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Propensity score-based analysis of long-term follow-up in patients supported with durable centrifugal left ventricular assist devices: the EUROMACS analysis

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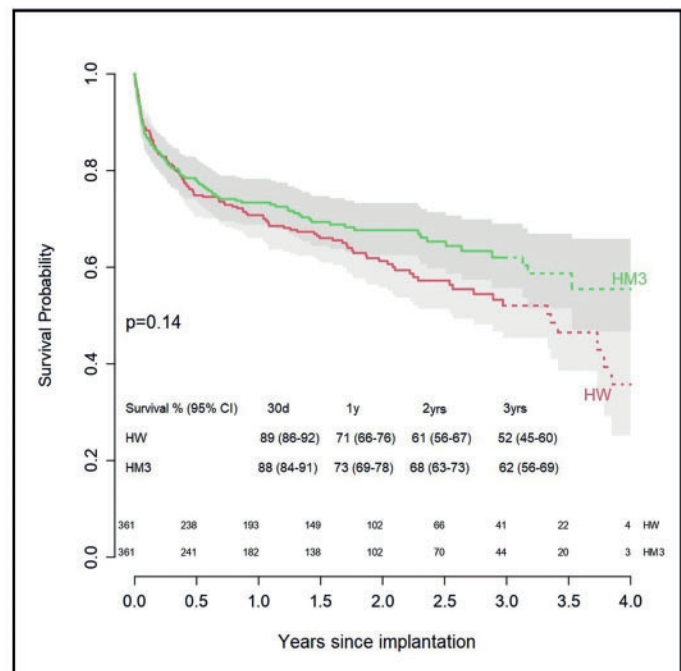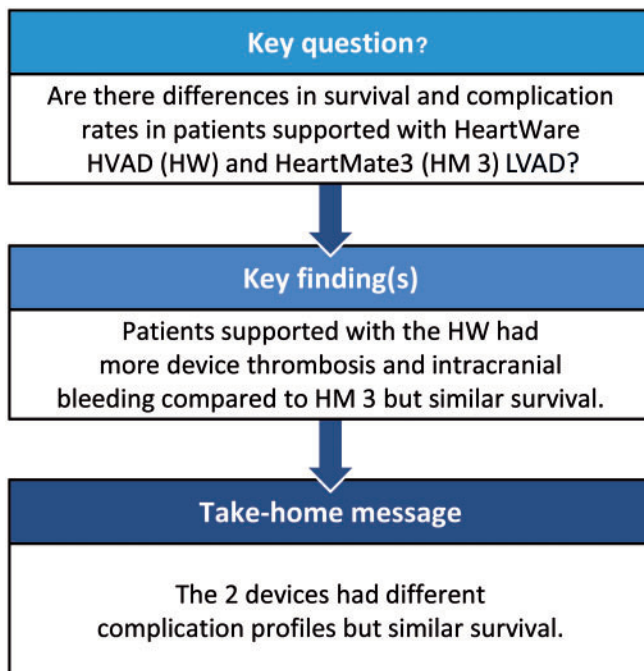
Abstract

OBJECTIVES: The HeartWare HVAD (HW) and the HeartMate3 (HM3) are presently the most commonly used continuous-flow left ventricular assist devices worldwide. We compared the outcomes of patients supported with either of these 2 devices based on data from the EUROMACS (European Registry for Patients with Mechanical Circulatory Support).

METHODS: A retrospective analysis of the survival and complications profile in propensity score-matched adult patients enrolled in the EUROMACS between 01 January 2016 and 01 September 2020 and supported with either an HW or HM3. Matching included demographic parameters, severity of cardiogenic shock and risk-modifying end-organ parameters that impact long-term survival. Survival on device and major postoperative adverse events were analysed.

RESULTS: Following 1:1 propensity score matching, each group consisted of 361 patients. Patients were well balanced (<0.1 standardized mean difference). The median follow-up was similar in both groups [396 (interquartile range (IQR) 112–771) days for HW and 376 (IQR 100–816) days for HM3]. The 2-year survival was similar in both groups [HW: 61% 95% confidence interval (CI) (56–67%) vs HM3: 68% 95% CI (63–73%) (stratified hazard ratio for mortality: 1.13 95% CI (0.83–1.54), $P = 0.435$].The cumulative incidence for combined major adverse events and unexpected readmissions was similar in both groups [subdistribution hazard ratio (SHR) 1.0 (0.84–1.21), $P = 0.96$]. Patients in the HW group demonstrated a higher risk of device malfunction [SHR 2.44 (1.45–3.71), $P < 0.001$], neurological dysfunction [SHR 1.29 (1.02–1.61), $P = 0.032$] and intracranial bleeding [SHR 1.76 (1.13–2.70), $P = 0.012$].

CONCLUSIONS: Mid-term survival in both groups was similar in a propensity-matched analysis. The risk of device malfunction, neurological dysfunction and intracranial bleeding was significantly higher in HW patients.

Keywords: Left ventricular assist device • EUROMACS • HeartWare • HeartMate3

ABBREVIATIONS

CI	Confidence interval
EUROMACS	European Registry for Patients with Mechanical Circulatory Support
HM3	HeartMate3
HR	Hazard ratio
HW	HeartWare HVAD
INTERMACS	Interagency Registry of Mechanically Assisted Circulatory Support
IQR	Interquartile range
LVAD	Left ventricular assist device
SD	Standard deviation
SHR	Subdistribution hazard ratio
VAD	Ventricular assist device

INTRODUCTION

Modern durable left ventricular assist devices (LVADs) are part of the standard care in patients with end-stage heart failure with reduced ejection fraction [1]. Among the commercially available continuous-flow LVADs, 2 devices are most commonly used worldwide: the HeartWare HVAD (HW; Medtronic, Minneapolis, MN, USA), implanted in >18 000 patients, and HeartMate3 (HM3; Abbott, Chicago, IL, USA), in >13 000 patients (as of September 2020; numbers provided by device manufacturers).

Few retrospective studies based on single-centre experience with a small number of patients and a short follow-up [2–4] that have compared these 2 devices have been published. The studies demonstrated a different complication profile but a similar short-term survival.

The largest published retrospective analysis based on data from the INTERMACS (Interagency Registry of Mechanically Assisted Circulatory Support) suggested a similar survival for the first year, but a more favourable complication profile and better survival in patients supported with the HM3 LVAD beyond the

first year of support [5]. However, this study was criticized with regard to the quality of the statistical analysis and the interpretation of the data [6, 7]. Patients supported with the HW as presented 2019 in the INTERMACS annual report were sicker and had comorbidities that had a stronger impact on prognosis. All of these important issues were not considered in the analysis.

The aim of the study presented here, which is based on data from EUROMACS (European Registry for Patients with Mechanical Circulatory Support), was to perform a retrospective analysis of the complication profile and intermediate-term survival of propensity score-matched patients supported with HW and HM3 using optimal statistical tools.

METHODS

The study was designed as a multicentre register based on an observational, retrospective analysis of propensity score-matched patients. The complications, as defined in the EUROMACS database according to the INTERMACS definitions, were recorded and followed up [1, 8]. All adult patients (≥18) from the EUROMACS database who received a primary HW or HM3 LVAD between 1 January 2016 and 1 September 2020 were included in the analysis (Fig. 1). Patients with primary biventricular, implantable VADs were excluded from the study. The analysis included pre- and intraoperative data, as well as postoperative complications and outcomes recorded during the follow-up [9].

Surgical procedures

The LVAD implantation, postoperative management including blood products and factors administration was performed according to institutional protocols, which differ between participating institutions. Different implantation techniques with regard to the circulatory support technique including cardiopulmonary bypass, veno-arterial extracorporeal life support as well as an off-pump approach were reported [3, 10]. Surgical access was performed via a full median sternotomy, left lateral thoracotomy or
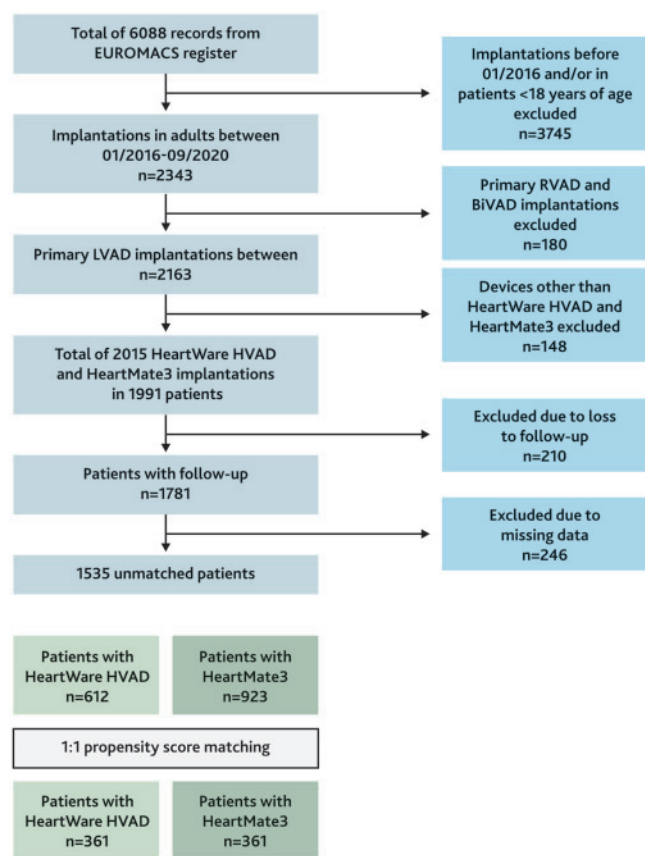
Figure 1: Flow-chart patient selection. BiVAD: biventricular assist device; EUROMACS: European Registry for Patients with Mechanical Circulatory Support; LVAD: left ventricular assist device; RVAD: right ventricular assist device.

using a minimally invasive approach, including bilateral thoracotomy or a combination of left anterolateral thoracotomy and upper partial sternotomy [11, 12]. In the case of severe right ventricular failure after LVAD implantation, temporary right ventricular support was established using a right ventricular assist device (with or without an oxygenator) as well as veno-arterial extracorporeal life support.

Statistical analysis

For baseline characteristics, continuous variables are summarized as mean and standard deviation (SD), or as median and interquartile range (IQR) (25th quantile–75th quantile) in the case of skewed data. For categorical variables, numbers and percentages are reported. To account for imbalances in the HW and HM3 patient groups, a propensity score was calculated by logistic regression. Parameters including demographics, severity of cardiogenic shock, organ dysfunction and risk-modifying end-organ parameters that impact long-term survival were used for propensity score matching and included age, gender, body mass index, ventilation on intensive care unit, INTERMACS profile, cardiac arrest before implantation, renal replacement therapy, previous cardiac surgery, preoperative support with intra-aortic balloon pump, extracorporeal life support or other short-term mechanical circulatory support device. Relevant preoperative laboratory parameters included haemoglobin, international normalized ratio, white blood cell count, C-reactive protein, platelet count and glutamic-

oxaloacetic transaminase; 1:1 propensity score matching using the nearest-neighbour algorithm without replacement and a caliper matching (0.1 SD of the propensity score) was performed. The balance was verified by means of the standardized mean difference (Table 1) and is presented graphically in a balance plot (Fig. 2).

Survival was evaluated by Kaplan–Meier estimates with 95% confidence intervals (CIs) censoring for transplantation, weaning and ongoing support. The risk of all-cause mortality in the HW group compared to the HM3 group was estimated using a stratified Cox regression.

Competing risk analyses were used to evaluate the incidence of adverse events with explant due to all-cause death, weaning or heart transplantation as competing outcomes. In case of recurrent adverse events, the first event in a patient was analysed. Subdistribution hazard ratios (SHRs) were calculated using clustered Fine–Gray models [13].

Cumulative incidence functions are presented with explant as a competing outcome. The difference in continuous variables between patient groups was analysed using the exact Wilcoxon signed-rank test, and the McNemar test was used for categorical variables. *E*-values for the point estimator and the confidence limit nearest to zero were calculated to assess the impact of unmeasured confounding on a risk ratio scale, with high *E*-values indicating a robust treatment–outcome association [9]. We assumed a *P*-value of <0.05 as the threshold for statistical significance. The analysis was exploratory in nature.

R version 4.0.2 [R development Core team (2020). R: A Language and Environment for Statistical Computing] was used for all statistical analysis [14]. The packages tidyverse [15], MatchIt, cmprsk [16] and cobalt [17] were used.

RESULTS

Patient characteristics

Six hundred and twelve HW and 923 HM3 adult patients supported with an isolated LVAD during the study period were included in the analysis. Patients were matched with a 1:1 propensity score; this resulted in 361 patients in each group (Fig. 1).

Preoperative baseline data in unmatched groups are shown in Supplementary Material, Table S1. Data after 1:1 propensity matching are shown in Table 1.

Postoperative outcomes

Immediate postoperative outcomes are shown in Table 1. There were no differences except for a longer operating time in HM3 patients.

Follow-up

The median follow-up in the matched cohort was 396 days (IQR 112–771) in HW patients and 376 days (IQR 100–816) in HM3 patients, resulting in cumulatively 486.6 and 476.1 patient-years, respectively. The cumulative incidence rates during the postoperative follow-up, SHRs with CIs and adjusted *P*-values for important clinical complications in matched cohorts are shown in Table 2.

A Kaplan–Meier analysis of survival in matched patients showed no differences in mid-term follow-up (Fig. 3). In particular, the 2-year survival was 61% [95% CI (56–67%)] in HW and

Table 1: Patient demographics and postoperative outcomes in matched cohorts

Parameters	HW	HM3	SMD
Number	361	361	NA
Gender, *n* (%)			
Female	50 (13.9)	52 (14.4)	0.016
Male	311 (86.1)	309 (85.6)	
Age (years)	55.49 ± 11.6	56.13 ± 11.6	0.06
BMI (kg/m^2)	26.61 ± 5.46	26.91 ± 4.96	0.06
WBC (10^3/μl)	8.20 (6.60–10.8)	8.20 (6.5–10.9)	0.026
Platelet (10^3/μl)	196 (143–251)	194 (148–257)	0.003
Haemoglobin (g/l)	11.5 (10–13.4)	11.5 (9.9–13.1)	0.06
INR	1.30 (1.1–1.6)	1.28 (1.11–1.55)	0.08
CRP (mg/dl)	1.92 (0.6–5.8)	2.14 (0.7–5.6)	0.07
IABP, *n* (%)			
No	337 (93.4)	339 (93.9)	0.023
Yes	24 (6.6)	22 (6.1)	
ECLS, *n* (%)			
No	312 (86.4)	308 (85.3)	0.032
Yes	49 (13.6)	53 (14.7)	
INTERMACS profile, *n* (%)			
1	50 (13.9)	55 (15.2)	0.046
2	115 (31.9)	93 (25.8)	0.14
≥3	196 (54.3)	213 (59.0)	0.10
Previous cardiac arrest, *n* (%)			
No	339 (94)	338 (93.6)	0.011
Yes	22 (6.1)	23 (6.4)	
Previous cardiac surgery, *n* (%)			
No	327 (90.6)	323 (89.5)	0.037
Yes	34 (9.4)	38 (10.5)	
Invasive ventilation before surgery, *n* (%)			
No	307 (85.0)	304 (84.2)	0.023
Yes	54 (15.0)	57 (15.8)	
Dialysis/ultrafiltration, *n* (%)			
No	325 (90.0)	323 (89.5)	0.018
Yes	36 (10.0)	38 (10.5)	
Propensity score	0.57 ± 0.13	0.59 ± 0.13	0.08
Intraoperative parameters, *n* (%)			
Concomitant procedures	55 (15.2)	82 (22.7)	0.18
Valve surgery	45 (12.5)	70 (19.4)	0.25
Aortic valve surgery	13 (3.6)	11 (3)	NA
Mitral valve surgery	3 (0.8)	6 (1.6)	NA
Tricuspid valve surgery	25 (7)	39 (10.8)	NA
Multivalve surgery	4 (1.1)	14 (3.9)	NA
Other concomitant procedure[a]	10 (2.8)	12 (3.3)	NA
Postoperative outcomes			
Parameter	HW	HM3	*P*-value
CPB time (min)	76 (52–113)	85 (60–115.5)	0.11
Surgery time (min)	211 (170–270)	241 (180–327)	<0.001
Ventilation time (h)	30 (14–283)	36 (17–192.8)	0.84
ICU stay (days)	11 (5–22)	12 (5–25)	0.88
Stepdown care stay (days)	18 (9–27)	20 (9–27)	0.36
INR (at discharge)	2.39 (1.98–2.73)	2.29 (2.00–2.70)	0.72

Data presented as number and percentage, median and interquartile range 25th–75th or as mean and standard deviation.

[a]Other concomitant procedures include atrial/ventricular septal defect closure, coronary artery bypass grafting.

BMI: body mass index; CPB: cardiopulmonary bypass; CRP: C-reactive protein; ECLS: extracorporeal life support (for preoperative support); HM3: HeartMate3; HW: HeartWare HVAD; IABP: intra-aortic balloon pump; ICU: intensive care unit; INR: international normalized ratio; INTERMACS: Interagency Registry of Mechanically Assisted Circulatory Support; NA: not applicable; SD: standard deviation; SMD: standardized mean difference; WBC: white blood cells.

68% [95% CI (63–73%)] in HM3 patients. Kaplan–Meier analysis with a landmark at 1-year follow-up (Supplementary Material, Fig. S1) showed better survival for HM3 patients [hazard ratio 4.34 (1.2–14.3), *P* = 0.022].

There was no difference between the incidence of heart transplantation and device weaning between the groups. These were 72 (20%) in HW vs 51 (14%) in HM3 and 14 (4%) vs 19 (5.3%), respectively. Cumulative incidence functions for competing outcomes (death, heart transplantation, weaning from support) in matched cohorts are shown in Fig. 4, and the proportion (percentage) of patients in each category is summarized in Supplementary Material, Table S2.

The cumulative incidence function for major adverse events (device-related infections, major bleedings, device malfunction and neurological dysfunction) during the follow-up was similar in both groups [SHR 1.0 (0.84–1.21), *P* = 0.96] (Fig. 5).
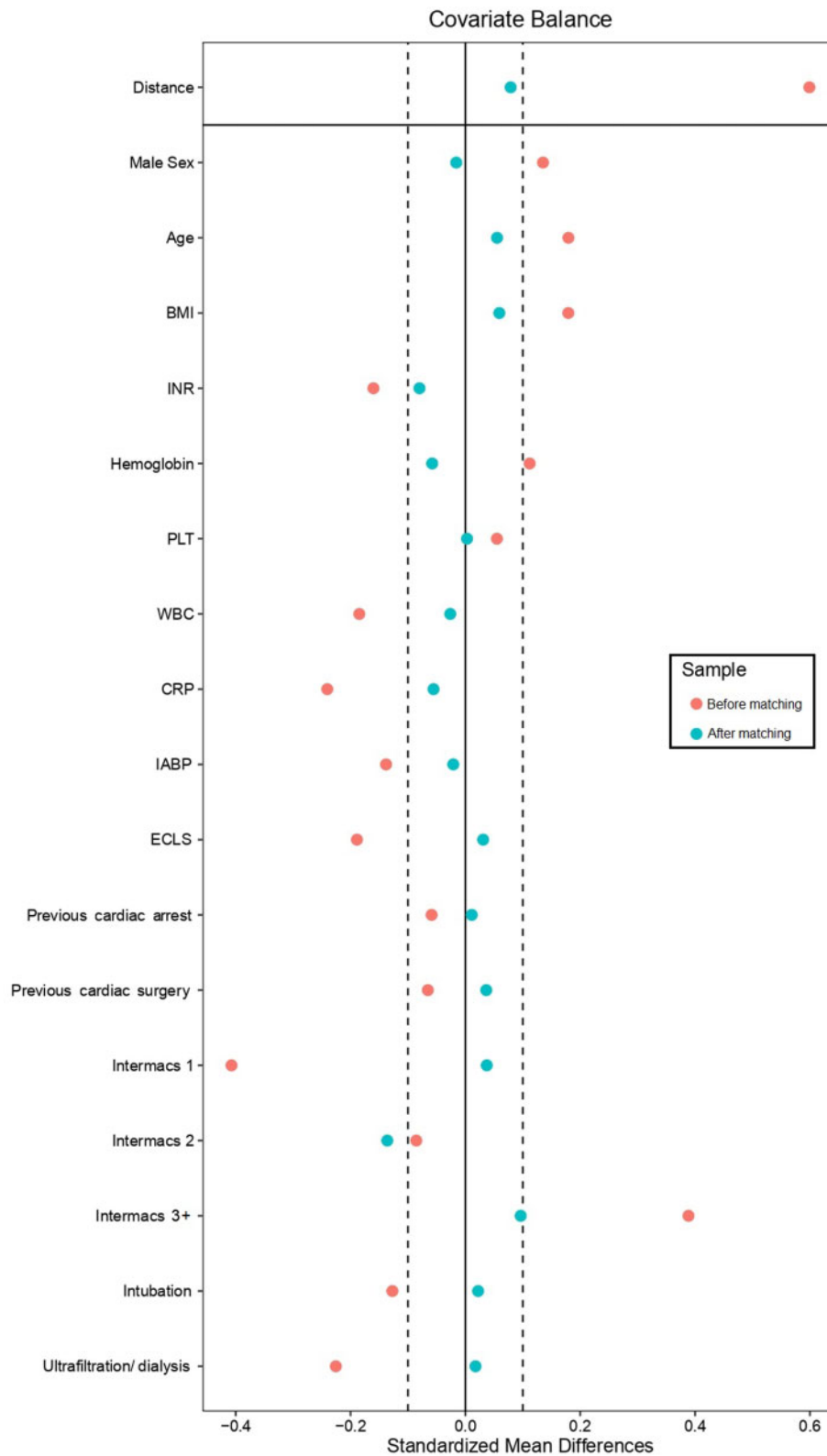
Figure 2: Balance plot for matching parameters. BMI: body mass index; CRP: C-reactive protein; ECLS: extracorporeal life support; IABP: intra-aortic balloon pump; INR: international normalized ratio; PLT: platelets; WBC: white blood cells.

Patients supported with an HW LVAD had a higher risk of device malfunction (SHR) [2.44 (1.45–3.71), *P* < 0.001] (Fig. 6A); LVAD pump thrombosis [SHR 5.99 (2.87–12.5), *P* < 0.001] (Fig. 6B); device malfunction leading to explantation/replacement [SHR 3.13 (1.54–6.25), *P* = 0.002] (Fig. 6C); neurological dysfunction [SHR 1.29 (1.02–1.61), *P* = 0.032] (Fig. 6D); and intracranial bleeding [SHR 1.76 (1.13–2.70), *P* = 0.012] (Fig. 6E) as compared to patients supported with the HM3 LVAD. There was no

Table 2: Follow-up events in matched cohorts

Event	HW	HM3	SHR	95% (CI)	*P*-value
Major adverse events and unexpected readmissions	1275	1148	0.928	0.79–1.10	0.38
Major bleeding	189	189	1.01	0.53–1.3	0.91
Major bleeding requiring transfusion/surgery	120	130	0.95	0.70–1.28	0.72
GI and intra-abdominal bleeding	43	47	1.12	0.69–1.82	0.66
Major infection	477	453	0.93	0.63–1.35	0.69
Bloodstream infection	92	97	0.94	0.68–1.29	0.69
Pump-related infection (DL and pump pocket)	218	193	1.23	0.93–1.62	0.14
Pump-related infection requiring surgical treatment	34	42	0.67	0.38–1.17	0.16
Device malfunction[a]	118	37	2.44	1.45–3.71	<0.001
Device thrombosis	89	10	5.99	2.87–12.5	<0.001
Device malfunction leading to explantation/replacement	36	16	3.13	1.54–6.25	0.002
Fatal device malfunction[b]	6	1	NA	NA	NA
Neurological dysfunction (CVA)	120	72	1.29	1.02–1.61	0.032
Fatal stroke	20	13	1.43	0.71–2.86	0.32
Intracranial bleeding	35	14	1.76	1.13–2.70	0.012
Right heart failure	96	94	0.88	0.63–1.22	0.45
Cardiac arrhythmia requiring CV/DF or medical therapy	107	117	0.94	1.06–1.31	0.72

[a]Device malfunction includes: pump thrombosis, outflow graft obstruction, driveline dysfunction.
[b]All fatal device malfunctions occurred due to pump thrombosis.
CI: confidence interval; CV: cardioversion (medical); CVA: cerebrovascular accident; DL: driveline; DF: defibrillation; HM3: HeartMate3; HW: HeartWare HVAD; NA: not applicable; SHR: subdistribution hazard ratios.
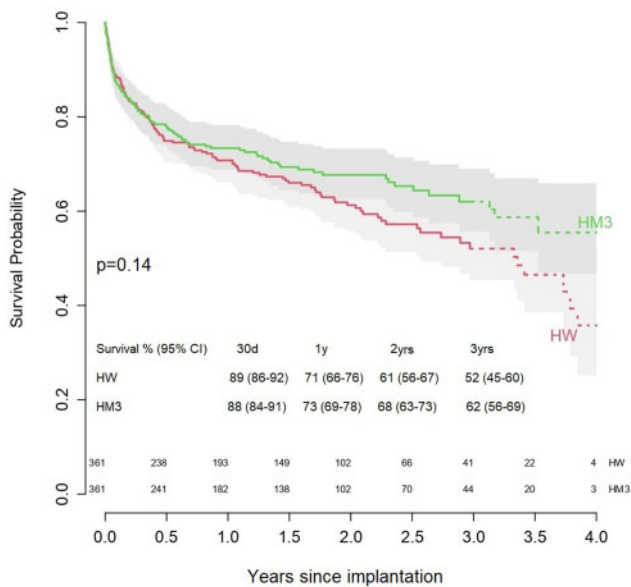

Figure 3: Kaplan–Meier estimates for survival probability in matched cohorts. CI: confidence interval; d: day; HM3: HeartMate3; HW: HeartWare HVAD; y(rs): year(s).

Figure 4: Cumulative incidence functions for competing outcomes (death, heart transplantation, weaning from support) in matched cohorts. HM3: HeartMate3; HW—HeartWare HVAD.

difference in the incidence of fatal stroke between the groups [SHR 1.43 (0.71–2.86), *P* = 0.32] (Fig. 6F).

DISCUSSION

The study presented here showed that patients who received either an HW or HM3 have a similar survival up to 4 years after implantation. However, patients supported with the HW have a higher risk of device malfunction, including pump thrombosis, and neurological dysfunction, including intracranial bleeding.
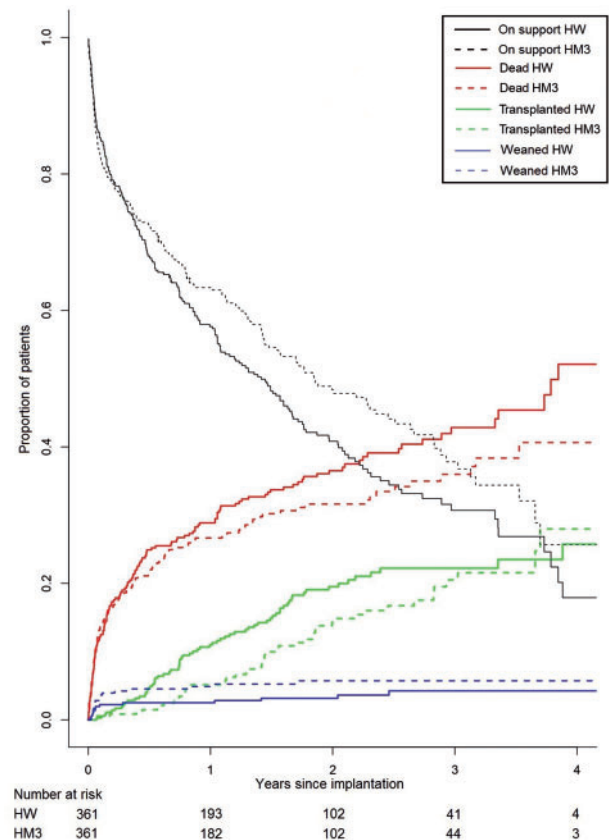
Our study is the largest propensity score-matched retrospective comparison between the most commonly implanted commercially available LVADs, based on data from the second largest

VAD register [18]. Previous retrospective single-centre studies with an intermediate-term follow-up revealed a similar survival for both groups [2–4]. Our study showed that this trend continues for up to 4 years on support.
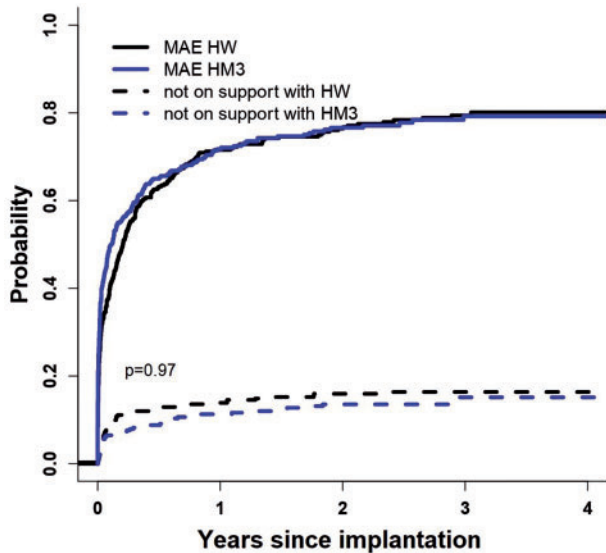

Figure 5: Cumulative incidence function of major adverse events and unexpected readmissions in both groups. MAE: major adverse events (including unexpected readmissions); HM3: HeartMate3; HW: HeartWare HVAD; Not on support: death, transplant or weaning.

The similar survival may be explained by the fact that the overall incidence of major complications (Fig. 5), especially bleeding, infection, arrhythmia and right heart failure, which are important contributors to mortality, was similar in both groups [1]. Serious device malfunction leading to device explantation or replacement was more prevalent in the HW group but contributed to <3% of all recorded complications.

An earlier report demonstrated a significantly higher stroke incidence for HW patients compared to HM3 patients; this, however, was the result of a small observational study without propensity score matching [4]. Our study revealed a higher incidence of neurological dysfunction in HW patients, probably due to the higher incidence of cerebral bleeding in this group. Similar results have been reported by Mueller *et al.* [3]. Based on the EUROMACS data, we were unable to distinguish between disabling and non-disabling strokes; however, the incidence of a fatal stroke was similar in both groups.

Postoperative anticoagulant therapy and patient compliance have a strong impact on the incidence and severity of bleeding and thromboembolic complications. Due to the anonymized nature of the EUROMACS dataset, we are not able to provide centre-specific anticoagulation protocols. However, the international normalized ratio at discharge revealed no significant difference between the groups (Table 1).

Schramm *et al.* [2, 3, 19] reported a significantly higher risk for driveline infections in HW patients, while groups from Berlin and Vienna suggested a trend towards more driveline infections in HM3 patients. Our study showed no difference for combined device-related infections (driveline and pump pocket infections) between the groups. It should be noted that infection-related
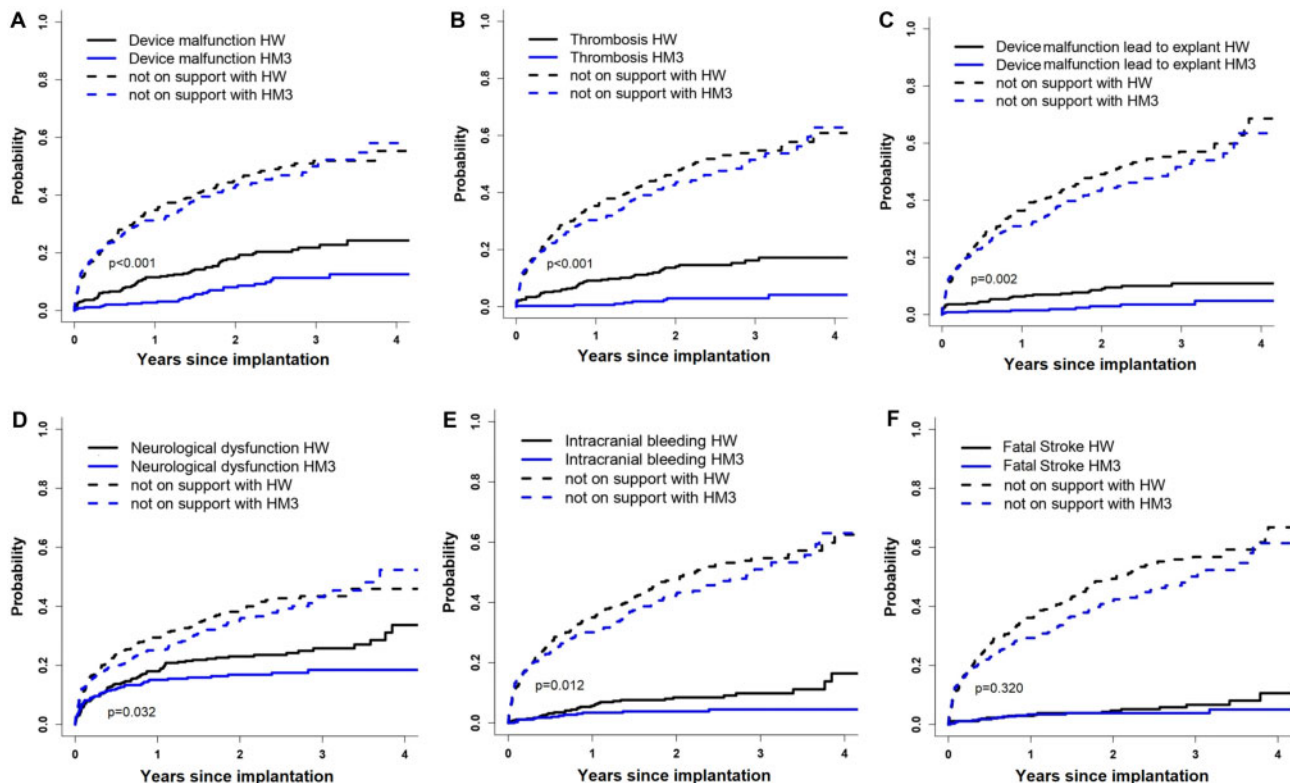

Figure 6: (**A**) Cumulative incidence function of device malfunction in both groups. (**B**) Cumulative incidence function of pump thrombosis in both groups. (**C**) Cumulative incidence function of device malfunction leading to explantation (or replacement). (**D**) Cumulative incidence function of neurological dysfunction. (**E**) Cumulative incidence function of intracranial bleeding. (**F**) Cumulative incidence function of fatal stroke. HM3: HeartMate3; HW: HeartWare HVAD; Not on support: death, transplant or weaning. Created with BioRender.com.

complications contributed to more than one-third of all major complications. A prompt introduction of secure transcutaneous energy transfer, making drivelines obsolete, would notably improve the quality of life and decrease morbidity and mortality in LVAD patients for all commercially available pumps [1].

In some cases life-threatening complications, such as outflow graft twist or outflow graft obstruction by fibrin deposits between the outflow graft and bend relief in HM3 patients, causing morbidity and mortality, may remain unrecognized in EUROMACS [20–23].

It should be noted that our analysis refers to patients who were matched specifically for a comparison of HW and HM3 devices from the EUROMACS registry. Therefore, due to the propensity score matching, these data cannot be used for a direct comparison with other studies.

Limitations

In this study, we retrospectively analysed data from the EUROMACS, which is part of and financially supported by EACTS. In contrast to some other registries, participation in EUROMACS is not mandatory in Europe. Therefore, surveillance and improvement of data quality are ongoing efforts.

As with other multicentre international registries, we were confronted with missing data. Various measures were taken to safeguard the completeness and correctness of the data that were submitted by the participating centres to improve data quality. These methods include data input control, onsite audits and statistical analyses. Another limitation is the observational origin of the data, which means our results may be confounded by indication.

The next limitation is the variability in standard-of-care practices in participating EUROMACS centres, especially concerning the heterogeneity in anticoagulation and antithrombotic therapeutic goals. Anticoagulation and long-term patient management, in particular blood pressure management, are not available and were thus not analysed.

Ultimately, only a multicentre, prospective, randomized study can answer the question regarding the advantages of a certain continuous-flow LVAD for each individual patient and help select an appropriate pump in each individual case.

CONCLUSION

HW and HM3 durable LVADs have a similar survival in mid-term follow-up. HW was associated with a significantly higher incidence of device malfunction, pump thrombosis and neurological dysfunction while on support. A multicentre, prospective, randomized trial is required in order to compare the HW and the HM3.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *EJCTS* online.

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Author contributions

Evgenij V. Potapov: Conceptualization; Formal analysis; Methodology; Supervision; Writing—original draft; Writing—review & editing. **Gaik Nersesian:** Conceptualization; Visualization; Writing—original draft; Writing—review & editing. **Daniel Lewin:** Conceptualization; Writing—original draft; Writing—review & editing. **Mustafa Özbaran:** Writing—review & editing. **Theo M.M.H. de By:** Data curation; Resources; Writing—review & editing. **Julia Stein:** Formal analysis; Software; Writing—original draft; Writing—review & editing. **Yuri Pya:** Writing—review & editing. **Jan Gummert:** Writing—review & editing. **Faiz Ramjankhan:** Writing—review & editing. **Michael O. Zembala:** Writing—review & editing. **Kevin Damman:** Writing—review & editing. **Thierry Carrel:** Writing—review & editing. **Bart Meyns:** Writing—review & editing. **Daniel Zimpfer:** Writing—review & editing. **Ivan Netuka:** Writing—original draft; Writing—review & editing.

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