

Results of the post-market Registry to Evaluate the HeartWare Left Ventricular Assist System (ReVOLVE)

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KEYWORDS:

HeartWare;
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system;
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BACKGROUND: The post-market Registry to Evaluate the HeartWare Left Ventricular Assist System (ReVOLVE) is an investigator-initiated registry established to collect post-CE Mark Trial clinical data on patients receiving a HeartWare ventricular assist device (HVAD) in the European Union and Australia.

METHODS: The ReVOLVE is a multi-center, prospective, single-arm registry performed at seven centers in Europe and two in Australia. Herein we describe a total of 254 commercial HVAD implants according to labeled indications between February 2009 and November 2012. Summary statistics included patients' demographics, adverse events, length of support and outcomes.

RESULTS: Compared with the clinical trial supporting the CE Mark of the HeartWare system, patient selection differed in that patients were older, and there were higher proportions of females and patients with idiopathic cardiomyopathies in the ReVOLVE cohort. Duration of support ranged from 1 to 1,057 days, with a mean of 363 ± 280 days (median 299.5 days). Transplantation was done in 56 patients (22%), explant for recovery was performed in 3 patients (1%), 43 died while on support (17%), and 152 (60%) remain on the device. Success in patients with the HeartWare system was 87% at 6 months, 85% at 1 year, 79% at 2 years and 73% at 3 years. Adverse event rates were low, comparable or improved when compared to the CE Mark Trial.

CONCLUSION: Real-world use of the HeartWare system continues to demonstrate excellent clinical outcomes in patients supported with the device.

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Heart failure is a significant medical problem worldwide. Among patients diagnosed with heart failure, 50% die within 4 years, whereas 40% of heart failure patients who are hospitalized die within 1 year.¹ Heart transplantation remains the best long-term treatment for patients with advanced heart failure, but the limited supply of available

hearts curtails the utility of this option. The use of ventricular assist systems as a bridge to transplantation (BTT) has increased in recent years due to design enhancements leading to improved survival and quality of life when compared with medical therapy in these advanced heart failure patients.^{2–6} Recently updated European Society of Cardiology guidelines for treatment of acute heart failure added the use of left ventricular assist devices (LVADs) or biventricular assist devices (BiVADs) as a Class I/B recommendation in patients deteriorating on medical therapy while waiting for a heart transplant.¹

In results from the pivotal international CE Mark Trial of the HeartWare system, the survival rates during support were 90%, 84% and 79% at 6, 12, and 24 months, respectively, and significantly improved measures of quality of life over baseline were noted.⁷ The HeartWare system received CE Mark for use as an LVAD in the BTT indication in March 2009, and for long-term use in all patients with advanced, refractory heart failure at risk of death in May 2012. The U.S. Food and Drug Administration (FDA) has approved use of the HeartWare system as a BTT. We report here data from the Registry to Evaluate the HeartWare Left Ventricular Assist System (i.e., the ReVOLVE Registry), a prospective, post-market registry of patients receiving the HeartWare system at nine centers in Europe and Australia.

Methods

Study design

ReVOLVE was an investigator-initiated registry of commercial implants performed between February 2009 and November 2012. Patients receiving the HeartWare system for labeled indications only are included in this report. Data were collected at nine centers in Europe⁷ and Australia.² We report here the data on patients' demographics, the most common adverse events, length of support and outcomes. ReVOLVE was not sponsored by HeartWare, Inc., although the company did provide support and assisted in analysis of the data. Although the data were not monitored on-site, steps were taken to verify the accuracy through telephone and e-mail communications with the users at each participating center.

End-points

The primary outcome was actuarial success throughout the follow-up period. Success was defined as survival to transplant, successful recovery with device explant, or remaining on continued HeartWare system support. Success was reported descriptively by Kaplan–Meier survival and the estimated hazard ratio from Cox proportional hazards regression.

Secondary end-points included incidence of major adverse events, including unanticipated adverse device effects and incidence of all device failures requiring device exchange. Descriptive statistics were used to evaluate incidences and event rates and changes from baseline. Adverse events, including device failure, were defined using INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support) adverse event definitions.⁸ The adverse event definitions were the same as those used in the HVAD CE Mark Trial. Adverse event data were

collected from 254 patients, with a total of 252.6 patient-years of support.

Suspected pump thrombosis was defined as any suspicion of thrombus through evidence of hemolysis, elevated lactate dehydrogenase (LDH) or plasma free hemoglobin, power spikes with flow disconnect, or sound auscultation of pump “effort.” The event was a confirmed pump thrombus if blood clot was visualized upon pre-exchange echocardiography or by visual confirmation in the pump of the explanted device.

HVAD system

The HVAD system has a miniaturized, implantable, centrifugal design with a continuous-flow blood pump. It utilizes a hybrid magnetic/hydrodynamic impeller suspension system for wearless rotation. The HVAD pump has an integrated inflow cannula, allowing implantation within the pericardial space, and requires no abdominal surgery for a pump pocket. The HVAD pump is connected to simple-to-use, lightweight patient peripherals. Details of the HeartWare system and its implantation have been described in previous studies.^{9,10}

Results

A total of 314 commercial implants were collected in the ReVOLVE study at these nine centers. Off-label cases (BiVAD use or right VAD use, age <18 years) accounted for 27 of the cases, and another 33 implants were performed using a thoracotomy approach. This report excludes those off-label patients and thoracotomy implants (addressed in separate studies). Baseline patient data for the 254 on-label cases are presented in Table 1. Mean age of patients was 52.5 ± 12.0 years, and females accounted for 23% of the total patient population. Mean body surface area (BSA) was 1.93 ± 0.23 m². The diagnosis or type of cardiomyopathy at baseline is also shown in Table 1. Idiopathic cardiomyopathies accounted for 65% of heart failure cases, whereas ischemic cardiomyopathies accounted for only 27%.

Implants were performed via sternotomy utilizing cardiopulmonary bypass (CPB) in all cases in this report. Table 2 shows the outcomes and duration of support. Duration of support ranged from 1 to 1,057 days, with a mean of 363 ± 280 days (median 299.5 days). Fifty-six of the 254 patients were transplanted, 3 regained myocardial

Table 1 Patients' Characteristics at Baseline (N = 254)

Demographics	N	Percent or range
Male	195	77%
Female	59	23%
Mean age (years)	52.5 ± 12.0	19–75
Mean body surface area (m ²)	1.93 ± 0.23	1.19–2.41
Type of cardiomyopathy		
Idiopathic	164	65%
Ischemic	69	27%
Hypertrophic	6	2%
Familial	4	2%
Valvular	2	1%
Myocarditis	3	1%
Other	6	2%

function and had the device removed, 43 died on support, and 152 patients remained on the device. Patients were transplanted after 19 to 958 days (mean 363 ± 250 days) of support. For the patients who died during the observation period, death occurred after a mean of 159 ± 228 days on support (range <1 to 730 days). The most frequent causes of death in the 254 patients studied included multisystem organ failure (7.1% patients, at a mean time to death of 124 days, range 1 to 609 days), neurologic complications (4.3% patients, at a mean time to death of 145 days, range 1 to 730 days) and sepsis (2.8% patients, at a mean time to death of 89 days, range 6 to 368 days) (Table 3).

One hundred forty-five patients were supported for <1 year, 85 patients for 1 to 2 years and 24 patients for 2 to 3 years. Survival post-transplant was excellent: of 56 patients transplanted, 2 died post-transplant, 1 of multiple-organ failure and 1 of intracranial hemorrhage. Post-transplant survival at 1 month was 96% (54 of 56 patients).

The Kaplan–Meier actuarial success estimate is shown in Figure 1. The 6-, 12-, 24- and 36-month success rates were 87%, 85%, 79% and 73%, respectively.

Adverse event rates based on the INTERMACS definitions are shown in Tables 4A. The most common adverse event reported was bleeding. There were 101 bleeding events (0.40 event per patient-year [EPPY]) occurring in 28% of patients (71 of 254), and an additional 5% of patients (12 of 254) had gastrointestinal (GI) bleeding (16 events, 0.06 EPPY). Drive-line infections occurred in only 6% of patients (14 of 254) at a rate of 0.07 EPPY (18 events). A total of 12 patients (5%, 0.05 EPPY) developed sepsis, which was the cause of death in 7 patients. Stroke occurred in 8% of patients (20 of 254, 0.08 EPPY). Right heart failure occurred in 9% of patients (24 of 254, 0.10 EPPY), whereas renal failure was reported in 4% (10 of 254, 0.04 EPPY).

Pump thrombus events are presented in Table 5. There were 17 patients with 22 events of suspected device thrombus (6.7%, 0.09 EPPY). Many of the thrombus events were successfully treated with intravenous medications (e.g., heparin, platelet-inhibiting agents and thrombolytic agents) and 8 were treated with pump exchange (3.1%, 0.03 EPPY, although 2 followed failed thrombolytic therapy. Of the 9 patients who did not have an exchange, 4 underwent heart transplant, 1 had a successful explant with recovery after 2 suspected pump

Table 3 Overall Causes of Death on Support ($N = 43$ of 254)

Cause of death	Patients (% of total)
Multiple-organ failure	7.1%
Neurologic	4.3%
Sepsis	2.8%
Right heart failure	0.4%
Other	1.6%
Unknown	0.8%
Total	16.9%

thrombus events that were managed medically with thrombolytic agents, and the remaining 4 continued on support with their original device after resolution of the event. Of the 17 patients with pump thrombosis, all 17 were alive at the end of the study period.

Discussion

Data from the ReVOLVE study demonstrate continued high-level safety and performance of the HeartWare system as an LVAD. The small size and pericardial placement permit a less invasive implant procedure and theoretically less post-operative morbidity.

Compared with the HeartWare system CE Mark Trial,⁷ commercial patients (patients who are not in REVOLVE Registry) were older (52.5 vs 48.5 years) with 64% more females (23% vs 14%) in the commercial group as compared with the CE Mark Trial group. More commercial patients had heart failure of idiopathic origin (65%) than was observed in the CE Mark Trial (44%). Mean BSA was similar to that of the trial population.

Survival was excellent, comparing favorably to survival reported previously for both the HeartWare system and other commercially available LVADs (Table 6). The 1-year survival in the HeartWare system CE Mark Trial was 84%, and at 2 years was 78%. We observed a 1-year survival of 85% and at 2-year survival of 79%. In the U.S. BTT trial, 1-year survival for patients with the HeartWare system was 86%,⁶ which continued with the addition of the continued

Table 2 Outcomes ($N = 254$)

Outcome	Number of patients (%)	Duration of support
Remain on device	152 (59.8%)	Mean 422 ± 279 days (range 6–1,057 days)
Transplanted	56 (22.0%)	Mean 363 ± 250 days (range 19–958 days)
Weaned after recovery	3 (1.2%)	Mean 321 ± 237 days (range 73–546 days)
Died	43 (16.9%)	Mean 159 ± 228 days (range 1–730 days)

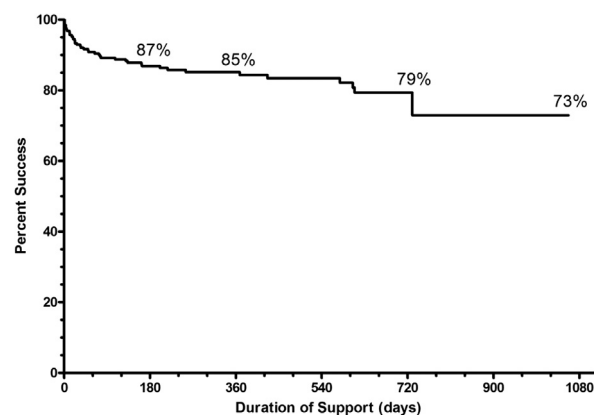


Figure 1 Kaplan–Meier estimate of success ($N = 254$).

Table 4A Adverse Events in the ReVOLVE Study (*N* = 254 with 252.6 Patient-Years of Support)

Complication	Patients with event [<i>n</i> (%)]	Number of events	Event rate (EPY)
Bleeding	71 (28)	101	0.40
Gastrointestinal bleeding	12 (5)	16	0.06
Right heart failure	24 (9)	24	0.10
Stroke	20 (8)	20	0.08
Drive-line infection	14 (6)	18	0.07
Sepsis	12 (5)	12	0.05
Renal failure	10 (4)	10	0.04

access protocol (CAP) patients, where 1-year survival of 84% was reported in the BTT and CAP study.¹¹ One-year survival data reported in clinical trials for the HeartMate II device were 68% at 1 year in the pivotal trial¹² and 73% at 1 year in the continued access study.² Starling et al conducted a post-market study of the HeartMate II device and observed 85% survival at 1 year.¹³ Recent INTERMACS data indicated 1-, 2- and 3-year survival rates of 85%, 70% and 64%,¹⁴ respectively, compared with 85%, 79%, and 73% reported here, although there was a materially lower transplant rate in the ReVOLVE study than in the work by Starling and colleagues.

A comparison of major adverse events in ReVOLVE and among various trials is presented in Table 4B to provide context for evolution of patient outcomes. Statistical comparisons cannot be made as these trials were not randomized in a head-to-head manner.

The pericardial placement of the pump and avoidance of an abdominal pump pocket as required for other LVAD systems may reduce the incidence of post-operative bleeding and infection. Although it is difficult to directly compare bleeding rates among studies and devices due to differences in reporting and definitions, it does appear that the HVAD has a lower risk of re-operative bleeding than the HeartMate II, which has demonstrated bleeding episodes requiring re-operation in clinical trials at a rate of 0.45 to 0.78 EPY,^{2,12} and in the post-market study the overall bleeding rate was reported at 1.44 EPY.¹³ In the U.S. BTT trials, bleeding events requiring re-operation were noted to occur at a rate of 0.19 to 0.26 EPY.^{6,11} Nevertheless, we still observed bleeding events in 28% of patients at a rate of 0.40 EPY, which included post-operative bleeding, tamponade, and bleeding that required transfusion or re-operation. Bleeding appeared to occur at a rate similar to that observed in the CE Mark Trial, where bleeding other than tamponade occurred in 30% of patients at a rate of 0.33 EPY.⁷ These findings should be compared with less invasive implant techniques (thoracotomy) in future investigations.

Pericardial placement and the small size of the HVAD allows for the use of minimally invasive implant techniques, which may further minimize bleeding events. Anti-coagulation management, device design improvements and minimally invasive implant techniques continue to evolve, which could lead to lower rates of bleeding. The rate of GI bleeding observed in the ReVOLVE study was quite low, occurring in 5% of patients (0.06 EPY). The incidence of GI bleeding was reported to occur in 10% of 1,496 post-trial patients receiving a HeartMate II device for BTT (0.38 EPY),¹⁵ which is higher than what we observed. In more rigorous clinical trial settings of the U.S. BTT and CAP studies, gastrointestinal bleeding

Table 4B Comparative Adverse Events

Complication	ReVOLVE (<i>N</i> = 254) [% EPY] (252.6 PY)	Strueber et al ⁷ (<i>N</i> = 50) [% EPY] (47.8 PY)	Aaronson et al ⁶ (<i>N</i> = 140) [% EPY] (89.1 PY)	Slaughter et al ¹¹ (<i>N</i> = 322) [% EPY] (305.9 PY)	Miller et al ¹² (<i>N</i> = 133) [% EPY] (61.7 PY)	Pagani et al ² (<i>N</i> = 281) [% EPY] (181.8 PY)	Starling et al ¹³ (<i>N</i> = 169) [% EPY] (142.0 PY)	John et al ¹⁵ (<i>N</i> = 1,496) [% EPY] (1081.8 PY)
Re-operative bleeding	NR	20%, 0.23	14.3%, 0.26	14.8%, 0.19	31%, 0.78	26%, 0.45	NR	7%, 0.12
Gastrointestinal bleeding	5%, 0.06	NR	10.7%, 0.23	12.7%, 0.27	NR	NR	NR	10%, 0.38
Right heart failure	9%, 0.10	12%, 0.12	19.2%, 0.33	19.3%, 0.33	17%, 0.36	19%, 0.29	14.8%, 0.18	12%, 0.18
Stroke	8%, 0.08	12%, 0.12	12.8%, 0.20	14.8%, 0.18	9%, 0.20	9%, 0.15	6.5%, 0.08	6 %, 0.10
Drive-line infection	6%, 0.07	18%, 0.20	12.1%, 0.29	16.5%, 0.25	14%, 0.37	14%, 0.31	17.8%, 0.32	13%, 0.28
Sepsis	5%, 0.05	10%, 0.10	11.4%, 0.24	17.2%, 0.23	20%, 0.62	17%, 0.35	18.9%, 0.33	11%, 0.22
Renal failure	4%, 0.04	10%, 0.10	8.6%, 0.16	9.6%, 0.13	14%, 0.31	11%, 0.17	10.1%, 0.13	9%, 0.14
Exchange for thrombus	3.1%, 0.03	8.0%, 0.08	3.5%, 0.05	4.2%, 0.05	2%, 0.03	1.4%, 0.02	1.2%, 0.01	1%, 0.02

Stroke events include all hemorrhagic and ischemic cerebrovascular accidents, and right heart failure includes right ventricular assist device or inotropic support requirements. However, inotrope requirements differed: the HeartMate II required 2 weeks and the HVAD required 1 week. EPY, events per patient-year; NR, not reported.

Table 5 Pump Thrombus (*N* = 254 With 252.6 Patient-Years of Support)

	Patients with event [<i>n</i> (%)]	Number of events	Event rate (EPY)
Pump thrombus	17 (6.7)	22	0.09
Pump replaced	8 (3.1)	8	0.03

One patient had 2 pump thrombus events, 1 successfully treated with medical therapy and 1 (occurring >1 year later) requiring exchange after failed medical treatment. EPY, events per patient-year.

was reported to occur in 10.7% to 12.7% of HVAD patients (0.23 to 0.27 EPY).^{6,11} This may have been due to differences in axial vs centrifugal pump designs, or patient management strategies.

Drive-line exit site infections and sepsis were very low (0.07 and 0.05 EPY, respectively) compared with the CE Mark Trial (0.20 and 0.10 EPY, respectively). Special infection prophylaxis programs that were started in some participating centers may have become effective and could help to explain this finding.¹⁵ The rate of drive-line infections observed with the HVAD system (0.07 EPY) was also favorable when compared with rates of 0.32 and 0.28 EPY previously reported for HeartMate II patients by Starling et al¹³ and John et al,¹⁵ respectively.

Adverse event rates for stroke, sepsis, right heart failure, renal failure and pump exchange for thrombus were all lower in the commercial group than those seen in the HeartWare system CE Mark Trial. Strokes occurred in 8% of patients at a rate of 0.08 EPY, compared with the CE Mark Trial, which reported strokes in 12% of patients at a rate of 0.13 EPY. In the U.S. BTT study an even higher rate of overall strokes of 0.20 EPY (in 12.8% of patients) was reported.⁶ Herein we did not differentiate between hemorrhagic and embolic events, but instead gave the overall rate. However, we believe that vigorous control of anti-coagulation and less aggressive protocols for outpatient follow-up may have contributed to this favorable outcome. The incidence and rate of strokes was similar to that

reported for commercial BTT use of the HeartMate II as described by Starling et al¹³ (7%, 0.08 EPY) and John et al¹⁵ (6%, 0.10 EPY).

Pump exchange for suspected thrombus occurred at a rate of 0.03 EPY in the ReVOLVE study, compared with 0.08 EPY in the CE Mark Trial. The incremental improvements in adverse events compared with the CE Mark Trial may be a reflection of increased user experience with the device and patient management.

Limitations

The ReVOLVE study data were collected retrospectively, and therefore comparisons to clinical trials and other post-market trials should be interpreted with caution due to inherent differences in reporting and trial design. Variability may also exist in patient selection and management at the different ReVOLVE participating centers. Finally, as with other registries, the data were not monitored, and therefore reporting inconsistencies and/or data collection biases cannot be excluded.

In conclusion, the excellent survival and low occurrence of adverse events observed in commercial use of the HVAD system in advanced heart failure continues to support its safety and effectiveness in this population. In addition, the adverse event profile has exhibited improvement since the clinical trial. This highlights the importance of increased experience with this device at participating centers. Further, the study has demonstrated excellent outcomes when moving from clinical trial setting to commercial, real-world use of this technology.

Disclosure statement

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Table 6 Comparison of ReVOLVE Study Data vs Outcomes with HVAD and HeartMate II LVADs

Reference	Study	Enrollment period	<i>N</i>	K-M survival	
				30 days	1 year
Strueber et al ⁷	CE Mark HVAD BTT Trial	3/2006 to 12/2008	50	NR	84%
Aaronson et al ⁶	Pivotal U.S. HVAD (ADVANCE) BTT Trial	8/2008 to 8/2010	140	99%	86%
Slaughter et al ¹¹	U.S. BTT+CAP HVAD Trial	8/2008 to 12/2011	332	> 97%	84%
Miller et al ¹²	Pivotal U.S. HeartMate II BTT Trial	3/2005 to 5/2006	133	89%	68%
Pagani et al ²	U.S. BTT+CAP HeartMate II Trial	3/2005 to 3/2007	281	92%	73%
Starling et al ¹³	Post-Approval HeartMate II BTT registry	4/2008 to 8/2008	169	96%	85%
John et al ¹⁵	Post-market registry	4/2008 to 9/2010	1,496	96%	85%
Current ReVOLVE	Post-CE Mark HVAD commercial registry	2009 to 2012	254	93%	85%

K-M, KaplanMeier. See text for other abbreviations; NR, not reported.

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