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INTERMACS ANNUAL REPORT

Seventh INTERMACS annual report: 15,000 patients and counting

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INTERMACS;
mechanical support;
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The seventh annual report of the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) summarizes the first 9 years of patient enrollment. The Registry includes >15,000 patients from 158 participating hospitals. Trends in device strategy, patient profile at implant and survival are presented. Risk factors for mortality with continuous-flow pumps are updated, and the major causes/modes of death are presented. The adverse event burden is compared between eras, and health-related quality of life is reviewed. A detailed analysis of outcomes after mechanical circulatory support for ambulatory heart failure is presented. Recent summary data from PediMACS and MedaMACS is included. With the current continuous-flow devices, survival at 1 and 2 years is 80% and 70%, respectively.

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The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS),[1] a public–private partnership among the National Heart, Lung and Blood Institute (NHLBI), hospitals and industry, enters its ninth year of data collection. This report focuses on the ongoing experience with continuous-flow (CF) devices, presents recent activity with the total artificial heart, updates enrollment in the pediatric component of INTERMACS (PediMACS), summarizes enrollment in the medical arm of the Registry (MedaMACS), and provides a special analysis of mechanical circulatory support (MCS) therapy in ambulatory heart failure patients.

Patient and site enrollment

Between June 23, 2006 and December 31, 2014, 15,745 patients who received a U.S. Food and Drug Administration (FDA)-approved MCS device were entered into the INTERMACS database. Of the 158 participating hospitals, 123 (78%) were certified by the Joint Commission for destination therapy (DT). The rate of patient enrollment has continued at a pace exceeding 2,000 patients per year.

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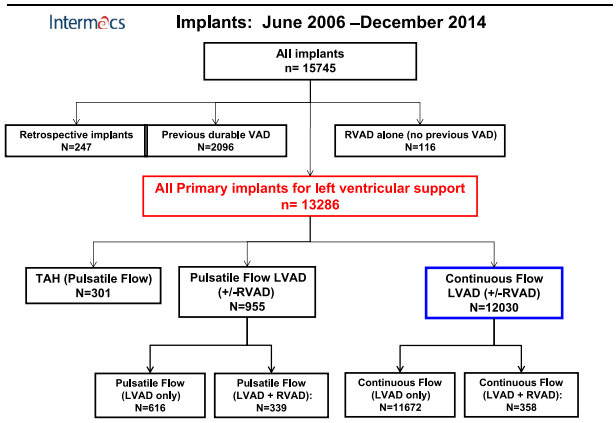

Figure 1 Summary of INTERMACS implants. VAD, ventricular assist device; R, right; L, left; TAH, total artificial heart.

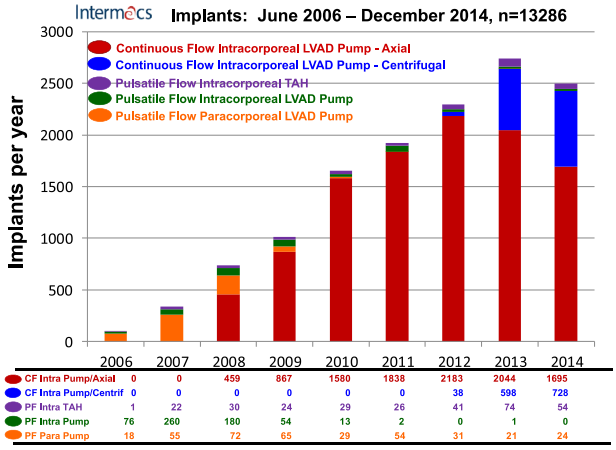

Figure 2 Distribution of device types by year of implant. LVAD, left ventricular assist device; TAH, total artificial heart; CF, continuous flow; PF, pulsatile flow.

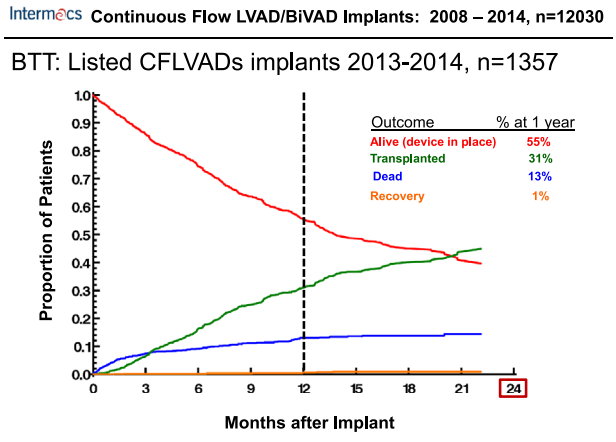

Figure 3 Competing outcomes depiction for continuous-flow left ventricular assist devices (CFLVADs) that were implanted with the bridge-to-transplant (BTT) strategy. Note that the sum of the proportion of patients with each outcome event equals 1 at each time-point.

Of the 12,030 patients who received a CF device, >90% received a left ventricular assist device (LVAD) only (Figure 1). The adult durable devices entered into this database are included in Table 1. The HeartMate II

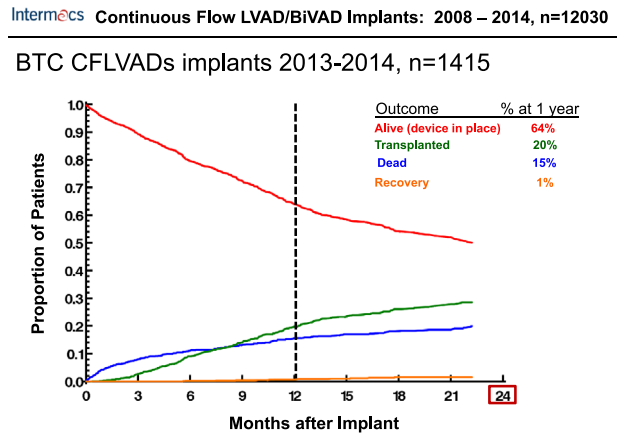

Figure 4 Competing outcomes depiction for continuous-flow left ventricular assist devices (CFLVADs) that were implanted with the bridge-to-candidacy (BTC) strategy.

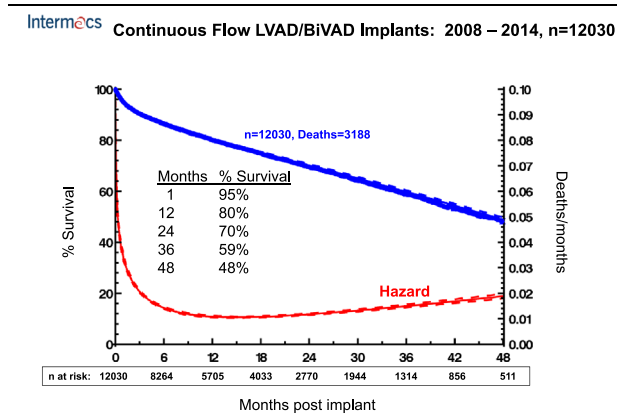

Figure 5 Parametric survival curve and associated hazard function with the 70% confidence limit for survival after implantation of a continuous-flow left ventricular assist device (LVAD) or biventricular assist device (BiVAD). The number of patients at risk during each time interval is indicated below.

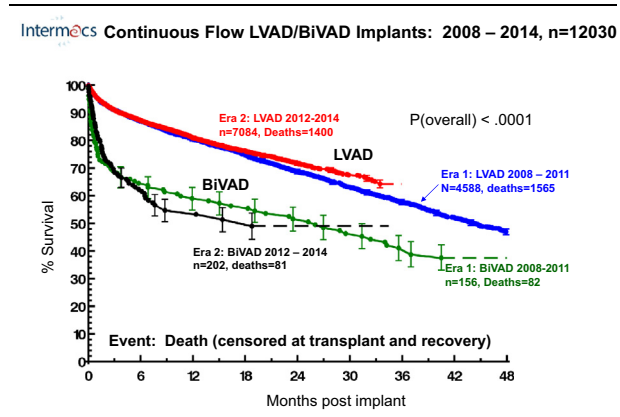

Figure 6 Actuarial survival curve for continuous-flow LVADs and BiVADs, stratified by era. The error bars indicate ±1 SE. LVAD, left ventricular assist device; BiVAD, biventricular assist device.

(Thoratec, Pleasanton, CA) axial-flow pump was approved for bridge-to-transplant (BTT) therapy in 2008, and for DT in 2010. The HeartWare HVAD (HeartWare International,

Table 1 FDA-approved Adult Durable Devices Included in INTERMACS

Type	Device
Durable devices	
Continuous flow	Thoratec HeartMate II
	HeartWare HVAD
	MicroMed DeBakey Child VAD
Pulsatile extracorporeal	Thoratec PVAD
Pulsatile intracorporeal	HeartMate IP
	HeartMate VE
	HeartMate XVE
	Thoratec IVAD NovaCor
	PC NovaCor PCq
Total artificial heart	SynCardia CardioWest

FDA, U.S. Food and Drug Administration; VAD, ventricular assist device.

Inc., Framingham, MA) centrifugal-flow pump was approved for BTT on November 20, 2012.

The continued dominance of CF technology is evident (Figure 2), with >90% of patients receiving an intracorporeal CF pump. During 2014, approximately twice the number of axial-flow CF pumps, as compared with centrifugal-flow CF pumps, were entered into the Registry. It should be noted that the total numbers and trends for durable device implantation do not include patients enrolled in the investigational arm of regulatory trials.

Device strategy

The progressive increase in VADs implanted for DT, evident between 2008 and 2013, plateaued in 2014, with nearly 46% of implants designated as DT (Table 2). Thirty percent of patients were listed for heart transplantation at the time of device implant, and an additional 23% were implanted with an anticipated possibility of listing ("bridge to candidacy").

By competing outcomes analysis, about 30% of patients have undergone heart transplantation within 1 year if listed at time of implant (Figure 3). When patients were not actually listed for transplantation at the time of device implant, the likelihood of transplantation within 1 year has fallen to 20% (Figure 4). This is likely related to the burden of comorbidities at implant that excluded patients from transplantation and have not been resolved during VAD therapy.

Table 2 CF and BiVAD Implants: April 2008 to December 2014 (n = 12,030)

	Implant era (years)									
	2008 to 2011		2012		2013		2014		Total	
Device strategy at time of implant	N	%	N	%	N	%	N	%	N	%
BTT listed	1,529	32.2%	404	18.2%	623	23.6%	734	30.3%	3,290	27.3%
BTT likely	1,163	24.5%	513	23.1%	511	19.3%	323	13.3%	2,510	20.9%
BTT moderate	480	10.1%	230	10.4%	273	10.3%	187	7.7%	1,170	9.7%
BTT unlikely	164	3.5%	73	3.3%	67	2.5%	54	2.2%	358	3.0%
DT	1,355	28.6%	983	44.2%	1,152	43.6%	1,108	45.7%	4,598	38.2%
BTR	29	0.6%	11	0.5%	10	0.4%	4	0.2%	54	0.5%
Rescue therapy	15	0.3%	7	0.3%	6	0.2%	10	0.4%	38	0.3%
Other	9	0.2%	0	0%	0	0%	3	0.1%	12	0.1%
Total	4,744	100%	2,221	100%	2,642	100%	2,423	100%	12,030	100%

BiVAD, biventricular assist device; BTR, bridge to recovery; BTT, bridge to transplant; CF, continuous flow; DT, destination therapy.

Table 3 CF LVAD/BiVAD Implants: April 2008 to December 2014 (n = 12,030)

	Implant date era					
	2008 to 2011		2012 to 2014		Total	
Patient profile at time of implant	*N*	%	*N*	%	*N*	%
1—Critical cardiogenic shock	465	16.0%	961	14.3%	1,803	15.0%
2—Progressive decline	1,249	43.0%	2,416	36.0%	4,507	37.5%
3—Stable but inotrope-dependent	660	22.7%	1,987	29.6%	3,471	28.8%
4—Resting symptoms	372	12.8%	968	14.5%	1,646	13.7%
5—Exertion-intolerant	83	2.9%	198	3.0%	331	2.7%
6—Exertion-limited	48	1.6%	81	1.2%	141	1.2%
7—Advanced NYHA Class III	29	1.0%	44	0.7%	76	0.6%
Not specified[a]	0	0%	46	0.7%	55	0.5%
Totals	2,906	100%	6,701	100%	12,030	100%

CF, continuous flow; NYHA, New York Heart Association.

[a]Due to change in web-based data entry capture in Protocol v3.0 (May 2012).

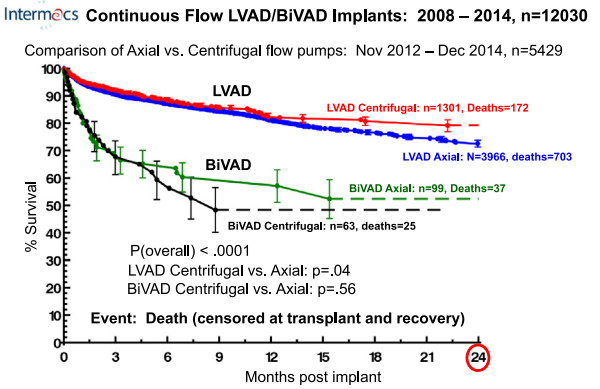

Figure 7 Actuarial survival curve for continuous-flow LVAD and BiVAD patients, stratified by pump type. The depiction is as shown in Figure 6.

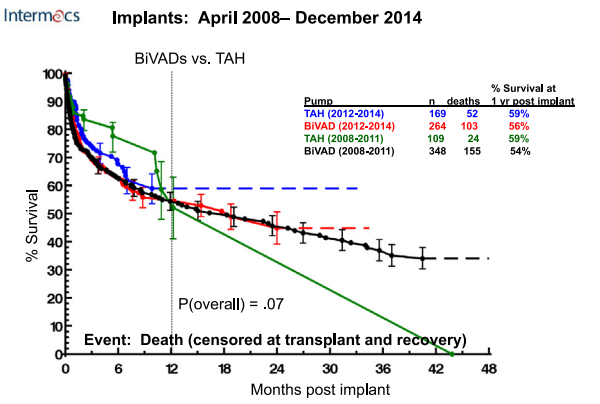

Figure 8 Actuarial survival curves stratified by BiVAD vs total artificial heart (TAH) and by era. The depiction is as shown in Figure 6.

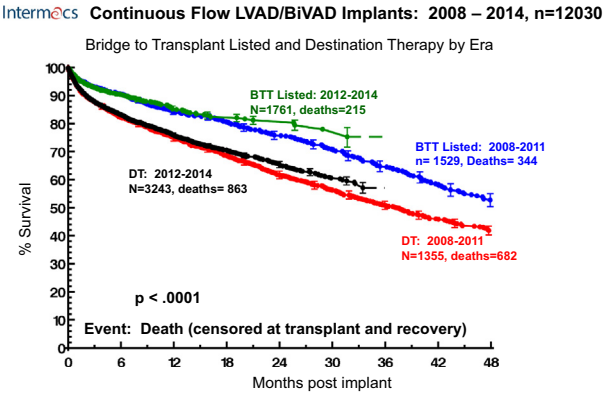

Figure 9 Actuarial survival curves stratified by implant strategy and era. BTT, bridge to transplant; DT, destination therapy. The depiction is as shown in Figure 6.

Patient profile at implant

The proportion of patients in cardiogenic shock at the time of implant has remained stable at about 15% since 2008 (Table 3). The proportion of patients in INTERMACS Level

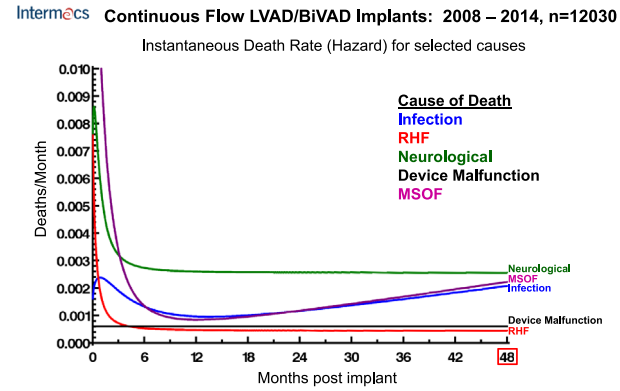

Figure 10 Hazard function curves indicating the instantaneous risk of death over time for the major causes/modes of death. RHF, right heart failure; MSOF, multisystem organ failure.

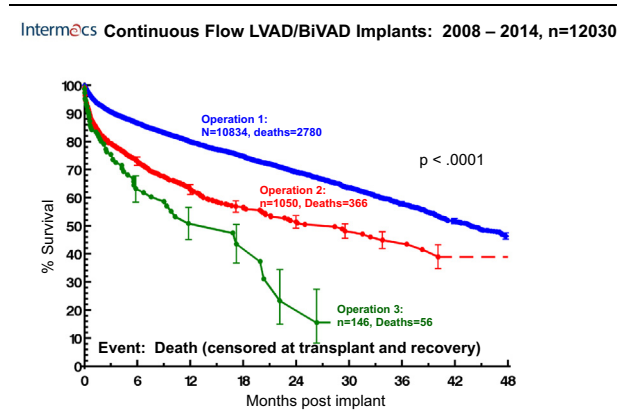

Figure 11 Actuarial survival stratified by the whether the VAD implant represented the original operation (blue curve), the second operation (first pump replacement) (red curve) or the third operation (second pump replacement) (black curve). The depiction is as shown in Figure 6.

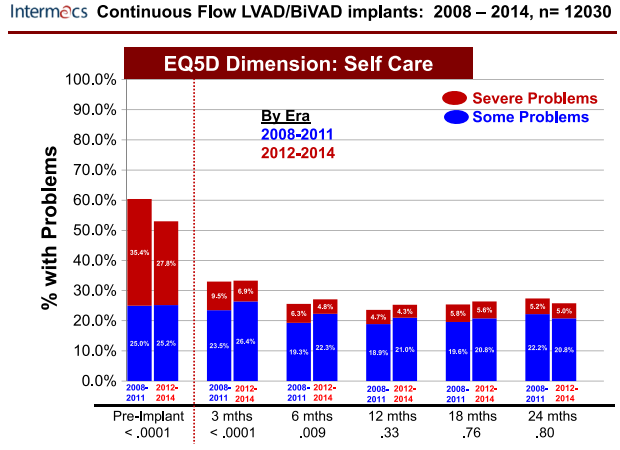

Figure 12 Health-related quality of life at specified time-points before and after VAD implant for the EQ-5D dimension of Self-care. Two different eras are depicted at each time-point. The red shading indicates percent of patients with severe problems and blue shading indicates the percent of patients with some problems.

Table 4 Adult Primary CF LVADs and BiVADs Implants: April 2008 to December 2014 ($n = 12,030$)

	Early hazard		Late hazard	
Risk factors for death	Hazard ratio	*p*-value	Hazard ratio	*p*-value
Demographics				
Age (older)	1.03	<0.0001	20.75	0.008
Female	1.32	<0.0001		
BMI (higher)	1.10	<0.0001		
Blood type not O			10.24	0.004
Clinical status				
History of stroke	1.33	0.03		
Ventilator	1.25	0.02		
ICD	1.30	0.0001		
INTERMACS Level 1	1.55	<0.0001		
INTERMACS Level 2	1.37	<0.0001		
NYHA Class IV			10.23	0.03
Destination therapy	1.23	<0.0001		
Non-Cardiac Systems				
Albumin (lower)	1.14	0.0007		
Creatinine (higher)	1.06	0.04	10.15	0.002
Dialysis	2.34	<0.0001		
BUN (higher)	1.05	<0.0001		
Right heart dysfunction				
Right atrial pressure (higher)	1.13	0.0004		
RVAD in same operation	2.57	<0.0001		
Bilirubin (higher)	1.48	<0.0001		
Surgical complexities				
History of cardiac surgery	1.24	0.003		
History of CABG	1.17	0.04		
Concomitant cardiac surgery	1.26	<0.0001		

BiVAD, biventricular assist device; BMI, body mass index; BUN, blood urea nitrogen; CABG, coronary artery bypass graft; CF, continuous flow; ICD, implantable cardioverter-defibrillator; LVAD, left ventricular assist device; NYHA, New York Heart Association; RVAD, right ventricular assist device.

II or III remains at about 65%. Patients with ambulatory heart failure comprise about 20% of implants.

Survival with CF pumps

The updated survival curve for CF devices implanted since 2008 shows an overall 1-year survival of 80% and 2-year survival of 70% (Figure 5). Survival with biventricular VAD (BiVAD) support has remained inferior to that of isolated LVAD (Figure 6). In the most recent era, only about 50% of patients are alive with BiVAD support at 1 year. Survival with axial-flow and centrifugal-flow pumps, unadjusted for risk, is depicted in Figure 7. Early and mid-term survival with a total artificial heart is currently somewhat better than with BiVAD support, but the patient groups may not be comparable (Figure 8).

Risk factors for mortality with CF technology

Table 4 lists the updated risk factors for mortality with CF devices through December 2014. Type of CF pump was not a risk factor for mortality. The updated stratified actuarial depictions to illustrate the effect of each risk factor can be found on the INTERMACS website (www.intermacs.org). Survival among DT patients has continued to be somewhat worse than among BTT patients, and this relationship has not changed very much over time (Figure 9). In the most recent era, survival with DT therapy at 1 and 3 years is 76% and 57%, respectively.

Causes/modes of death

The hazard functions for the major causes/modes of death are depicted in Figure 10. Neurologic events, right heart failure and multisystem organ failure are the predominant causes or modes of death early after implantation, whereas infection, multiorgan system failure and neurologic events are the major causes/modes of late mortality. In this analysis, the risk of death from device malfunction appears to be low and constant over time.

Adverse events

In Table 5, adverse event rates during the first year after implant are depicted for 2 eras. The overall adverse event burden is significantly lower in the most recent era. However, increasing event rates can be observed for hemolysis, stroke, renal dysfunction and respiratory failure.

Pump exchange

The complex issue of pump thrombosis for the HeartMate II device has been extensively reported elsewhere.[2,3] The overall rate of pump exchange for any reason for all CF pumps has continued to be somewhat higher in the more recent era. Of importance, the decrement in survival after each subsequent pump exchange is evident (Figure 11).

Quality of life

The EQ-5D Visual Analog Scale (VAS) and determination of specific dimensions continue to be the mainstay of our health-related quality of life (HRQOL) assessment. The trend of early, substantial improvement in these HRQOL indicators (Figures 12 to 14) has been maintained out to 2 years. There continues to be little difference by era.

MCS for ambulatory heart failure

In the INTERMACS classification, Levels 4 to 7 describe ambulatory advanced heart failure.[4] The difficulty in obtaining accurate information on this patient group is underscored by our finding that only about 20% of implants occur in patients with ambulatory heart failure

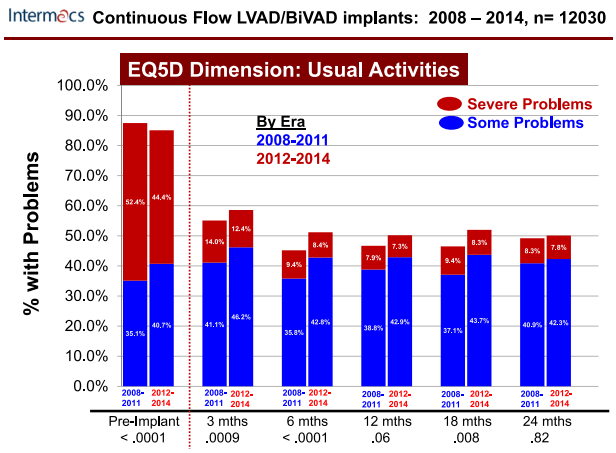

Figure 13 Health-related quality of life at various time-points before and after VAD implant, for the EQ-5D dimension of Usual Activities. The depiction is as shown in Figure 12.

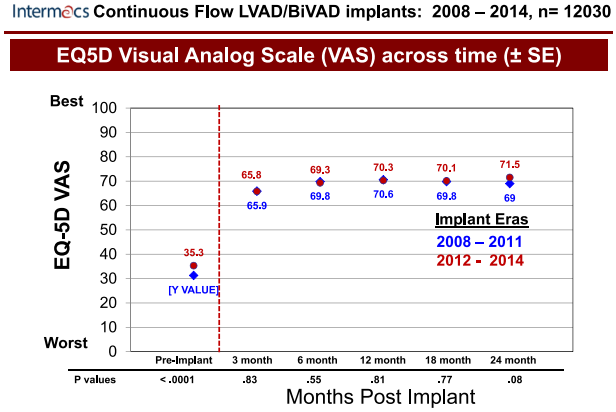

Figure 14 Visual Analog Scale at specified time-points before and after VAD implant.

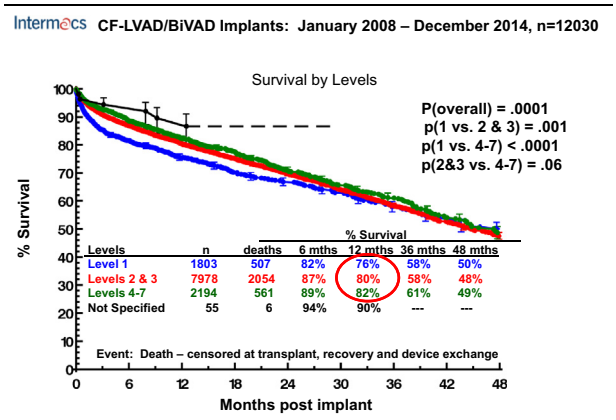

Figure 15 Actuarial survival after continuous-flow VAD implant, stratified by INTERMACS level at the time of implant. The depiction is as shown in Figure 6.

(see Table 3). Early and mid-term survival among patients at Level 1 continues to be significantly worse than for less sick profiles. However, survival in Levels 2 and 3 is nearly superimposable on the survival curve for Levels 4 through 7 (Figure 15). In the current era

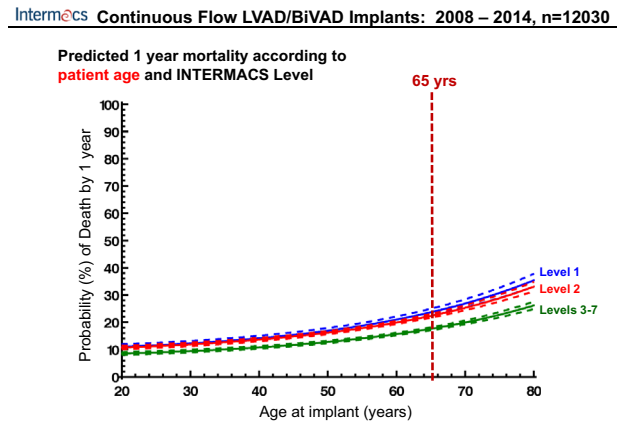

Figure 16 Nomogram depicting the solution to the multivariable equation for death by 1 year, depicting the interaction between patient age and INTERMACS level.

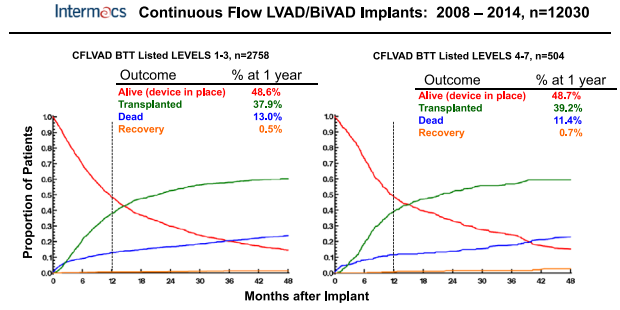

Figure 17 Competing outcomes depictions comparing bridge-to-transplant strategies for patients in Levels 1 to 3 compared with Levels 4 to 7. The depiction is as shown in Figure 3.

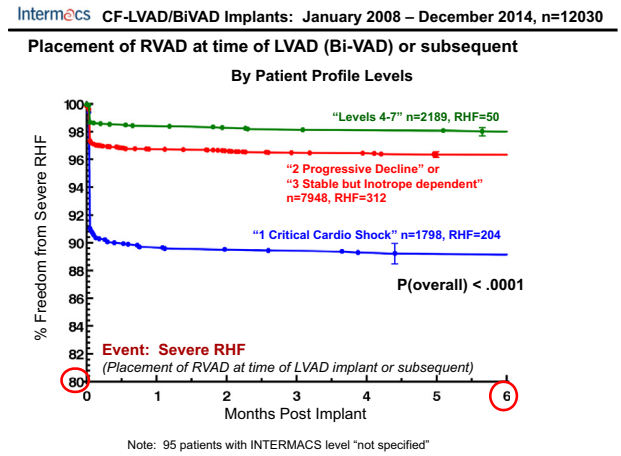

Figure 18 Actuarial freedom from severe right heart failure (RHF), stratified by INTERMACS level at implant. Note that the vertical scale ranges from 80% to 100%.

(2012 to 2014), 1- and 2-year survival for patients implanted in Levels 4 to 7 (ambulatory heart failure) is 81% and 72%, respectively. The interaction between advancing age and INTERMACS level is depicted in Figure 16. In contrast to more critically ill patients, the 1-year survival for ambulatory heart failure patients is less dramatically affected by older age.

Table 5 Adverse Event Rates (Events/100 patient months) in the First 12 Months Post-implant by Era for CF LVADs/BiVADs (n = 12,030)

	Era 1 (n = 4,744): continuous 2008 to 2011		Era 2 (n = 7,286): continuous 2012 to 2014		Era 1 vs Era 2: 2008 to 2011 / 2012 to 2014	
Adverse event	Events	Rate	Events	Rate	Ratio	p-value
Bleeding	3,932	9.41	4,420	7.79	1.21	<0.0001
Cardiac/vascular						
Right heart failure	238	0.57	276	0.49	1.17	0.07
Myocardial infarction	29	0.07	34	0.06	1.16	0.55
Cardiac arrhythmia	2,007	4.80	2,303	4.06	1.18	<0.0001
Pericardial drainage	271	0.65	305	0.54	1.21	0.02
Hypertension	182	0.44	115	0.20	2.15	<0.0001
Arterial non-CNS thrombosis	70	0.17	94	0.17	1.01	0.93
Venous thrombotic event	304	0.73	286	0.50	1.44	<0.0001
Hemolysis	200	0.48	314	0.55	0.87	0.11
Infection	3,435	8.22	4,132	7.28	1.13	<0.0001
Stroke	487	1.17	916	1.61	0.72	<0.0001
Renal dysfunction	601	1.44	876	1.54	0.93	0.19
Hepatic dysfunction	246	0.59	326	0.57	1.02	0.76
Respiratory failure	1,104	2.64	1,551	2.73	0.97	0.39
Wound dehiscence	81	0.19	96	0.17	1.15	0.36
Psychiatric episode	486	1.16	525	0.93	1.26	0.0003
Total burden	13,673	32.72	16,569	29.20	1.12	<0.0001

BiVAD, biventricular assist device; CF, continuous flow; CNS, central nervous system; LVAD, left ventricular assist device.

Ambulatory patients who receive devices while awaiting heart transplantation appear to have no particular advantage or disadvantage regarding access to organs when compared with Profiles 1 to 3, with just under 40% undergoing transplantation within 1 year (Figure 17).

When comparing the primary causes/mode of death by INTERMACS levels, no major differences could be seen between Levels 1 to 3 and 4 to 7 (Tables 6 and 7).

The susceptibility to adverse events in ambulatory heart failure patients appears primarily relevant for cardiac-related adverse events. For example, severity of post-implant right heart failure is highly dependent on INTERMACS level at implantation. Ambulatory heart failure patients are considerably less likely to have advanced right heart failure compared with patients in INTERMACS Levels 1 and 2 (Figure 18). With regard to other adverse events, ambulatory heart failure patients appear equally susceptible to stroke events (Figure 19), infection episodes (Figure 20), combined adverse events (Figure 21) and hospital re-admissions (Figure 22).

Table 6 CF LVAD/BiVAD Implants: 2008 to 2014 (n = 12,030), Levels 1 to 3 (n = 9,781, deaths = 2,596)

Primary cause/mode of death	n	%
Neurologic event	466	18.0
Multisystem organ failure	406	15.6
Withdrawal of support, specify	271	10.4
Major infection	228	8.8
Other, specify	135	5.2
Respiratory: respiratory failure	124	4.8
Circulatory: right heart failure	117	4.5
Circulatory: sudden unexplained death	111	4.3
Device malfunction	92	3.5
Circulatory: CHF	85	3.3

BiVAD, biventricular assist device; CF, continuous flow; CHF, congestive heart failure.

PediMACS

The pediatric component of INTERMACS began collecting all pediatric data (patients <19 years of age) in September 2012. Through April 2015, 36 centers have enrolled 251 devices in 216 patients (Figure 23). The durable and temporary mechanical circulatory devices that have been entered into the Registry are included in Table 8.

During the period September 19, 2012 through December 31, 2014, among patients up to 5 years of age, pulsatile LVADs (Berlin Heart EXCOR; Berlin Heart Steglitz,

Table 7 CF LVAD/BiVAD Implants: 2008 to 2014 (n = 12,030), Levels 4 to 7 (n = 2,194, deaths = 579)

Primary cause/mode of death	n	%
Neurologic event	118	20.4
Multisystem organ failure	81	14.0
Withdrawal of support, specify	64	11.1
Major infection	44	7.6
Respiratory: respiratory failure	35	6.0
Other, specify	29	5.0
Circulatory: sudden unexplained death	28	4.8
Device malfunction	23	4.0
Circulatory: right heart failure	20	3.5
Circulatory: other, specify	17	2.9

CF, continuous flow.

Table 8 FDA-approved Devices—Pediatrics (<19 years)

Type	Device
Durable devices	
Continuous flow	Thoratec HeartMate II
	HeartWare HVAD
Pulsatile extracorporeal	Berlin Heart EXCOR
Total artificial heart	SynCardia CardioWest
Temporary devices	
Short-term devices	Abiomed AB5000
	Thoratec CentriMag
	Tandem Heart Sorin
	Revolution Impella 2.5
	Thoratec PediMag
	Maquet Rotaflow

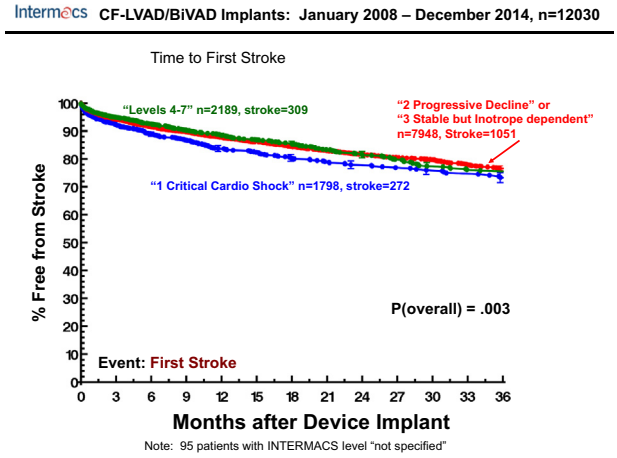

Figure 19 Actuarial freedom from first stroke, stratified by INTERMACS level at implant.

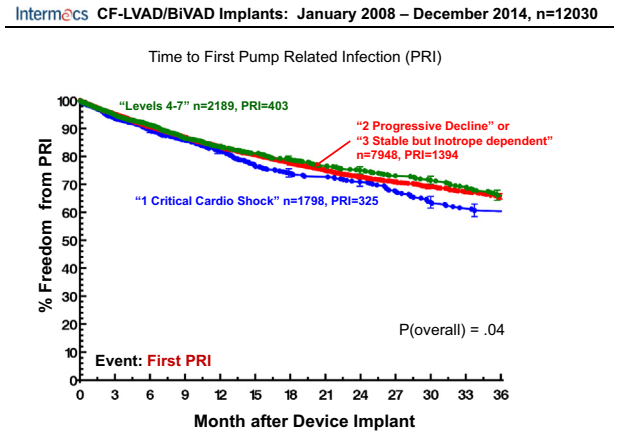

Figure 20 Actuarial freedom from first pump-related infection (PRI) stratified by INTERMACS level at implant.

Berlin, Germany) accounted for nearly 50% of implants (Table 9). Among patients 6 to 10 years of age, CF LVADs began to predominate (56% of patients). In patients 11 to 18 years of age, nearly 90% of patients received CF devices. Among patients receiving CF devices, the overall actuarial survival at 6 months has approached 90%, with 66% of patients undergoing cardiac transplantation by 12 months (Figures 24 and 25).

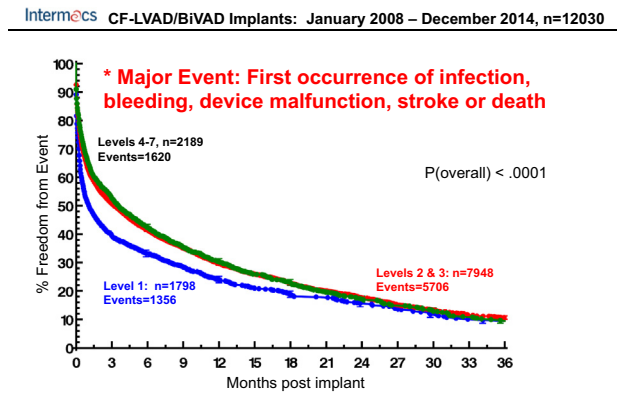

Figure 21 Actuarial freedom from the combined major event of infection, bleeding, device malfunction, stroke or death, stratified by INTERMACS level at implant.

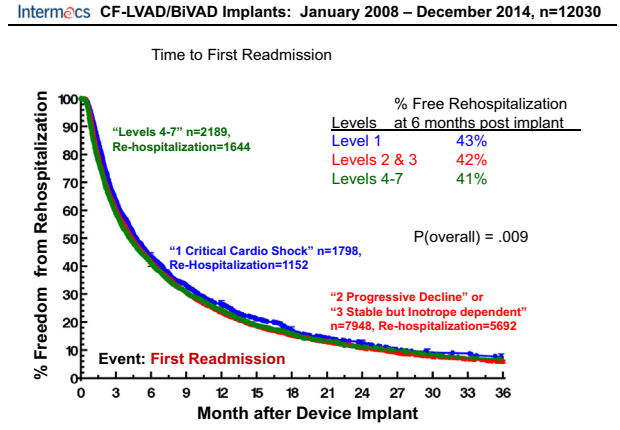

Figure 22 Actuarial freedom from rehospitalization, stratified by INTERMACS level at implant.

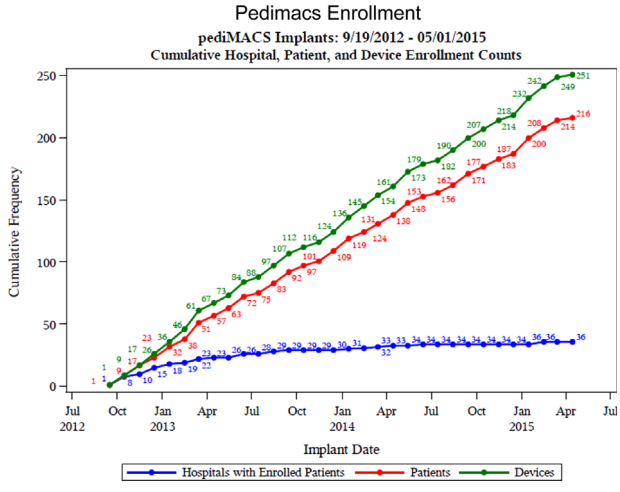

Figure 23 Cumulative depiction of hospitals with enrolled patients, devices and patients enrolled in the PediMACS Registry, September 19, 2012 to May 1, 2015.

MedaMACS

Since December 2012, MedaMACS, the medical arm of INTERMACS, has focused on data collection in ambulatory heart failure patients who have not received a

Table 9 PediMACS Implants: September 19, 2012 to December 31, 2014 ($n = 216$)

	Durable device														
	Pulsatile flow								Continuous flow						
	LVAD		RVAD		BiVAD		TAH		LVAD		RVAD		BiVAD		
Age at implant (years)	*n*	Row	*n*	Row	*n*	Row	*n*	Row	*n*	Row	*n*	Row	*n*	Row	Total (*n*)
0 to 5	43	48.9%	9	10.2%	11	12.5%	0	0.0%	23	26.1%	0	0.0%	2	2.3%	88
6 to 10	10	22.2%	1	2.2%	4	8.9%	1	2.2%	25	55.6%	0	0.0%	2	4.4%	45
11 to 18	0	0.0%	3	3.6%	6	7.2%	2	2.4%	64	77.1%	1	1.2%	9	10.8%	83
Total	90	41.7%	13	6.0%	21	25.3%	3	1.4%	112	51.9%	1	0.5%	13	3.3%	216

BiVAD, biventricular assist device; LVAD, left ventricular assist device; RVAD, right ventricular assist device; TAH, total artificial heart.

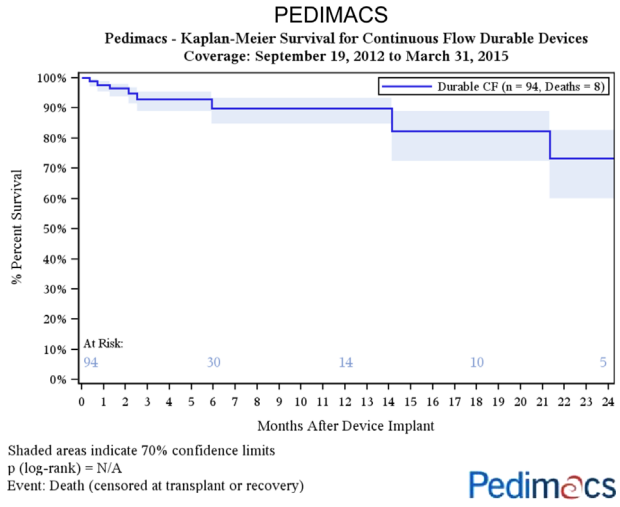

Figure 24 Actuarial survival among pediatric patients supported with a durable continuous-flow (CF) device.

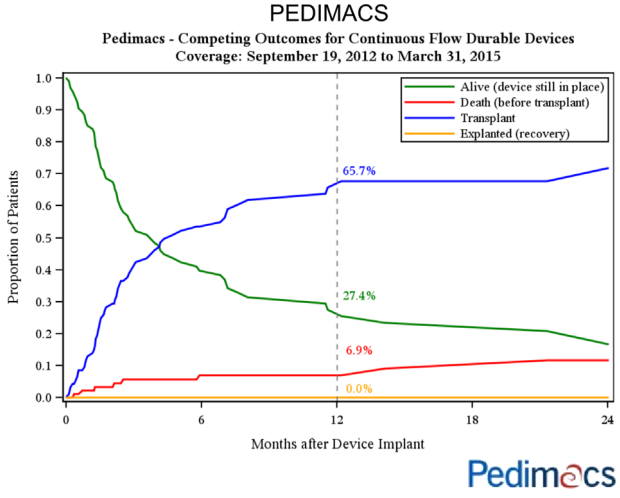

Figure 25 Competing outcomes depiction for patients with a continuous-flow pump, entered into the PediMACS Registry. The depiction is as shown in Figure 3.

durable MCS device at the time of entry into the Registry. The distribution of the 154 patients enrolled into MedaMACS is predominantly in INTERMACS Levels 5 and 6 (Table 10). VAD/transplant-free survival at 12 months has approached 75%.

Summary

- The INTERMACS database now exceeds 15,000 patients, with total implants approaching 2,500 per year.
- The 1- and 2-year survival with CF pumps is currently 80% and 70%, respectively.
- DT accounts for nearly half of all implants.
- Approximately one third of adult VAD patients receive a heart transplant by 1 year.
- Fifteen percent of all patients are implanted as INTERMACS Level 1.
- BiVAD support continues to be associated with 50% mortality at 1 year.
- Pump exchange is associated with a major reduction in subsequent 1-year survival compared with the original implant.
- With the exception of cardiac-related adverse events, freedom from major adverse events is not improved among ambulatory heart failure patients.

Table 10 MedaMACS Implants: December 12, 2012 to May 1, 2015 ($n = 154$)

Patient profile	*N*	%
1—Critical cardiogenic shock	0	0.0
2—Progressive decline	0	0.0
3—Stable but inotrope-dependent	0	0.0
4—Resting symptoms	19	12.3
5—Exertion-intolerant	45	29.2
6—Exertion limited	76	49.4
7—Advanced NYHA Class III	14	9.1
Total	154	100.0

NYHA, New York Heart Association.

- Quality of life as reported in MCS survivors remains markedly improved throughout 24 months.
- The PediMACS database now has >250 patients enrolled from more than 35 centers.
- Pediatric VAD patients have a 6-month survival approaching 90%, with two thirds of these patients receiving a heart transplant by 12 months of support.

Disclosure statement

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