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CLINICAL STUDY

Single centre 12 year experience with durable mechanical circulatory support: comparison with the EUROMACS registry

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ABSTRACT

OBJECTIVES: Mechanical circulatory support is an established therapy in end-stage heart failure. The EUROMACS registry was created to promote research in these patients. The aim of this report was to present our 12 year experience with the durable mechanical circulatory support devices and compare it with the EUROMACS registry.

METHODS: Data from the entire EUROMACS registry from January 2011 to April 2019 were included (4704 implantations in 4410 patients). During the 12 years of our experience, until April 2019,125 mechanical support devices were implanted, in 122 patients. We compare patients´ characteristics, operative data and results with the EUROMACS registry and we report the major complications during the observational period.

RESULTS: Primary end-point (death) occurred in 40 (32.8 %) patients in our cohort during the follow-up period, representing the survival rate 75 %, 68 %, and 58 % for 6, 12, 24 months respectively, which compares favourably with the data, reported by the EUROMACS registry, the survival 66 % and 53 % after 1 and 2 years respectively. Cerebrovascular accident occurred in 7 %, a bleeding event in 32 %, significant infection (driveline) in 78 % and a device malfunction in 13 % of the patients. Forty- three patients underwent a heart transplant with hospital and long-term mortality of 11.6 % and 14 % respectively.

CONCLUSION: Mechanical circulatory support is a valuable therapeutic option with excellent survival rates, nevertheless it is associated with clinically significant complications rates.

The direct comparison between our cohort and the EUROMACS registry showed that early implantation strategy and mini invasive approach may improve survival rates and decrease postoperative complications *(Tab. 3, Fig. 3, Ref. 16)*. Text in PDF *www.elis.sk*

KEY WORDS: durable mechanical circulatory support, EUROMACS registry.

Introduction

Long-term mechanical circulatory support (MCS) is an actively developing field in modern cardiac surgery and cardiology. International registries have been established to enhance scientific insights, to address safety concerns and to implement the standard of care in the patients receiving MCS.

The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) was created for North America in 2005 by the Food and Drug Administration (FDA) and the National Heart, Lung and Blood Institute (NHLB), with mandatory participation of all the centres implanting durable MCS in USA. The 8th annual report published in 2017, summarized implantation experiences involving 22866 MCS devices including 373 total artificial hearts (TAHs) in adult patients between June 2006 and 31 December 2016, making it the largest reported cohort to date (1).

The European Registry for Mechanically Assisted Circulatory Support (EUROMACS) was established in 2009 and at the end of April 2019, EUROMACS comprised 52 centres from 18 countries. Its international internet platform (Dendrite Clinical Systems Ltd) allows data entry for adults and paediatric patients implanted with durable ventricular assist devices (VAD) or TAHs that have been designed for prolonged MCS of longer than 6 months. Up to now, 4400 adult patients are registered and 2 summarizing reports were published (2-5). EUROMACS is a part of the International register for Mechanical Assisted Circulatory Support (IMACS), which collects data globally (6).

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Tab. 1. Demographic data.

Variable	EUROMACS		BRATISLAVA n=122		
	Mean, n,%	CI	Mean, n,%	CI	p
Age (years)	53.4	18–86	49	47–51	0.9669
Female gender	774 (16.99%)	18–83	14 (11%)	6–16	0,1081
Ethnic origin	n=4555				
African American or black	18 (0.4%)	0.3–0.5	0	0	>0.9999
Asian	276 (6.1%)	5.5–6.6	0	0	0.0013
Caucasian	33345 (73.4%)	71.2–74.6	122 (100%)	0	<0.0001
Hawaian or other pacific islander	3 (0.1%)	0.03–0.17	0	0	>0.9999
Unknown	913 (20%)	19–21	0	0	<0.0001
Weight (kg)	81	35–190	83	80–86	0.9934
Body Surface Area (m^2)	1.83	1.29–3.07	2.06	2.01–2.11	0.9339
Body Mass Index (kg/m^2)	25.5	12.9–62.8	26.7	25.9–27.5	0.9877
BNP preoperatively (pg/ml)	n/a	n/a	11239	8384–14094	
Primary diagnosis	n=4212				
Idiopathic dilated CM	958 (22.8%)	21.6–24.2	49 (40.2%)	31.6–48.8	<0.0001
Ischemic CM	1358 (32.2%)	31.8–33.6	44 (36.1%)	27.6–44.6	0.3734
Myocarditis	192 (4.5%)	3.9–5.1	10 (8.2%)	3.4–13	0.0602
Congenital heart disease	42 (1%)	0.7–1.3	1 (0.8%)	0–2.3	0.8454
Dilated cardiomyopathy familiar	94 (2.2%)	1.8–2.6	5 (4.1%)	0.6–0.7	0.1737
Coronary heart disease	438 (10.4%)	9.5–12.3	1 (0.8%)	0–2.3	0.0005
Cancer	9 (0.2%)	0.1–0.3	0	0	>0.9999
Dilated cardiomyopathy post partum	20 (0.5%)	0.3–0.7	0	0	>0.9999
Dilated cardiomyopathy toxic	76 (1.8%)	1.2–2.0	2 (1.6%)	0–3.8	0.8925
Dilated cardiomyopathy viral	25 (0.6%)	0.4–0.8	2 (1.6%)	0–3.8	0.1478
Hypertrophic cardiomyopathy	48 (1.2%)	0.9–1.5	3 (2.5%)	0–5	0.1828
Unknown	848 (20.1%)	18.9–21.3	0	0	<0.0001
Other	104 (2.5%)	2–3	5 (4.1%)	0.6–7.6	0.2572
Comorbidities					
Frequent flyer profile	n/a	n/a	13 (10%)	5–15	
Temporary circulatory support	477 (11%)	10.1–11.9	16 (13%)	7–19	0.5393
Haemodialysis	130 (0.3%)	0.25–0.35	2 (1.6%)	0–3.8	0.3592
ICD device in place	n/a	n/a	99 (81%)	74–88	
Diabetes mellitus	1056 (25%)	24–26	23 (18%)	11–25	0.1174
Insulin dependent	286 (7%)	6.3–7.7	11 (47%)	27–67	0.3373
Cerebrovascular event	n/a	n/a	18 (14%)	8–20	
Symptomatic PAD	n/a	n/a	1 (0.8%)	0–2.3	
Carotid artery disease	n/a	n/a	1 (0.8%)	0–2.3	
Medical therapy prior to implant					
Aspirin	1849 (44%)	43–45	34 (28%)	20–36	0.0004
ACE inhibitor	1573 (37%)	36–38	47 (39%)	31–47	0.7908
ARB	568 (13%)	12–14	14 (11%)	6–16	0.521
b-blocker	1768 (42%)	41–43	81 (68%)	60–76	<0.0001
Aldosterone antagonist	2190 (52%)	21–53	100 (84%)	78–90	<0.0001
iv inotropes immediately prior to implant	n/a	n/a	86 (70%)	78–94	
Current device therapy	n=4655				
Bridge to recovery	103 (2%)	1.6–2.4	0	0	0.1147
Bridge to candidancy	1502 (33%)	32–34	38 (31%)	23–39	0.7929
Bridge to transplant	1647 (36%)	35–37	70 (57%)	49–65	<0.0001
Destination therapy	753 (17%)	16–18	9 (7%)	3–11	0.0088
Rescue therapy	303 (7%)	6.3–7.7	5 (4%)	0.5–7.5	0.2845
Other and unknown	247 (5%)	0.4–5.6	0	0	0.0028

CM = cardiomyopathy, ICD = implantable cardioverter defibrillator, PAD = peripheral artery disease, ACE = angiotensin converting enzyme, ARB = angiotensin receptor blocker, n/a = non-available, data not sent by EUROMACS, CI = confidence interval

Our Institute participates in the EUROMACS registry, and the aim of this report was to present our 12 year experience with the durable mechanical circulatory support devices and compare it with the EUROMACS registry.

Patients and methods

EUROMACS registry

In EUROMACS, the anonymized patient baseline, follow-up and adverse events are transmitted from participating sites using

a secure, web-based system. All centres agreed that their data be made available for scientific analyses.

Study population

Data from the entire EUROMACS registry with the implantation date from January 2011 to April 2019 were included in this study, forming a cohort of 4704 implantations in 4410 patients. During the 12 years of experience in our institute until April 2019,125 MCS, mainly VAD and TAHs were implanted, in 122 patients. Our institute is a member of the EUROMACS registry since the year 2019, and up to February 2019, data to the EUROMACS registry were submitted retrospectively. Data from our centre is not included in the overall EUROMACS data analysed, and these are two independent patient cohorts. The annual mean number of LVAD implantations was 11.5 (2–21), and in terms of case number our centre belongs to the group of intermediate size centres that contribute data to the EUROMACS registry.

We used patients´ charts to collect demographic, operative and postoperative data. Death or serious adverse events (major infection, major bleeding, neurological complications-cerebrovascular accident and device malfunction) were all reported in the database. Also, minor incidents (cardiac arrhythmia, pericardial fluid collection, haemolysis, hepatic dysfunction, hypertension, psychiatric episode, renal dysfunction, respiratory failure, right heart failure, arterial non-CNS thromboembolism, wound dehiscence, venous thromboembolism and myocardial infarction), were also reported in the database.

In this report, we compare patients´ characteristics, operative data and results of a single centre (National Institute of Cardiovascular Diseases, Bratislava, Slovakia) with the entire EUROMACS registry and we report the major complications during the observational period.

Both, the EUROMACS registry and our cohort are comparable in terms of age, gender, primary diagnosis, INTERMACS level and preoperative hemodynamic.

Written informed consent, and an approval of the ethics committee were obtained for the submission of clinical data to the EUROMACS registry from all our patients, as well as for the publication of this report.

Primary and secondary end-points

All-cause mortality was the primary end-point of this study. Secondary end-points were serious adverse events.

Major infection was defined as clinically relevant if antibiotic administration or surgical intervention was required.

Any bleeding into a critical organ (cerebral, pericardial), irrespective of its magnitude or of bleeding in any other location, that required transfusion of at least two units of packed red blood cells or other intervention was considered major.

Tab. 2. Imaging and haemodynamic data.

Variable	EUROMACS		BRATISLAVA n=122		
	Mean, n, %	CI	Mean, n, %	CI	p
Left ventricular systolic ejection fraction	n=3166				
Very severely reduced (LVEF≤19%)	1514 (48%)	47–49	100 (81%)	75–87	<0.0001
Severely reduced (LVEF=20–29%)	1396 (44%)	43–45	21 (17%)	11–23	<0.0001
Moderately reduced (LVEF=30–39%)	194 (6%)	5.2–6.8	1 (0.8%)	0–2.3	0.0149
Mildly reduced (LVEF=40–50%)	35 (1.2%)	0.9–1.5	0	0	0.6396
>50%	27 (0.8%)	0.5–1.1	0	0	0.6236
New York Functional Class					
Class I	n/a	n/a	0	0	
Class II	n/a	n/a	0	0	
Class III	n/a	n/a	9 (7%)	3–11	
Class IV	n/a	n/a	113 (93%)	88–98	
INTERMACS level	n=4181				
1 (cardiogenic shock)	668 (16%)	15–17	11 (9%)	4–14	0.0376
2 (progressive decline)	1370 (33%)	32–34	39 (32%)	24–40	0.8527
3 (Inotrope-dependent)	1081 (26%)	25–27	36 (39%)	21–37	0.3643
4 (resting symptoms)	721 (17%)	16–18	22 (18%)	12–14	0.8204
5 (exertion intolerant)	159 (3.8%)	3.3–4.3	5 (4%)	1.7	0.8666
6 (exertion limited)	57 (1.4%)	1–1.6	3 (2.5%)	0–5	0.309
7 (advanced NYHA Class III)	135 (3.6%)	3.1–4.1	6 (5%)	2–8	0.3016
Haemodynamics					
Heart rate	86	40–218	84	82–86	0.994
Systolic blood pressure (mmHg)	100	33–192	100	98–102	>0.9999
PA systolic blood pressure (mmHg)	65	10–139	64	60–68	0.9959
PCWP (mmHg)	n/a	n/a	30	29–31	
Pulmonary vascular resistance (dyn.s/cm^5)	n/a	n/a	436	354–518	
Cardiac index (l/min/m^2)	2.04	0.52–3.82	1.7	1.55–1.85	0.8871
TAPSE (mm)	15	1–197	13	12–14	0.9945

LVEF = left ventricular ejection fraction, NYHA = New York Heart Association, PA = pulmonary artery, PCWP = pulmonary capillary wedge pressure, TAPSE = tricuspid annular plane systolic excursion, n/a = non-available, data not sent by EUROMACS, CI = confidence interval

Tab. 3. Operative and postoperative data.

Variable	EUROMACS n=4824		BRATISLAVA n=122		
	Mean, n, %	CI	Mean, n,%	CI	p
CPB time (min)	114	6–612	91	85–97	0.9811
Off–pump	370 (9.6%)	n/a	0	0	
Device type					
LVAD	3111 (64%)	63–65	112 (91%)	87–95	<0.0001
LVAD off-pump	781 (16%)	15–17	0	0	<0.0001
BiVAD	162 (3%)	2.5–3.5	0	0	0.0343
BiVAD off-pump	4 (0.08%)	0.07–0.09	0	0	>0.9999
LVAD/RVAD	144 (2.9%)	2.5–3.3	6 (5%)	2–8	0.2189
LVAD/RVAD off-pump	21 (0.4%)	0.3–0.5	0	0	>0.9999
RVAD	322 (6%)	5.3–6.7	3 (2.5%)	0–5	0.0634
RVAD off-pump	95 (1.9%)	1.6–2.2	0	0	0.1755
TAH	184 (3.8%)	3.3–4.3	4 (3%)	0.6	0.76
ICU/CCU stay	22	0–830	19	15–23	0.9982
Step-down care stay	n/a	n/a	15	14–16	

CPB = cardiopulmonary bypass, LVAD = left ventricular assist device, BiVAD = biventricular assist device, RVAD = right ventricular assist device, TAH = total artificial heart, ICU = intensive care unit, CCU = cardiac care unit

Loss of function of any vital part of the implanted devices mechanical system (pump, controller, cable) posing a threat to the patients´ health or life, requiring change in management or exchange was interpreted as device malfunction.

Cerebrovascular accident was defined as any transient or permanent neurological deficit in clinical or imaging studies believed to be caused by a central nervous abnormality (haemorrhagic or ischemic stroke, transient ischemic accident, epileptic event).

Statistical analysis

All variables were expressed as median, 95 % confidence intervals, and qualitative variables as numbers and percentages. Kaplan–Meier estimates of cumulative probabilities were calculated for the primary (death) and secondary end-points using the entire EUROMACS registry and the Bratislava cohort. The Kaplan–Meier curves include 95 % confidence intervals. Some EUROMACS data are missing from the tables because it was not possible to retrieve them from the database. Numeric variables were analysed with Student´s t-test. Chi square test or Fisher´s exact test were performed for categorical variables. Statistical significance was considered for $p < 0.05$.

Results

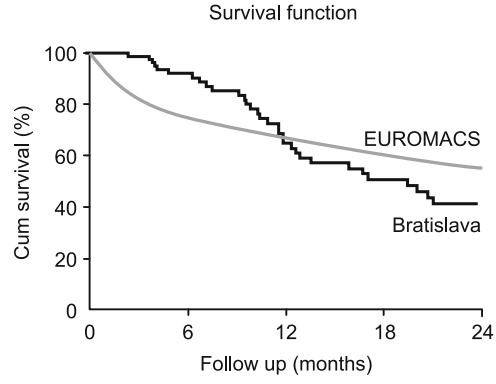
Baseline characteristics

The baseline characteristics of the patients in both groups are presented in Tables 1 and 2. At the time of analysis, the EUROMACS registry included 4655 implantations, of which 125 patients were recruited from Bratislava. The mean age in our cohort was 49 years , while in the EUROMACS registry it was 53 years Fewer female patients and patients with larger body surface area were observed in our cohort, 11 % vs 17 % and 2.06 m^2 vs 1.82 m^2 respectively. Body mass index of the patients in both cohorts was almost similar.

In our cohort, idiopathic dilated cardiomyopathy, followed by ischemic cardiomyopathy were the leading causes for heart failure, (40.2 % vs 22.8 %, $p < 0.0001$), while in the EUROMACS registry the leading cause for heart failure was ischemic cardiomyopathy followed by idiopathic dilated cardiomyopathy (32.2 % vs 36.1 %, $p = 0.3734$).

New York Heart Association class (NYHA) and INTERMACS profile were the parameters used to assess the optimal timing for implantation. In our cohort, 93 % of the patients were in NYHA class IV. Concerning the INTERMACS profile of the patients, data were comparable. In ours and EUROMACS cohort, most patients were considered as level 2 (progressive decline) (32 % vs 33 %, $p = 0.8527$) or level 3 (stable, but inotropic dependent) (39 % vs 26 %, $p = 0.3643$). Finally, in the EUROMACS registry, more patients were in INTERMACS level 1 (16 % vs 9 %, $p = 0.0376$).

Implantation strategies appear to differ between the cohorts. VADs were used as bridge-to-transplant (36 %), bridge-to-candidacy (33 %), bridge to recovery (2 %), destination therapy (17 %),



Number at risk					
Months	0	6	12	18	24
Bratislava	110	56	36	23	16
EUROMACS	2321	1384	1016	721	498

Fig. 1. Kaplan–Meier survival analysis of the Bratislava cohort compared with the entire EUROMACS cohort.

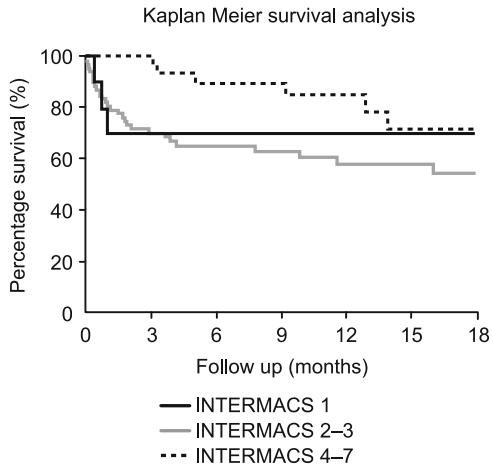


Fig. 2. Kaplan–Meier survival analysis of the Bratislava cohort dependent on the INTERMACS status at the time of implantation.

rescue therapy (7 %) and other causes (5 %) in the EUROMACS cohort, while in our cohort, they were used as bridge-to-transplant (57 %, $p < 0.0001$), bridge-to-candidacy (31 % $p = 0.7929$), destination or rescue therapy in 7 % ($p = 0.0088$) and 4 % ($p = 0.2845$) respectively.

Significant differences in medical therapy prior to VAD implantation were observed. Beta-blockade and aldosterone antagonist therapy was less used in the EUROMACS cohort (42 % vs 68 %, $p < 0.0001$ and 52 % vs 84 %, $p < 0.0001$ respectively), while aspirin use was more in the EUROMACS cohort (44 % vs 28 %, $p = 0.0004$) and corresponded with the higher number of patients with ischemic cardiomyopathy.

Operative and postoperative data

In our cohort, cardiopulmonary bypass was used for the VAD implantation, and the mean time was 23 minutes less compared to the EUROMACS cohort. No difference in the use of left ventricular assist devices and TAHs between the EUROMACS and our cohort was observed (80 % vs 91 %, 3.8 % vs 3 %) respectively. The stay in the intensive care unit was similar in both cohorts (Tab. 3).

Survival analysis

Kaplan–Meier estimates the survival in our cohort at 6 months 75 % (CI 65.7–82.4), at 12 months 68 % (CI 57.8–77.3), at 18 months 61 % (CI 49.2–72.1), at 2 years 58 % (CI 44.9–69.8) and at 3 years 43 % (CI 18–67.8) (Fig. 1). During the follow-up period, 43 patients underwent heart transplant with a hospital and long-term mortality (April 2019) of 11.6 % (5 patients) and 14 % (6 patients) respectively. The median waiting period time was 470.8 (53–1352) days.

Kaplan–Meier analysis of our cohort, grouped by INTERMACS level prior to implantation, demonstrated a correlation between INTERMACS level and both early (< 30 days) and long-term survival. INTERMACS level 1 and 2 exhibited the high early mortality, and might stabilization afterwards, but the number of the patients at risk is small. INTERMACS levels 4–7 have better early and long-term survival (Fig. 2).

Follow-up

The median follow-up and MCS support time was 14 (2–66) months.

Complications in the Bratislava cohort

Freedom from device malfunction at 2 years was 96 % (CI 87.9–98.7), and after the second year fell to 88 % (CI 62.6–96.9), resulting in 0.11 events per patient year. The most frequent device malfunction was device thrombosis that was treated mainly conservatively, followed by controller, which was replaced. One patient had pump exchange because he denied anticoagulation treatment.

Most infections occurred during the early period. The most frequent infection was, driveline infection (78 % of the patients), followed by bronchopneumonia. Two patients had positive blood cultures, most probably due to device-related infection, and both patients were treated successfully conservatively. Freedom from infection at first, second and third year was 94 % (CI 83.8–98.2), 77 % (CI 56.7–89.5) and 54 % (CI 26.6–75.3) respectively, resulting in 0.22 events per patient year. No patient underwent the pump exchange due to infection.

Freedom from neurologic complications during follow-up was 97.5 % (CI 91.6–99.5), resulting in 0.06 events per patient year. Intracranial bleeding was observed in 5 patients, and stroke occurred in 4 patients. Two patients died as the result of the intracranial bleeding.

In our cohort, the incidence of late bleeding complications during the follow-up period was low and was observed in 4 patients, resulting in 0.02 events per patient year. Gastrointestinal bleeding occurred in 3 patients. Bleeding events of the central nervous system are discussed separately. On the other hand, 32 % of the patients had re-exploration due to postoperative bleeding, representing 10.9 events per 100 patients-month during the first three months after a device implantation. In our cohort, we observed a significant decline in the post-opertative bleeding complications after the year 2014. At that that time, we introduced the mini invasive approach through upper mini-sternotomy and left mini-thoracotomy. There was a decline from 48.9 % (22 patients from 45) to 18.9 % (17 patients from 97).

The corresponding Kaplan-Meier estimates are depicted in Figure 3.

Discussion

Survival

Primary end-point (death) occurred in 40 (32.8 %) of the patients in our cohort over the entire period of follow-up, representing the survival rate of 75 %, 68 %, and 58 % for 6, 12, 24 months respectively. This compares favourably with the data of the 2nd EUROMACS annual report, which reported the survival of 66 % after 1 year and 53 % after 2 years. On contrary, data from the 8th INTERMACS annual report (1) and the 2nd IMACS annual report (6) showed 1-and 2-year survival of 81 %, 70 % and 80 % and 70 %

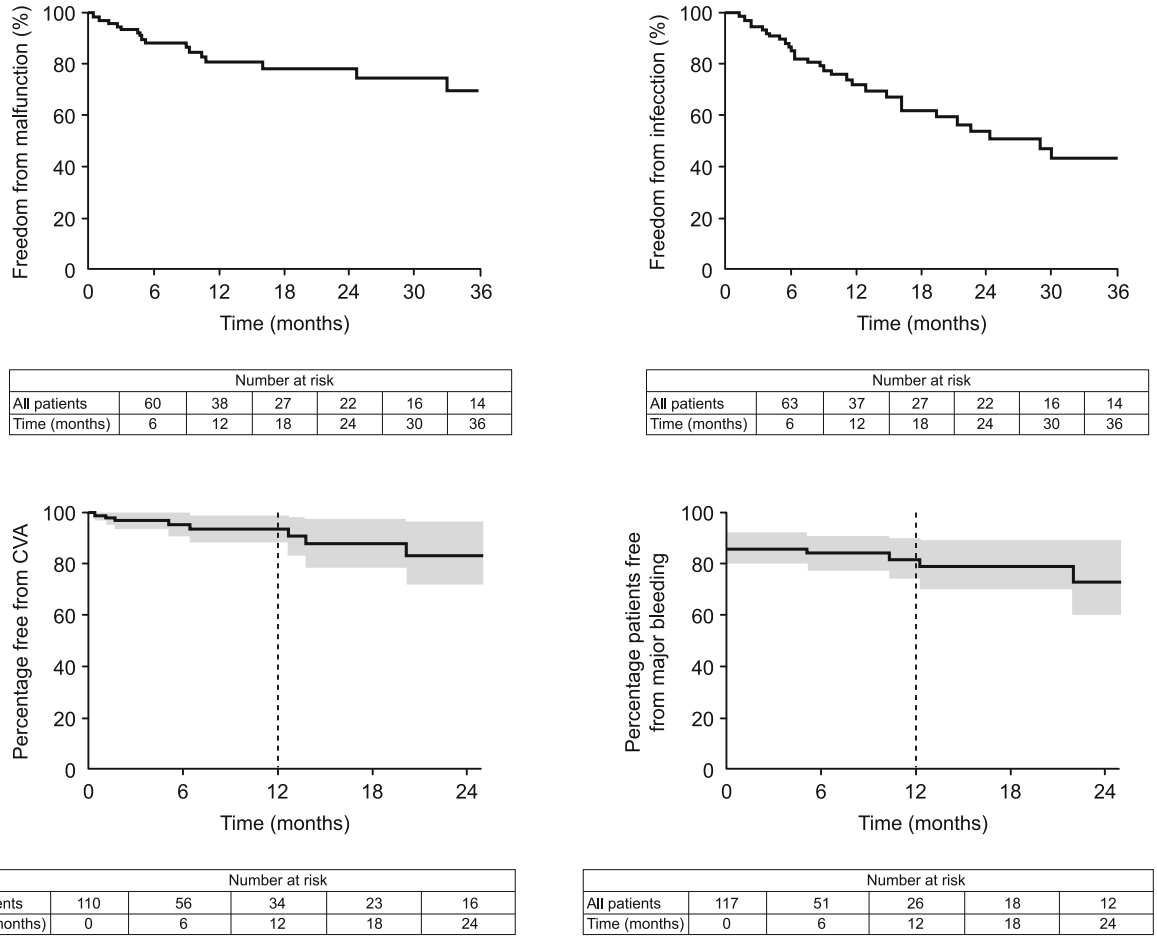


Fig. 3. Time of first event analysis of (A) device malfunction, (B) clinically significant infections, (C) cerebrovascular accident (CVA), and (D) major bleeding of the Bratislava cohort.

respectively. In our cohort, an improvement was observed also in the postoperative results in terms ICU stay after the introduction of the minimal invasive approach in 2014. Since then, 42 patients had a VAD implantation with this procedure. Favourable results with the use of the minimal invasive approach in VAD implantation are also reported by other authors (7, 8).

Moreover, although, in our institute we are in favour of the early implantation strategy in relatively stable patients, which may improve survival rates, our data tend to indicate that our patients were generally of more advanced INTERMACS stage, with severely reduced LVEF (81 % patients with LVEF less than 20 %). This is related to disease pathology and status of the patients at initial presentation.

Complications

During the follow-up period in our cohort, the most prevalent complication was infection, and according to the most recent INTERMACS report (1), it was still the fourth most common cause of death within 1 year after implant. In our cohort, 78 % of the patients had driveline infections. Driveline infections increased the mortality (9), but with proper measures like earlier detection, frequent dressing changes, local antiseptics, prolonged or lifelong antibiotics, surgical revision and emergency transplantation, the patients might have a favourable outcome (10). Finally, no patient underwent the pump exchange due to infection. Data from the 2nd EUROMACS annual report (3) showed that the incidence of infections at 3 months was 5.49 events per 100 patients per year. On contrary, data from the IMACS registry showed that the incidence of infections at 3 months was 3.51 events per 100 patients per year (6).

The recently reported incidence of cerebrovascular accident after VAD implantation in the IMACS registry was 19 %. In the recently published comparison of neurological outcomes between the recipients of HeartWare (Medtronic) and HeartMate II (Abbott), complications were reported in 19 % for 0.44 median years of follow-up and 16 % for 0.95 median years of follow-up. Advancing age was found to be a risk factor for any adverse neurologic outcome (12). Other risk factors for cerebrovascular accident included international normalized ratio (INR) level, aortic cross clamping, stroke in the past and postoperative infection

(13). In the 2nd EUROMACS annual report (3), the incidence of the neurologic complications at 3 months was reported to be 1.87 events per 100 patients per month. In our cohort, the incidence of neurologic complications was relatively low, 7 % of the patients, resulting in 0.06 events per patient year.

The incidence of pump malfunction in our cohort was 13 %, resulting in 0.11 events per patient year, and the main reason was pump thrombosis. During the whole follow-up period, only one patient needed the pump exchange due to thrombosis and the rest of the patients were successfully treated conservatively. Moreover, two patients had the control unit replacement due to malfunction, and in one patient with TAH, a mechanical malfunction of the Freedom driver system controller due to mechanical damage appeared, which was managed successfully by the controller change. Data from the 2nd EUROMACS annual report (3) showed that the incidence of pump malfunction at 3 months was 14.7 %, resulting in 2.88 events per 100 patient months. According to the MOMENTUM 3 trial (14), the incidence of pump thrombosis was lower in HeartMate 3 (Abbott) compared to the HeartMate II (Abbott). In our cohort, during the follow-up in patients with HeartMate 3 (Abbott) VAD we did not observe any pump thrombosis.

Data from our cohort showed that 32 % of the patients, resulting in 10.9 events per 100 patients-months during the first 3 months, had re-exploration due to severe postoperative bleeding. There was a significant decline in postoperative bleeding complications after the year 2014 and the introduction of the mini invasive approach through upper mini-sternotomy and left mini-thoracotomy, from 48.9 % to 18.9 % (0.03 events per 100 patients-months Vs 0.013 events per 100 patients-months). The incidence of postoperative bleeding in the EUROMACS, INTERMACS and IMACS registries at 3 months were, 6.45 events per 100 patients-month, 16.24 events per 100 patients-months, and 35 % of the patients, resulting in 13.78 events per 100 patients-months respectively (1, 3, 6). On contrary, in our cohort, we observed a lower incidence of post-operative bleeding complications compared to the INTERMACS, IMACS and EUROMACS registries. The introduction of the mini invasive approach through the upper mini-sternotomy and left mini-thoracotomy, had a significant role in this incidence decline of the postoperative bleeding complication. Similar results with the use of the minimal invasive approach in VAD implantation are also reported by other authors (7, 8).

The standard medical therapy consists of acetylsalicylic acid 100 mg daily and warfarin with target INR 2-3.5. The patients were all well educated about warfarin treatment, they had frequent INR controls and the dose was adjusted appropriately, they all used CoaguCheckXS (Roche Diagnostics, GmbH), and the INR level was kept on the lower therapeutic level. All these factors might contribute to the low incidence of bleeding complications in our cohort. Moreover, gastrointestinal bleeding was the most prevalent bleeding complication after continuous flow VAD implantation as the result of the creation of arteriovenous malformations and acquired von Willebrand factor deficiency, and published data presented up to 26.6 % of the patients had this complication (15, 16). In the EUROMACS registry (3), the incidence of gastrointestinal bleeding events after 3 months from implantation was 1.86 events per 100 patients-month. In the eighth annual INTERMACS report (1), the incidence of gastrointestinal bleeding reported was 7.09 events per 100 patients-month axial flow pumps and 5.26 per 100 patients –months for centrifugal flow pumps. The longer the mechanical circulatory support, the more frequent were the bleeding complications. In our cohort, the mean circulatory support time was 426 days and 3 patients had a gastrointestinal bleeding, with an incidence of 0.02 events per patient per year.

Conclusion

We conclude that international registries provide valuable data, which may in turn, lead to benchmarking new insights, approaches and discussions. Consequently, this will lead to quality improvement. Comparing local with international data is clearly feasible and comparison of the single centre experience with the EUROMACS database generates interesting observations and shows differences in the approaches and outcomes of the MCS therapy. In our institute, we are in favour of the early implantation strategy in relatively stable patients, which may improve the survival rates. However, the rate of complications after MCS implantation remains considerable. The take home message from this direct comparison between our cohort and the EUROMACS registry is that early implantation strategy and mini invasive approach may improve the survival rates and decrease postoperative complications such as postoperative bleeding.

Limitations

This is mainly a retrospective report and some data may not be complete. Also, some data could not be provided by the EUROMACS registry. The primary diagnosis in 20 % of the patients, as well as the NYHA clinical status, PCWP and pulmonary vascular resistance for all EUROMACS patients is not known. This would seem to demonstrate some of the limitation of registry data. On the other hand, the missing details do not significantly reduce the importance of being able to analyse a large number of cases, especially for hard outcomes like mortality. Moreover, in our centre, we do not perform off-pump assist device implantation, so we do not have any data to compare with the EUROMACS registry. Finally, in our cohort, only 4 patients received a TAH, 6 a BiVAD and 3 an RVAD, and in this way bias may be caused by the larger number of BiVAD, RVAD and TAH patients in the EUROMACS registry.

The EUROMACS 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.

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