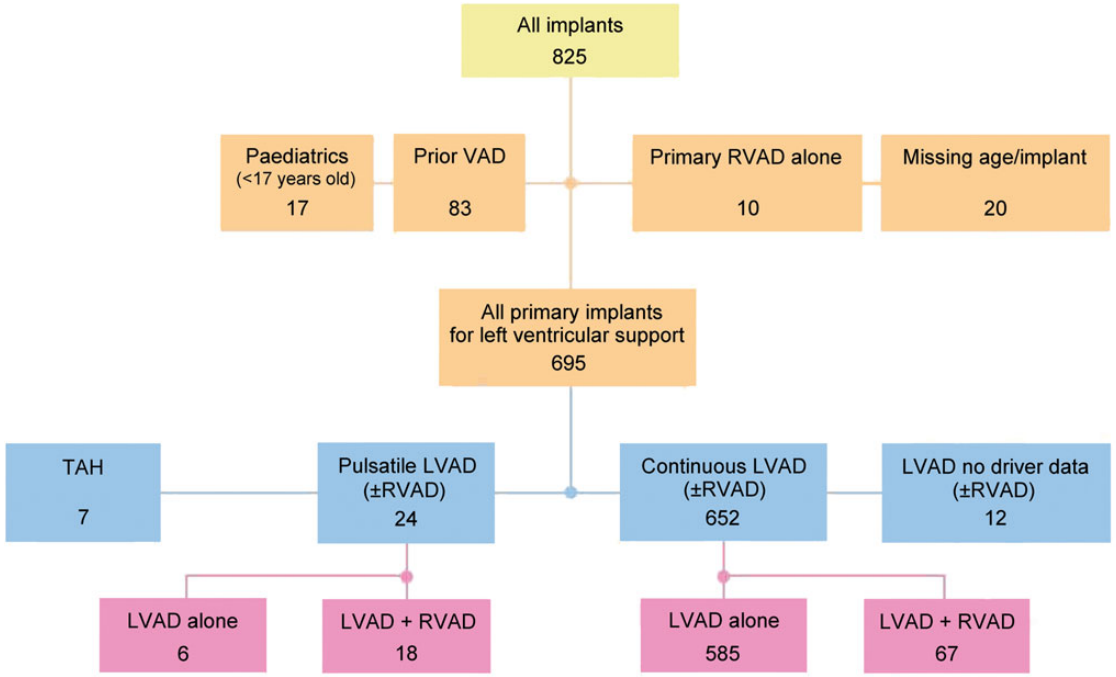

Figure 2: Types of VAD implanted from 1 January 2011 to 31 December 2013. VAD: ventricular assist device.

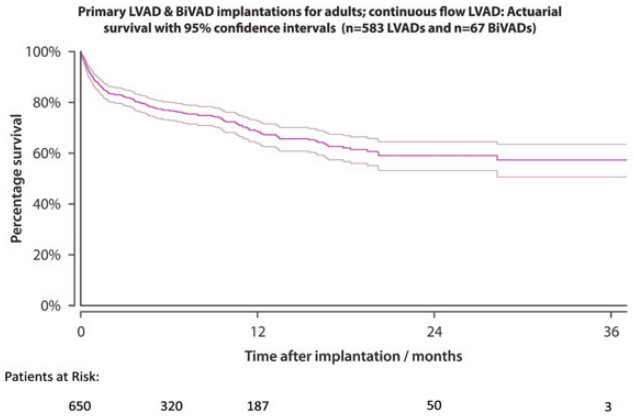

Figure 3: Overall survival of primary LVD and BiVAD implantations in adults; continuous flow LVAD: actuarial survival with 95% confidence intervals (n = 583 LVADs and n = 67 BiVADs). LVAD: left ventricular assist device; BiVADs: biventricular assist devices.

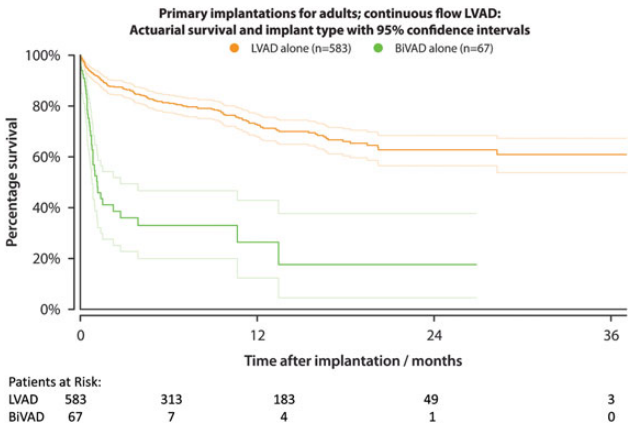

Figure 4: Actuarial survival of 650 adult primary implant patients stratified according to the type of VAD; continuous flow LVAD: actuarial survival and implant type with 95% confidence intervals.

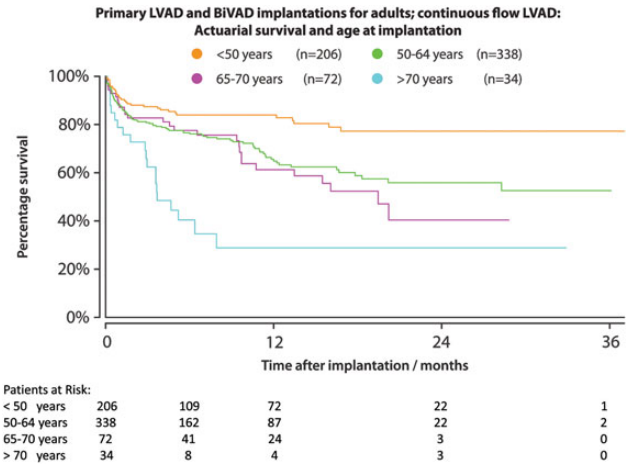

Figure 5: Age group-based actuarial survival of adult patients with primary LVAD and BiVAD support; continuous flow LVAD; age at implantation.

as the fact that the registry overcomes multiple languages and cultural differences and its ability to function as an industry-independent post-market surveillance system. In addition, the EUROMACS actively supervises the registry itself, and has taken the initiative to commence the auditing of individual centres, instead of the respective government agencies.

Our goal is for the database to assume a stature and quality, which other agencies can compare with, make use of and respect. We would like to see this database to be utilized more for scientific research; hence, we encourage clinicians to submit research proposals with general and specific objectives to answer relevant issues and concerns.

Presently, EUROMACS prepares to share data with IMACS, which is an ISHLT subsidiary. Whereas INTERMACS receives data from US hospitals, IMACS implemented all INTERMACS data and strives to combine data from several regional registries such as from Japan, South-East Asia and Australia. The cooperation of

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Table 9: Major adverse events

Major adverse events	*n*	%
Device malfunction	87	20.1
Major bleeding	113	26.1
Major infection	153	35.3
Neurological dysfunction	71	16.4
combination	9	2.1
Total	**433**	**100.0**

Table 10: Causes of death

Causes of death	*n*	%
Infection and sepsis	69	23.5
Cerebro-vascular	20	6.8
Cardiopulmonary	37	12.6
Multiorgan failure	89	30.4
Bleeding	18	6.1
Other	60	20.5
Total	**293**	**100**

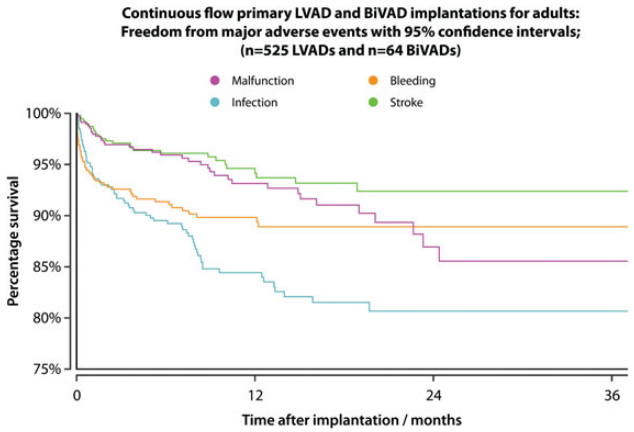

Figure 6: Three-year freedom from major adverse events with 95% confidence intervals; (*n* = 525 LVADs and *n* = 64 BiVADs); continuous flow primary LVAD and BiVAD implantations for adults.

EUROMACS with IMACS has been decided upon recently by sharing compressed data sets.

EUROMACS is now a well-established instrument of increasing importance for its members, giving them insights into their own results as well as the possibility to compare these results with outcomes of other clinical groups. With MCS being an established treatment for patients with end-stage heart failure, the collection of a carefully collected, high-quality and valid data is essential to document the efficacy, long-term durability and impact on the quality of life of patients who underwent MCS implantation. EUROMACS database is necessary to yield reliable scientific data; thus, it allows for continuing improvement in the quality of patient care.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *EJCTS* online.

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Conflict of interest: none declared.

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APPENDIX: CONFERENCE DISCUSSION

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Dr T. Bottio *(Padova, Italy):* I would firstly like to congratulate for the initiative of creating the European database and the progress made so far. I consider it a project with excellent perspectives given the continuing interest in the field of mechanical circulatory support during the recent years. Additionally, considering the progress not only in the device technology but also in the surgical techniques, a continuous approachable comparison of single centre results with the data collected in similar centres promotes meaningful scientific research. I have four simple technical questions for you.

What are the criteria to be fulfilled for a centre to become a member of the EUROMACS registry? Is it a membership on invitation from the EUROMACS association or on the request of the different centres?

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Mr de By: Any surgeon can become a member of EUROMACS and any centre can, of course, start contributing the data. The only criterion is that you sign a quite simple agreement with the association. The agreement states, on the one hand, that we will keep your data safe and that we are punishable if we wouldn't do that, and of course we have safeguards. Our data are behind secure protection, firewalls. Second, as a centre, you promise that you will provide your data on a regular basis, not one year or two years after the date, and that you will include all the patients and not leave out any of the cases. This is a simple agreement, and if it has been signed, you can start entering your data.

Dr Bottio: Are the input data subjected to modification or enlargement? If yes, on what basis is a new parameter considered suitable to be collected for the registry?

Mr de By: I am not sure if I understood your question correctly.

Dr Bottio: The data that is entered in the database can be changed over time?

Mr de By: Yes, of course. There is a board consisting of colleagues, cardiologists and cardiac surgeons. If the question comes up, should we add a new data field, yes or no, because of scientific developments or because of innovation, then this question will be answered. If the committee is not sure, then we have a scientific advisory committee which could advise us to do so or not.

Dr Bottio: Are part of the inserted data also the surgical access, the management of the anaesthesiology, and the management of anticoagulation arrangement?

Mr de By: Anaesthesiology no; anticoagulation, yes.

Dr Bottio: And type of access?

Mr de By: Type of?

Dr Bottio: Surgical access, surgical approach.

Mr de By: Not yet, no.

Dr Bottio: To obtain access to the registry data, the centre must be a member?

Mr de By: It is only logic that you become a member. There are no financial requirements. Well, technically it is possible not to be a member and to provide data. Yes, it is.

Dr M. Siepe *(Freiburg, Germany):* From what you saw in the EUROMACS data so far, is there a major difference as compared to the INTERMACS patient's profile or to the outcome? What was your first impression?

Mr de By: Of course, we started EUROMACS because there is a difference between Europe and the United States. In Europe all CE mark devices are allowed on the market and can be entered into the EUROMACS database. In the United States, only FDA-approved devices can be entered into a registry such as INTERMACS. We recently submitted our annual report showing more analyses than I could show today, and we did not see, I cannot use the word significant because we could not have a direct comparison, but we did not see any large difference between United States outcomes and European outcomes.

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