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ORIGINAL PAPER

Successful support of biventricular heart failure patients by new EXCOR® Adult pumps with bileaflet valves: a prospective study

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Abstract

Aims The Berlin Heart EXCOR® Adult biventricular assist device (BiVAD) is an approved mechanical circulatory support for patients with end-stage biventricular heart failure. In this prospective post-market clinical follow-up study, we present the first clinical experience of the new EXCOR® Adult pump with bileaflet (BL) valves in Europe.

Methods and results After CE-mark approval in August 2014, a total of 12 patients were enrolled with a mean age of 44 years ± 11 (range 21–58 years). The majority of patients ($n = 11$) were in INTERMACS level 1 or 2. Eight patients had a median pre-operative extracorporeal life support (ECLS) of 6 days (range 1–37 days). Primary end point was survival, either to heart transplantation (HTx), recovery or alive at 12 months on device, whichever occurred first. Secondary end point was the number of adverse events throughout EXCOR® BiVAD support. Median support time up to last follow-up on EXCOR® BiVAD device was 248 days (range 57–381 days) and patient survival at 1 year was 92%. Half of the EXCOR® BiVAD patients ($n = 6$) were transplanted and five patients were still on support at 1 year post-implantation. Complications during EXCOR® BiVAD support were thoracic bleeding, exit site infection and ischemic cerebrovascular incidents in three cases, respectively.

Conclusion The new EXCOR® Adult pump with BL provides pulsatile high cardiac output with excellent outcome and successful bridging to HTx, particularly in critically ill patients with INTERMACS level 1 or 2 at the time of implantation.

Keywords Biventricular heart failure · Ventricular assist device · Bridge to transplant

Introduction

For patients treated with ventricular assist device (VAD) as bridge to heart transplantation (HTx), the prognosis is largely dependent on right ventricular (RV) function. Previous studies have shown that planned biventricular assist device (BiVAD) implantation using paracorporeal pulsatile VAD leads to better outcomes compared to planned continuous-flow left ventricular assist device (cf-LVAD) implantation with additional intervention due to RV failure [1]. Patients who develop late RV failure during cf-LVAD support also have a significantly reduced 1-year survival of 40–50% [2]. When two cf-VADs are used as a BIVAD, 1-year survival is between 50 and 60% [3, 4].The strategy of optimal patient selection and BiVAD implantation improves outcome using pulsatile VAD compared to delayed conversion of cf-LVAD to BiVAD [5].

EXCOR® Adult (Berlin Heart GmbH) BiVAD is a paracorporeal pulsatile VAD approved for short-, mid- and

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long-term biventricular cardiac support. Several studies have described the experiences with EXCOR® Adult and demonstrated that EXCOR® was effective, safe and resulted in long survival and improved quality of life [6, 7].

In August 2014, a new generation of EXCOR® Adult pumps with bileaflet (BL) valves was introduced. The new EXCOR pump with BL valves was developed to offer a successor model to the EXCOR pumps with tilting disks as their production was discontinued. The benefits of EXCOR pumps with BL valves are noise reduction of pump and simplified pump preparation at implantation by easy de-airing. The revised design, in contrast to the former tilting disk valve design, is presented in Fig. 1. We therefore designed a prospective, observational post-market clinical follow-up (PMCF) study to confirm the long-term clinical safety and device performance of EXCOR® Adult BiVAD at three European cardiovascular surgery centers. Within the approved indication and under the conditions of routine use, the objectives of the PMCF study were to evaluate the clinical safety and to determine the device performance of EXCOR® pumps with BL valves. The primary end point was survival of patients either until HTx, myocardial recovery or support up to 12 months on the device. Secondary end points were the number of adverse events (AE) and the course of selected laboratory parameters throughout the device support period.

Methods

Patients

A prospective, observational, non-invasive PMCF study was started after CE-certification of the EXCOR® pump with BL valves according to the principles outlined in the "Declaration of Helsinki" and MEDDEV 2.12/2. The study documents were submitted prior to the study for review by each local ethics committee of the medical faculties. Each center was provided with case report forms and all patients gave their written informed consent. Patients who were on EXCOR® systems (replacement of EXCOR® blood pumps with polyurethane valves or tilting disks), patients with signs of sepsis, progressive irreversible multi-organ failure, age younger than 18 years and absence of given consent were excluded from the study. Finally, 12 patients were enrolled from three hospitals between September 2014 and June 2015. The last follow-up (FU) time point was April 2016.

Data collection

Patient baseline data, medical history including hemodynamic and laboratory data were collected. Cases of the prospective study were assessed at the time of implantation, 7, 30, 90, 180 days and 1 year after EXCOR® BiVAD implantation. FU forms tracked the occurrence of AE, overall survival (on device, transplanted or deceased), laboratory data [hemoglobin, hematocrit, lactate dehydrogenase (LDH) and international normalized ratio (INR)] and 6 months

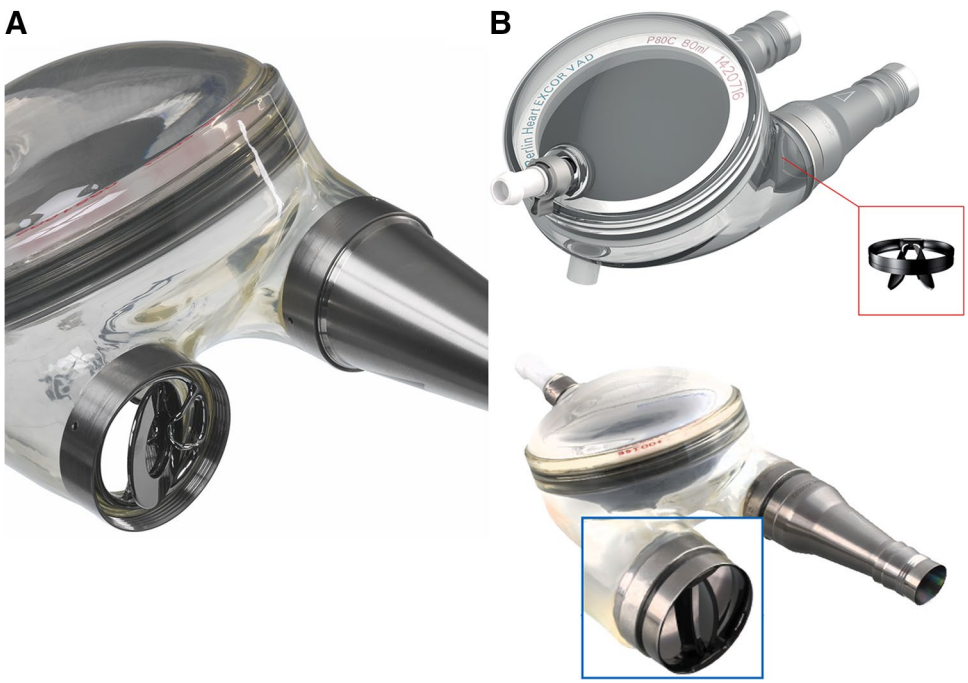

Fig. 1 The schematic structure of the former tilting disk EXCOR chamber (**a**) and the newly developed bileaflet valve pump model

post-HTx outcome. AE were defined according to INTERMACS definition [6]. Additionally, data regarding anticoagulation management and pump changes were recorded.

Surgical and peri-operative management

There is no consensus on any scores predicting RV-function following LVAD implantation and low survival in patients with temporary RVAD after LVAD implantation [1, 8–10]. We individually evaluated every patient within our multidisciplinary team including cardiothoracic surgeons, heart failure cardiologists, cardiac anesthesiologists and intensivists. Generally, indication for the implantation of a permanent BiVAD was severe biventricular failure unsuitable for left-sided support only. 50% of our patients were already on emergency ECLS. In this group, determining RV recovery is difficult as the ECLS systems could only be deactivated for a short period. If response to inotropic agents under echo control was unsatisfactory, the decision for long-term BIVAD implantation was taken. In the non-ECLS group, the assessment of the RV function was performed using transthoracic and transesophageal echocardiography (TAPSE, RV-dimensions) as well as laboratory parameters including blood chemistry and renal and hepatic function tests. The cutoff point was a TAPSE less than 13 mm and laboratory signs of congestion and reduced end-organ function.

Whenever possible, pre-operative consultation of our clinical psychosomatic specialists with the patients and/or relatives was performed. In all cases, post-operative psychosomatic care for patients and relatives was provided, as it is our standard for both the inpatient and outpatient period.

The standard surgical approach was median sternotomy. In case of an already ongoing central extracorporeal life support (ECLS), the upgrade procedure was ensured by reopening the previous sternotomy. As per standard, the implantation procedure was performed on cardiopulmonary bypass (CPB). Heparin (300U/kg) was given and standard cannulation to the distal ascending aorta and bicaval venous cannulation were established. Once on CPB, the implantation (or upgrade from ECSL, if applicable) started with the implantation of the left apical cannula, followed by the cannula to the distal pulmonary artery trunk, the right atrium and the ascending aorta. After channelling all four cannulas throughout the chest, the chambers were connected accordingly with a sharp focus on proper de-airing. In all 12 cases, 80 ml pumps for the left side and 60 ml pumps for the right side were applied. In all but one patient, implantation procedures included 122B mm cannulas (while one patient received a right-sided outflow cannula sized 9 mm). After complete connection of both EXCOR® pumps, initial test ejections were accomplished to assure correct function, followed by a stepwise reduction of the CPB flow with a simultaneous increase of BiVAD pump rate to achieve a target blood flow of 2.6 l/min/m^2 body surface area for all patients. After successful weaning and de-cannulation from CPB, protamine was used to antagonize heparin completely.

Post-operative anticoagulation therapy was started according to EXCOR® instruction for use with individual modification. Within a period of 24 h, depending on the platelet count (> 50,000/µL), the results of thrombelastography and the bleeding situation, administration of unfractionated heparin (UFH) was started. Anticoagulation with vitamin K antagonists was titrated to an international normalized ratio (INR) 3.0–3.5 and low-molecular weight heparin (LMWH) was used to bridge for long term. In addition, patients received dipyridamole 150 mg/d, if ADP activity < 50%, and/or aspirin 100 mg/day, if ARA activity < 30%, from the post-operative day (POD) 2 and 4, respectively, for inhibition of platelet aggregation. Overall, five patients (41.6%) received dual platelet inhibition.

Wound care and dressing changes were performed according to EXCOR® instruction for use. When the wound was dry and free of infection, dressing changes were performed daily at POD 1–10, every 2 days at POD 11–28 and weekly twice from POD 28. When the wound was infected, wound care and dressing change were done daily twice.

Statistics

Continuous variables are reported as median or mean ± standard deviation (range), and categorical variables are reported as relative frequencies. Kaplan–Meier analysis was used to estimate the survival after EXCOR® Adult BiVAD implantation with patients censored for HTx. The competing results were reported with follow-up to 1 year after EXCOR® BiVAD implantation. Box plots have been used to compare the course of different laboratory parameters during FU assessment. Post-operative AE rate was shown as event per patient year (EPPY). Laboratory values were analyzed by the paired *t* test. *P* value < 0.05 was considered to be statistically significant. All data were analyzed using SPSS Statistics 22.0 software (SPSS, Chicago, IL, USA).

Results

Patient's characteristics

A total of 12 consecutive patients (10 male; 83.3%) with biventricular heart failure were implanted with EXCOR® Adult BiVAD. The mean age was 44 years ± 11 (range 21–58 years), and mean BSA was 1.9 m^2 ± 0.3 (range 1.5–2.5 m^2). Half of the patients ($n = 6$) had idiopathic dilative cardiomyopathy (CMP). Other diagnoses were ischemic CMP in three cases, and myocarditis, acute myocardial

infarction (AMI) and cardiogenic shock after aortic dissection Type A in one case each. The majority of patients ($n=11$) were in INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support) level 1 or 2 with eight patients having a median pre-operative extracorporeal life support (ECLS) of 6 days (1–37 days). Patients' pre-operative data are presented in Table 1.

Follow-up and outcome

All patients could be mobilized successfully on EXCOR® Mobile after a median time of 10 days (4–40 days). Laboratory values of hemoglobin, hematocrit, LDH and INR were determined during the follow-up (FU) time of EXCOR® BiVAD-supported patients. LDH values of FU 1 and 4 weeks were only available for ten patients. There were no significant changes in hemoglobin, hematocrit and LDH parameters (Fig. 2a–c).

Nine patients were discharged from hospital after a median time of 58 days (31–98 days). The remaining three patients remained in hospital due to high-urgency listing and reached an end point within 6 months (2x HTx, 1 death). he median support time up to the last FU on the EXCOR® BiVAD device was 248 days (57–381 days) and cumulative time on the device was 2973 days (8.14 years). Table 2 demonstrates the outcome of patients at 30, 180 days and 1 year. One patient died at post-operative day (POD) 57 following thoracic bleeding from the anastomosis of the pulmonary artery cannula due to suspected vasculitis. Half of the BiVAD patients ($n=6$) were transplanted after a median time of 175 days (99–284 days) within FU time. One patient died due to primary graft dysfunction after HTx at POD 10. The overall survival after 6 months of HTx was 83% ($n=5$). Five outpatients were still on THE device at 1 year post-implantation. Figure 3a shows the estimated survival of the supported patients at 1 year (92%), whereas Fig. 3b demonstrates the competing outcome for the patients on BiVAD support. Beyond the 1 year observation period, the survival on EXCOR® BiVAD was also 92% (status October 2016). According to the implant registry, eight patients were transplanted and three outpatients were still on EXCOR® BiVAD after more than 1.6 years of continuous biventricular support.

Table 1 Demographic and pre-operative profile of EXCOR® Adult BiVAD patients

Variable	$n=12$
Gender (*n*), male	10
Age, mean (range), years	45 (21–58)
BMI, mean (range), kg/m^2	23.9 (19.8–30.2)
BSA, mean (range), m^2	1.9 (1.6–2.5)
Etiology (*n*)	
Idiopathic CMP	6
Ischemic CMP / AMI	4
Myocarditis	1
Cardiogenic shock (aortic dissection)	1
INTERMACS Level (*n*)	
1	6
2	5
4	1
Pre-operative	
CPR (*n*)	1
Dialysis (*n*)	2
Cardiac surgery (*n*)	4
Ventilator (*n*)	5
ECMO (*n*)	8
MAP, mean (range), mmHg	70 (59–80)
CVP, mean (range), mmHg	12 (7–22)
LVEF, mean (range), %	18 (10–51)
Hb, mean (range), g/dl	10.3 (7.6–13.5)
Hct, mean (range), %	31.8 (25.6–39.7)
LDH, mean (range), U/l	566 (273–1250)
INR, mean (range)	1.3 (1.0–1.7)
Creatinine, mean (range), mg/dl	1.5 (0.6–3.5)
PTT, mean (range), s	46.5 (23.4–150.0)
CRP, mean (range), mg/dl	71.4 (8–234)
Bilirubin, mean (range), mg/dl	2.6 (0.5–12.6)
AST, mean (range), U/l	99 (22–516)
ALT, mean (range), U/l	91 (36–171)
Platelets, mean (range), number/µl	115,600 (52,000–312,000)

BMI body mass index, *BSA* body surface area, *CMP* cardiomyopathy, *AMI* acute myocardial infarction, *INTERMACS* Interagency Registry for Mechanically Assisted Circulatory Support, *CPR* cardiopulmonary resuscitation, *ECMO* extracorporeal membrane oxygenation, *MAP* mean arterial pressure, *CVP* central venous pressure, *LVEF* left ventricular ejection fraction, *Hb* hemoglobin, *Hct* Hematocrit, *LDH* lactate dehydrogenase, *INR* international normalized ratio, *PTT* partial thromboplastin time, *CRP* C-reactive protein, *AST* aspartate transaminase, *ALT* alanine transaminase

Adverse events

During the PMCF study, nine patients (75%) were affected by device or procedure-related complications (Table 3). Most complications were thoracic bleeds, exit site infections and ischemic cerebrovascular accidents (CVA) in three cases, respectively. Procedure-related thoracic bleeds were reported within the first 2 months of implantation and were managed successfully. Device-related exit site infections were reported only in outpatients. In two patients, infection became a deep wound which led to high-urgency listing. One patient's post-implantation period was complicated by heparin-induced thrombocytopenia. In this patient, an arterial cerebral thromboembolism with a need for a craniotomy for a bleed occurred on POD 22, followed by an ischemic CVA at POD 108 and a non-cerebral thromboembolism.

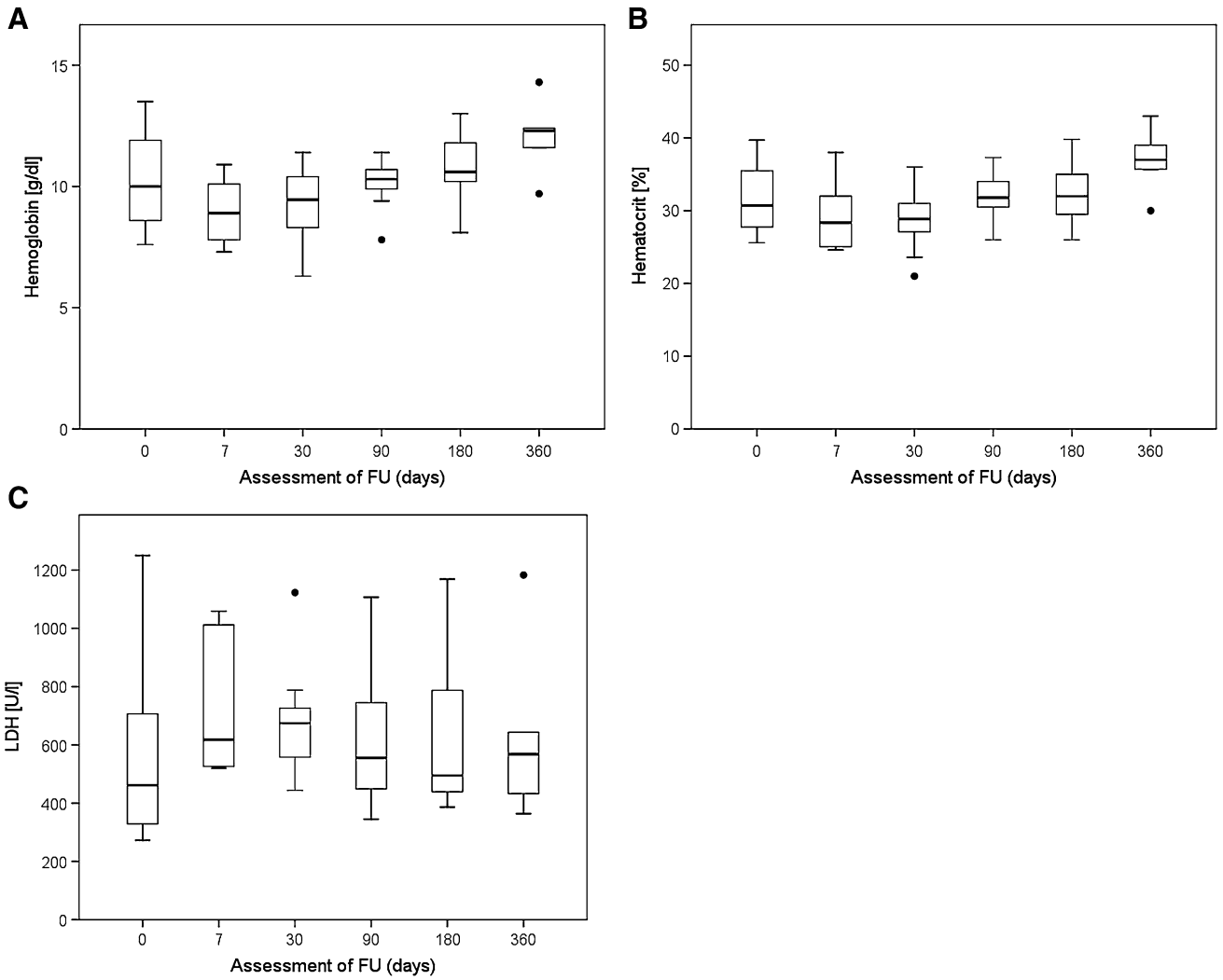

Fig. 2 The development of laboratory values of hemoglobin (**a**), hematocrit (**b**) and LDH (**c**) over the course of support with no significant change within the follow-up

Table 2 Outcome of EXCOR® Adult BiVAD patients up to 1 year follow-up

Outcome (*n*)	30 days	180 days	1-year
On system	12	8	5
Transplanted	0	3	6
Deceased	0	1	1

Furthermore, multiple pump replacements became necessary due to deposits up to HTx (on POD 212). Another patient with suspected thrombophilia had a device-related thromboembolism (pulmonary embolism) without any need for intervention at POD 21 and an ischemic CVA at POD 26 and was successfully transplanted at POD 110. None of the mentioned complications including CVAs were severe enough to preclude subsequent transplantation.

There were no signs of device-related or procedure-related gastrointestinal bleeds, hemorrhagic CVA, hemolysis, and renal or hepatic failure detected. No valve malfunction of EXCOR® pumps was detected. All study patients had at least one pump replacement due to deposit formation over the course of support or FU, following macroscopic visual assessment.

Discussion

The number of patients with cf-LVAD implantation has significantly increased worldwide. According to the INTRERMACS registry, during the same period, the share of critically ill patients with INTERMACS level 1 and 2 has been significantly dropping, indicating a more careful

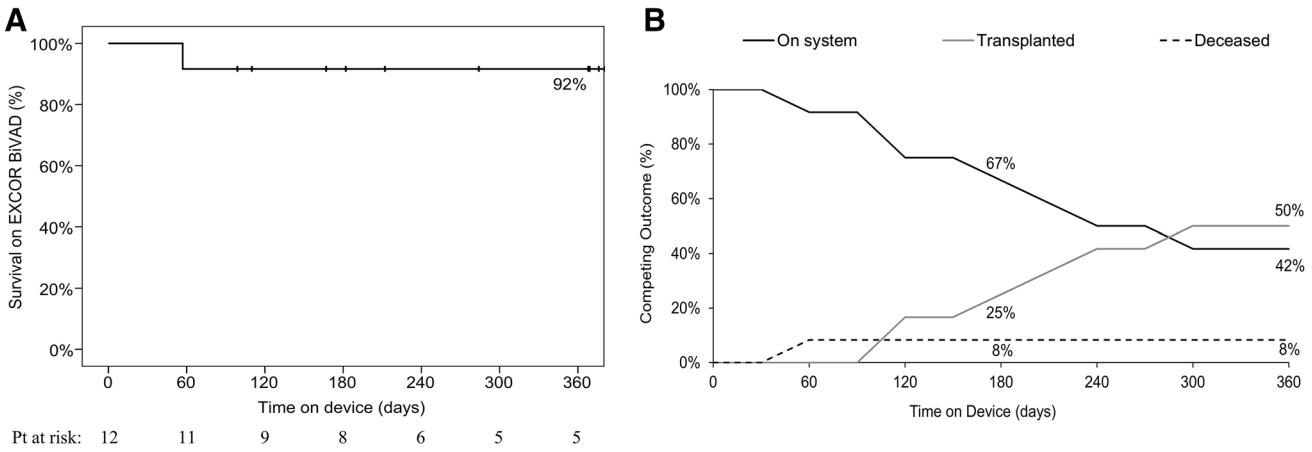

Fig. 3 The Kaplan–Meier survival (**a**) and competing outcome results (**b**) for the patients on BIVAD support

Table 3 Device- and procedure-related adverse events

Complications	Number	Affected patients (*n*)	EPPY
Major bleeding			
GI bleeding	0	0	0.00
Thoracic bleeding	3	3	0.37
Major infection			
Infection in retrocardiac hematoma	1	1	0.12
Exit site infection	3	3	0.37
Neurological dysfunction			
TIA	1	1	0.12
Ischemic CVA	3	3	0.37
Hemorrhagic CVA	0	0	0.00
Arterial non-CNS thromboembolism	2	2	0.25
Hemolysis	0	0	0.00
Hepatic dysfunction	0	0	0.00
Renal dysfunction	0	0	0.00
Device malfunction[a]	1	1	0.12

Patient years: 8.14

EEPY events per patient year, *GI* gastrointestinal bleeding, *TIA* transient ischemic attack, *CVA* cerebrovascular accident, *CNS* central nervous system

[a]No bileaflet valve malfunction

selection of patients [11]. Therefore, there is a need for treatment for the sickest patients.

In cases of likely occurrence of RV failure after LVAD implantation, mechanical RV support may become necessary (RV-MCS). RV-MCS can be temporary or long term. The results of temporary RVAD after LVAD implantation have been dismal [1, 8–10]. As to long-tern BIVADs, there can continuous flow (cf) and pulsatile BIVADs. As to cfBIVADs, there are several issues that need to be addressed: (1) cf-BIVADs are not designed as BIVAD and the companies do not officially recommend them (off-label use). (2) There is no reliable information about pulmonary blood flow. (3) There is no coordination between LVAD and RVAD and patients need to carry two independent controllers. (4) There is no real flow measurement, only calculation. (5) There is only limited response to peri-operative dynamic changes in pulmonary vascular resistance (PVR). Six months and 1 year survival reported are only 50–60% in highly selected patients [3, 4]. In contrast, pulsatile systems such as the Berlin Heart EXCOR® coordinate flows for the left and right side using one controller. Moreover, they perform real cardiac output measurement as a product of stroke volume and pump rate.

Our results demonstrate that in selected centers, it is possible to achieve excellent results using biventricular mechanical circulatory support, even in critically unwell patients, such as INTERMACS 1 ("crash and burn") patients. The EXCOR® Adult system is specifically designed for the comprehensive treatment of biventricular and consecutive end-organ failure with adjustable and pulsatile blood flow. It stands out for mid-term and long-term support, particularly for patients who are at INTERMACS level 1 and 2 at the time of implantation [6]. In summary, the PMCF study of EXCOR® Adult BiVAD with newly implemented BL valves endorses the safe and effective strategy of treating biventricular heart and severe end-organ failure.

In our European multi-center study, we were able to demonstrate outstanding long-term survival (92% at 1 year) even in patients with cardiogenic shock already supported by pre-operative ECLS. This figure is particularly notable when compared with the INTERMACS registry results, which show a poor 1-year survival of 45% for patients with pulsatile flow BiVAD (45%) [12]. The approach of ECLS in cardiogenic shock as a bridge-to-bridge strategy, followed by the implantation of a biventricular EXCOR® Adult system is effective and associated with an improvement of end-organ function. It achieves excellent early and long-term survival

with a low incidence of major complications. With regard to survival after heart transplantation, our EXCOR® Adult patients had an excellent outcome after 6 months of HTx (83% survival), which was also comparable to post-transplant survival of patients who were bridged with cf-LVAD [13].

Within the 1-year FU period, the new EXCOR® Adult pumps with BL showed no valve failure or hemolysis. The EXCOR® BiVAD device or procedure-related complications were easily identified and enabled effective clinical management, followed by either transplantation or pre-emptive EXCOR® pump exchange preventing potential thromboembolic events. The positive effect of pulsatile VAD therapy in direct comparison to cf-LVAD support has also been documented by Crow et al. Patients with non-pulsatile LVAD appear to have a higher rate of gastrointestinal bleeding events than pulsatile LVAD recipients [14].

Determining the best therapeutic approach to managing biventricular heart failure is still challenging. There is an up to 20% incidence of right ventricular failure after LVAD implantation with increased peri-operative morbidity and mortality (19–43%) and end-organ dysfunction associated with prolonged intensive care and hospitalization [8]. Takeda et al. showed an improved 6-month survival for planned BiVAD group compared to patients who underwent an unplanned RVAD implantation due to RV failure [9]. Alternative strategies are necessary in patients who require continuous RVAD support, as less than half of those patients who develop acute RV failure after LVAD implantation can be weaned successfully from a temporary RVAD support [9]. For severely decompensated heart failure patients with signs of significant right ventricular failure, cf-LVAD alone may not provide adequate circulatory support. In these cases, primary paracorporeal BiVAD is the most effective strategy. Patients with dual cf-LVAD as biventricular support may benefit from more mobility, but first limited clinical experiences with off-labelled use show that most patients suffered from early death without ever being discharged [4]. The seventh INTERMACS Report showed also only a moderate 1-year survival of cf-BiVAD which was lower than 60% [12].

As our study demonstrates, BiVAD implantation at experienced centers improves outcome. In high-risk patients, already on ECLS, the use of pulsatile biventricular mechanical circulatory support is particularly beneficial compared to delayed conversion from LVAD to BiVAD [5]. Cheng et al. demonstrated a comparable 1-year survival of patients with total artificial heart (TAH) and biventricular assist device as bridge to transplantation (78 vs. 83%) [15].

Mobilization and discharge of patients to their home environment were feasible for the vast majority of our patients ($n = 9$), demonstrating that patients with a paracorporeal BiVAD can be successfully discharged to home awaiting the HTx with better quality of life [16]. Moreover, BIVAD support not only allows for surviving the immediate situation of cardiogenic shock, but also enables the opportunity for the patient to regain physical strength and end-organ recovery while waiting for the pending HTx.

For general understanding, EUROTRANSPLANT organ allocation statutes exclude VAD patients from the "high-urgency" (HU) waiting list as the standard inclusion criteria are hemodynamic factors such as low cardiac index or reduced mixed venous saturation and end-organ dysfunction despite inotropic support. HU status for VAD patients can only be granted, if VAD-related complications occur that can only be treated by transplantation. Within our cohort, HU status was obtained due to deep wound infections as well as non-severe thromboembolic events.

In summary, the EXCOR® Adult with the new BL valves validated its value as an established and approved long-term VAD in biventricular heart failure to successfully bridge patients to HTx. BIVAD support allows for a favorable bridge-to-transplantation strategy, resulting in successful HTx in 5 out of 12 cases within 1 year of support. Beyond the initial follow-up period of 12 months, all 5 patients who were still alive on BIVAD support were then transplanted successfully with a median time on support of 668 days (range 373–926), which led to a total number of 11 patients successfully bridged to HTx using long-term pulsatile BIVAD support. The immediate establishment of a sufficient and reliable biventricular pulsatile cardiac output results in fast recovery of end-organ function and favorable outcomes post-HTx.

The limitation of this PMCF study is the small cohort of patients without randomization. Nevertheless, in times of a noticeably growing interest in a need of a permanent biventricular support, paracorporeal pulsatile BiVAD systems should be recognized as valuable alternatives to treat biventricular failure. To support these findings, further data collections are essential. A proposed prospective multicenter BiVAD study in adult patients should deliver further clinical evidence for the adaptation of cardiac heart failure treatment guidelines in biventricular heart failure.

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Compliance with Ethical Standards

Conflict of interest AR and BS received travel grant (for international conferences) from BH and consultancy fees from BH. MJW received speaker honoraria and travel grants from BH. AKM and NJ are employees of Berlin Heart GmbH.

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