
HeartWare®

HeartWare Investor Breakout Session at ISHLT

APRIL 16, 2015 · NICE, FRANCE

HeartWare

DOUG GODSHALL

PRESIDENT AND CEO

HeartWare

Safe Harbor Statement

Forward-Looking Statements

This presentation contains forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to progress and outcomes of clinical trials and registries, regulatory status, research and development activities and commercialization of the HeartWare® Ventricular Assist System. Management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on forward-looking statements because they speak only as of the date when made. HeartWare does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by federal securities laws and the rules and regulations of the Securities and Exchange Commission. HeartWare may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including without limitation those described in Part I, Item 1A. "Risk Factors" in HeartWare's Annual Report on Form 10-K filed with the Securities and Exchange Commission. HeartWare may update risk factors from time to time in Part II, Item 1A "Risk Factors" in Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, or other filings with the Securities and Exchange Commission.

Thank You to the ENDURANCE Sites

- Anthony Rongione: Fairfax Innova Research Center
- Antone Tatooles: Advocate Christ Medical Center
- Bartley Griffith: University of Maryland
- Brian Bruckner: The Methodist Hospital
- Bruce Reid: Intermountain Medical Center
- Bryan Whitson, C.B. Sai-Sudhaker: Ohio State Univ. Med
- Carmelo Milano: Duke University Medical Center
- Charles Klodell: University of Florida, Gainsville
- Christiano Caldeira: Tampa General Hospital
- Christopher Salerno: St. Vincent Health CorVasc
- Craig Selzman: University of Utah
- Dan Meyer: UT Southwestern Medical Center (Dallas)
- Daniel Goldstein: Montefiore Medical Center
- Duc Thinh Pham: Tufts Medical Center
- David Vega: The Emory Clinic
- Francis Downey: St. Luke's Medical Center
- Francis Pagani: University of Michigan Hospital
- Gonzalo Gonzalez-Stawinski: Baylor University Medical
- Hari Mallidi, Igor Gregoric: Texas Heart Institute
- Howard Song: Oregon Health & Science University
- Jamie Moriguchi: Cedars-Sinai Medical Center
- Jeffrey Miller, John O'Connell: St. Joseph Hospital Atlanta
- Johathan Philpott, Jeffrey Rich: Sentara Norfolk
- John Conte: Johns Hopkins Hospital
- Joseph Cleveland: Univ. of Colorado Hospital-Leprino
- Mark Slaughter: Jewish Hospital
- Mark Zucker: Newark Beth Israel Medical Center
- Michael Acker: University of Pennsylvania
- Michael Bowdish, Mark Barr: Univ. of Southern California
- Nadir Moazami, Barry Cabuay: Minneapolis Heart Institute
- Nahush Mokadam: University of Washington Medical
- Nicholas Smedira: Cleveland Clinic Foundation
- Octavio Pajaro, Francisco Arabia: Mayo Clinic – Phoenix
- Patrick Parrino: Jack Ochsner Heart & Vascular Institute
- Phillip Oyer: Stanford University School of Medicine
- Ranjit John: University of Minnesota
- Robert Brewer: Henry Ford Hospital
- Robert Kormos: UPMC Presbyterian
- Salpy Pamboukian: University of Alabama - Birmingham
- Samer Najjar: Washington Hospital Center
- Sandra Chaparro, Raymond Hershberger: Univ. of Miami
- Scott Silvestry, Akinobu Itoh: Washington Univ./Barnes
- Soon Park, Lyle Joyce: Mayo Rochester-St. Mary's Hospital
- Thomas Wozniak: IU Health Methodist Hospital
- Travis Abicht, Ed McGee: Northwestern Memorial
- Valluvan Jeevanandam: University of Chicago
- Walter Dembitsky: Sharp Memorial
- Walter Pae: Milton S. Hershey Medical Center
- Yoshifumi Naka: NY Presbyterian-Columbia University

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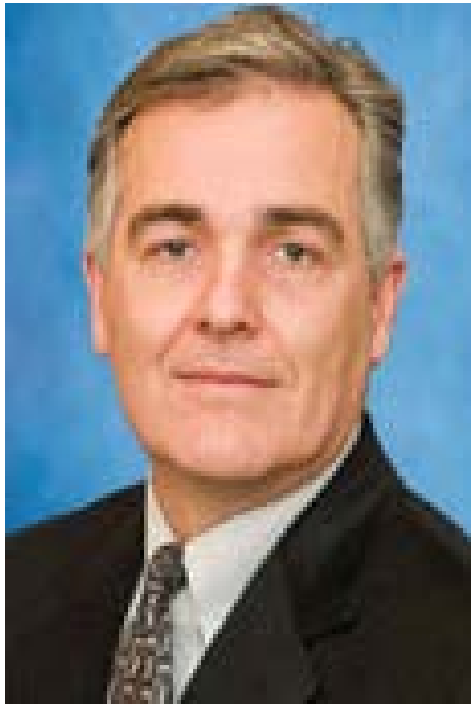
Special Thanks to Our Principal Investigators



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HeartWare HVAD for the Treatment of Patients with Advanced Heart Failure Ineligible for Cardiac Transplantation: Results of the ENDURANCE Destination Therapy Trial

FD Pagani[1], CA Milano[2], AJ Tatooles[3], G Bhat[3], MS Slaughter[4], EJ Birks[4], SW Boyce[5], SS Najjar[5], V Jeevanandam[6], AS Anderson[7], ID Gregoric[8], RM Delgado[9], K Leadley[10], KD Aaronson[1], JG Rogers[2]

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ISHLT 35th Annual Meeting and Scientific Sessions

15-18th April, 2015, Nice, France

hVAD® ENDURANCE Trial

Study Timelines

CAP initiated

FDA Approval, November 2012

ADVANCE (BTT+CAP)

BTT enrollment complete

Favorable FDA panel recommendation

2008 2009 2010 2011 2012 2013 2014 2015

DT enrollment begins

DT enrollment complete

Primary Endpoint complete

ENDURANCE (DT)

Improved Pump Sintering/Coring Tool

ENDURANCE Supplemental

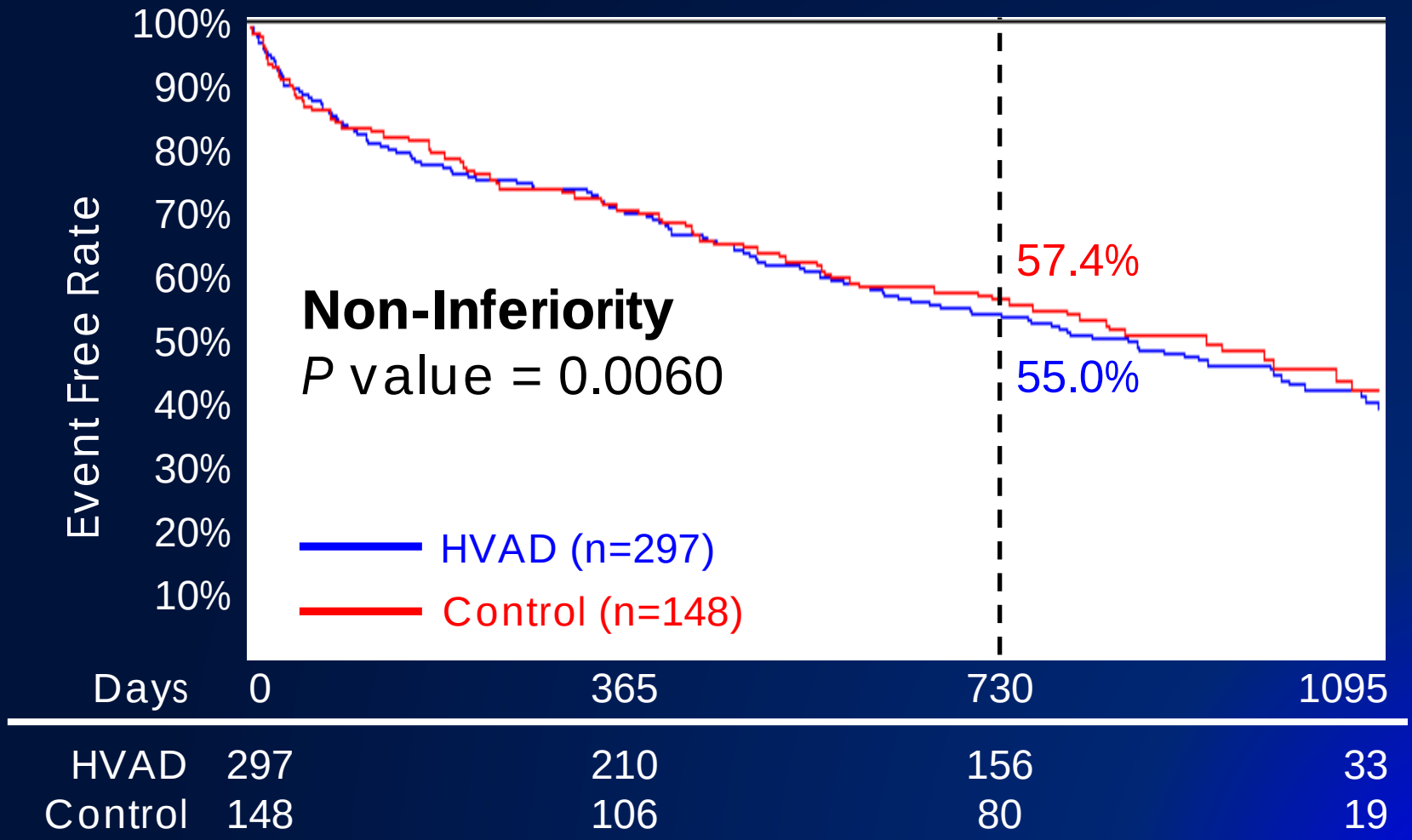
Enrollment begins (protocol BP management)

Patient Characteristics and Demographics

Baseline Characteristics	HVAD (n=297)	Control (n=148)	*P* value
Age (years)	**63.9**	**66.2**	**0.04**
Gender: Male Female	76.4% 23.6%	82.4% 17.6%	0.18
Height (cm)	173.8	175.5	0.07
Body Surface Area (m^2)	2.0	2.0	0.62
INTERMACS Profile 1 2 3 4 5 6 7	 3.4% 29.0% 40.4% 19.9% 4.0% 1.3% 2.0%	 3.4% 31.1% 40.5% 18.2% 3.4% 0.0% 3.4%	0.85
Ischemic Etiology of Heart Failure	57.9%	60.1%	0.68
Smoker	68.0%	62.2%	0.24
Stroke/TIA	19.2%	16.2%	0.51
Arrhythmia	78.1%	83.1%	0.26
Severe Tricuspid Insufficiency	**11.8%**	**5.4%**	**0.04**
Inotropes (pre-implant)	71.3%	71.1%	>0.99
Hypertension requiring medication	65.3%	70.9%	0.24

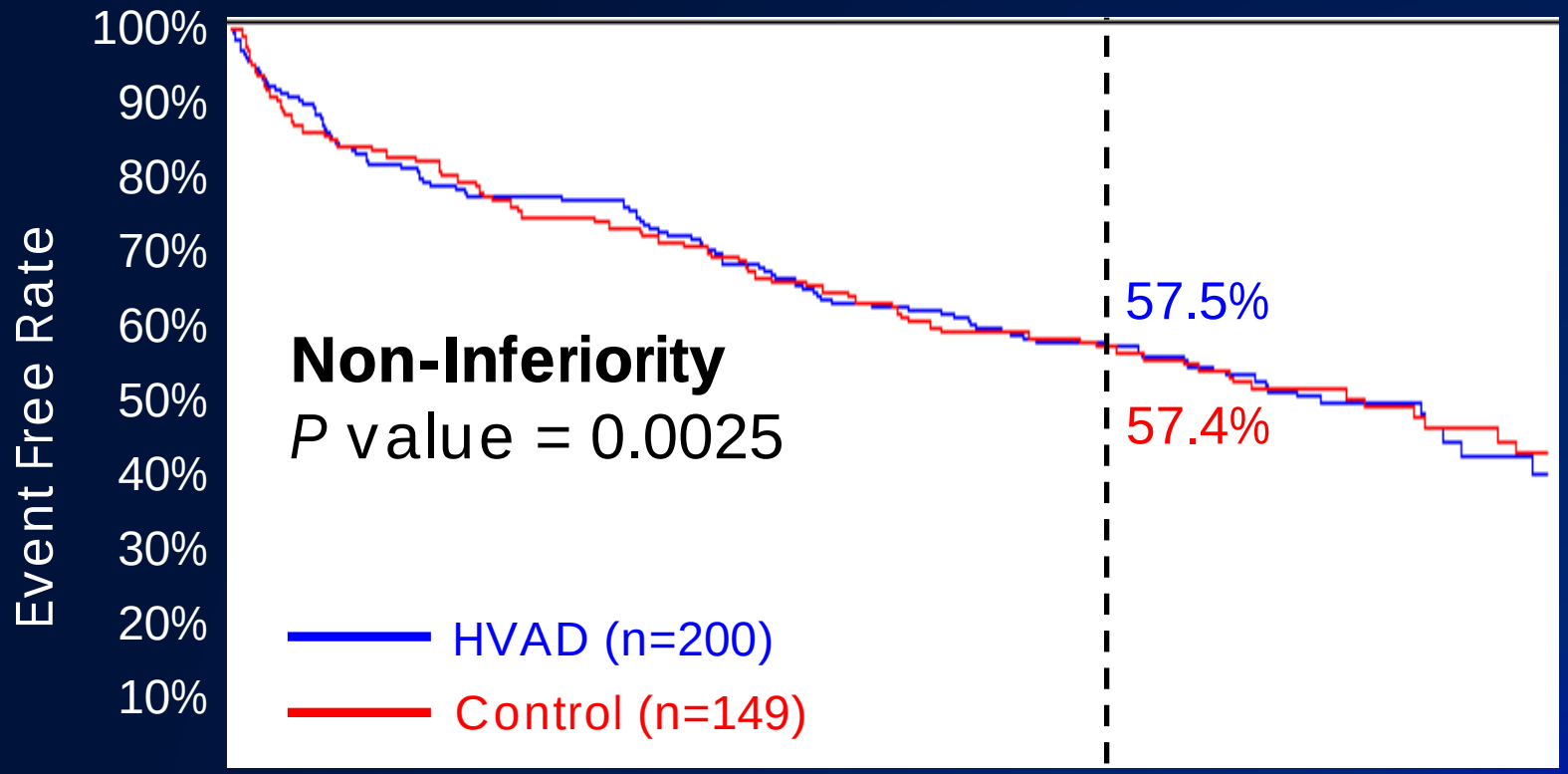
Primary Endpoint - Achieved

Survival at two years free from disabling stroke (MRS ≥4 at 24-weeks post-stroke), and alive on the originally implanted device, or transplanted or explanted due to patient recovery



Primary Endpoint - Sintered HVAD vs. Control

Survival at two years free from disabling stroke (MRS ≥4 at 24-weeks post-stroke), and alive on the originally implanted device, or transplanted or explanted due to patient recovery



Days	0	365	730	1095
HVAD	200	145	109	8
Control	149	106	80	19

Sintered HVAD Pump = currently available pump

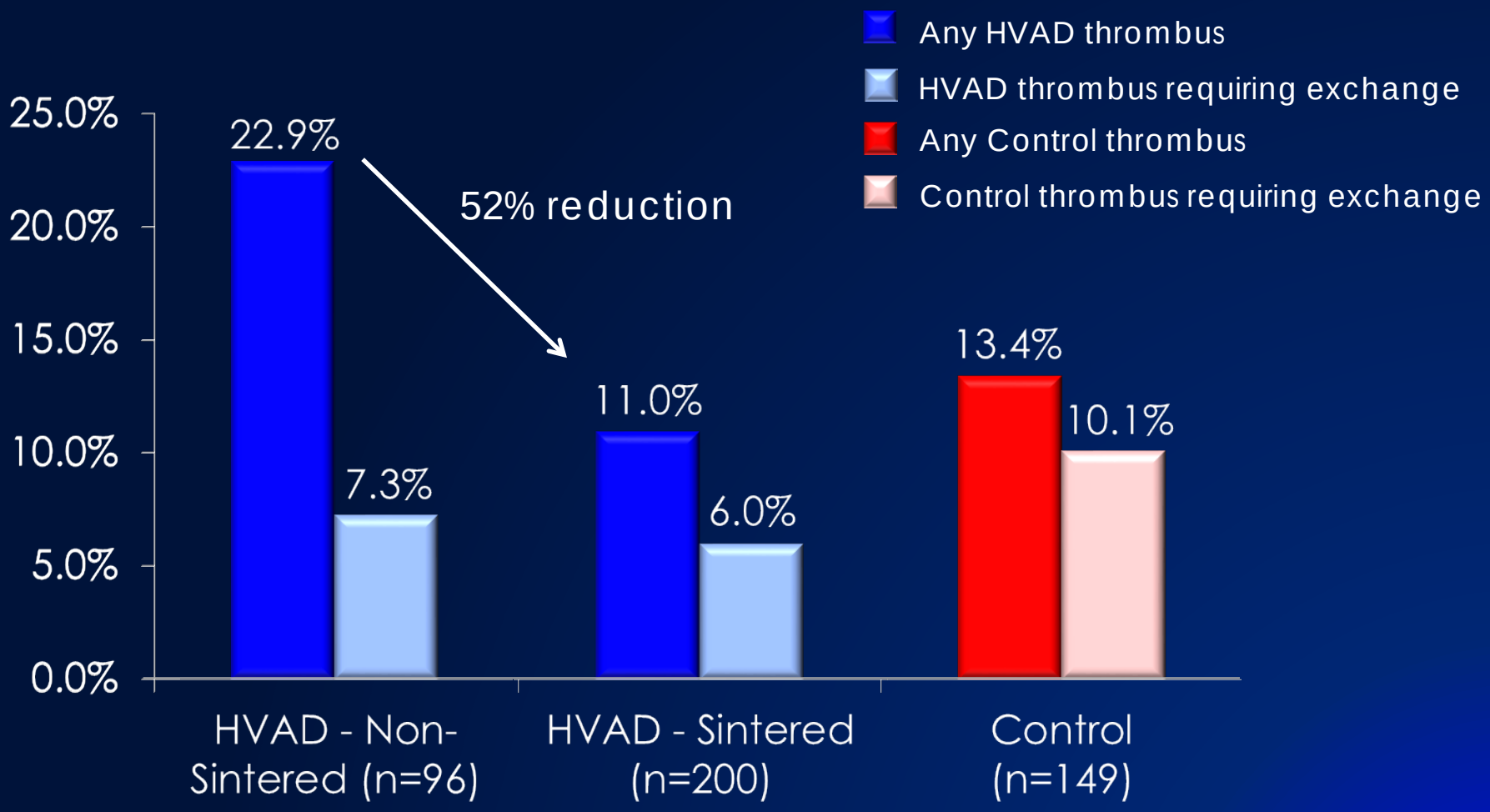
Overall CEC Adjudicated Adverse Events

INTERMACS defined events through 2 years

	HVAD (n=296)			Control (n=149)			
Adverse Event	No. of Patients	No. of events	EPPY (410.02PY)	No. of Patients	No. of events	EPPY (203.89PY)	*P* value
Bleeding	176 (59.5%)	400	0.98	90 (60.4%)	196	0.96	0.92
GI Bleed	103 (34.8%)	225	0.55	51 (34.2%)	90	0.44	0.92
Cardiac Arrhythmia	111 (37.5%)	175	0.43	61 (40.9%)	82	0.40	0.54
Infection	201 (67.9%)	452	1.10	92 (61.7%)	182	0.89	0.21
Driveline Infection	56 (18.9%)	72	0.18	21 (14.1%)	25	0.12	0.23
Stroke	85 (28.7%)	110	0.27	18 (12.1%)	19	0.09	<0.001
Ischemic CVA	50 (16.9%)	65	0.16	13 (8.7%)	13	0.06	0.021
Hemorrhagic CVA	42 (14.2%)	45	0.11	6 (4.0%)	6	0.03	0.001
TIA	24 (8.1%)	27	0.07	7 (4.7%)	7	0.03	0.24
Renal Dysfunction	43 (14.5%)	54	0.13	19 (12.8%)	22	0.11	0.67
Right Heart Failure*	110 (37.2%)	129	0.31	39 (26.2%)	45	0.22	0.025*
Pump Exchange	23 (7.8%)	27	0.06	20 (13.4%)	23	0.10	0.06

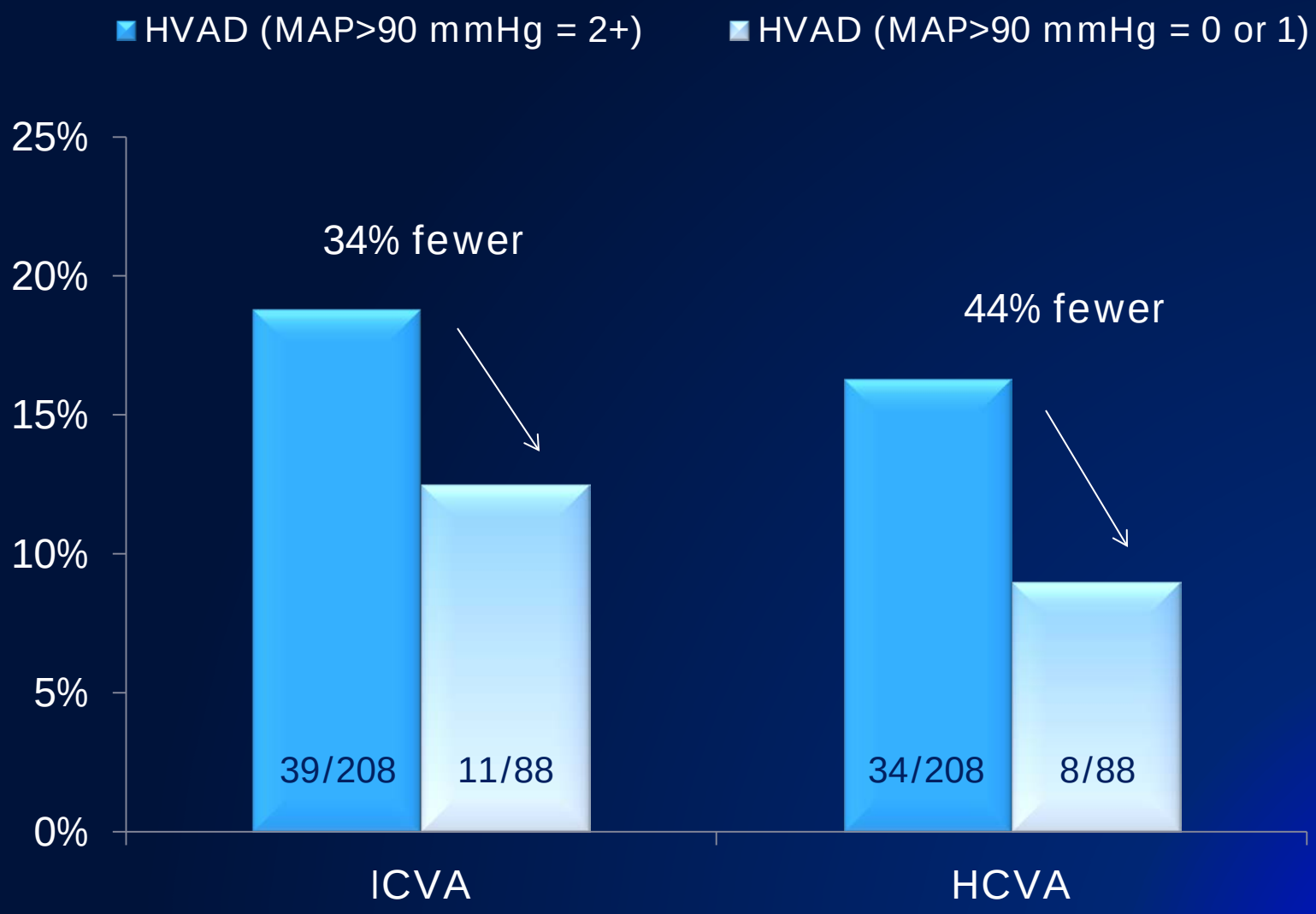
* There was no statistical difference in the rate of RHF in the sintered cohort vs . Control.

Pump Thrombosis (2 years)



Sintering reduced the overall rate of any suspected pump thrombus, and both overall thrombus rates and exchanges for thrombus were less frequent in patients with the currently available HVAD pump compared to control.

Influence of Blood Pressure on Stroke (HVAD)



✓BP management is associated with improved neurological outcomes

✓Blood pressure management was not mandated in ENDURANCE

hVAD® ENDURANCE Trial

Summary

- Primary Endpoint Achieved
- Patients had significant and sustained improvements in NYHA classification and quality of life measures
- Device malfunctions leading to exchange or urgent transplant are more frequent in the control group, whereas strokes occur more frequently in the HVAD group
- Device and design improvements, including sintering of the inflow cannula, resulted in marked improvements in outcomes, including a reduction in pump thrombosis
- Elevated MAP was the strongest predictor of stroke by multivariable analysis, and patients with well-managed blood pressure had fewer strokes

Conclusions

- There was no difference between HVAD and control in survival at two years free from disabling stroke (Modified Rankin Score ≥4 at 24-weeks post-stroke), and alive on the originally implanted device, or transplanted or explanted due to patient recovery

- Blood pressure management appears to reduce neurologic events

DOUG GODSHALL

PRESIDENT AND CEO, HEARTWARE

HeartWare

Long Term Support of Patients Receiving an LVAD for Advanced Heart Failure: A Subgroup Analysis of the Registry to Evaluate the HeartWare® Left Ventricular Assist System (The REVOLVE Registry)

J. D. Schmitto[1], D. Zimpfer[2], A. E. Fiane[3], R. Larbalestier[4], S. Tsui[5], P. Jansz[6], A. Simon[7], S. Schueler[8], M. Strueber[9].

[1]Hannover Medical School, Hannover, Germany, [2]Medical University of Vienna, Vienna, Austria, [3]Oslo University Hospital, Oslo, Norway, [4]Royal Perth Hospital, Perth, Australia, [5]Papworth Hospital NHS Foundation Trust, Cambridge, United Kingdom, [6]St Vincent's Clinic, Sydney, Australia, [7]Royal Brompton and Harefield Hospital, London, United Kingdom, [8]Freeman Hospital, Newcastle upon Tyne, United Kingdom, [9]University Heart Center Leipzig, Leipzig,Germany

ISHLT 35th Annual Meeting and Scientific Sessions

15-18th April, 2015, Nice, France

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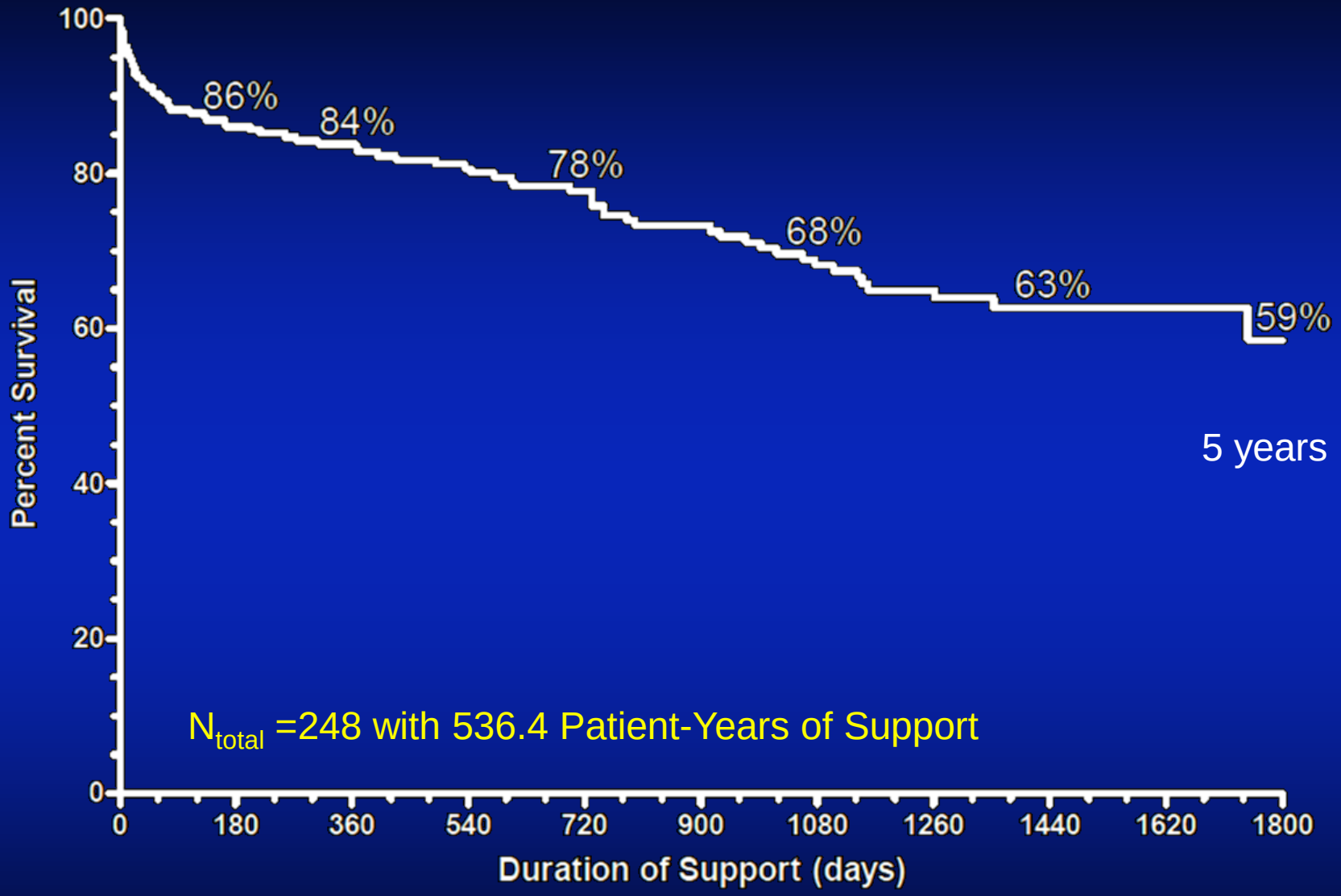
The ReVOLVE Registry Design

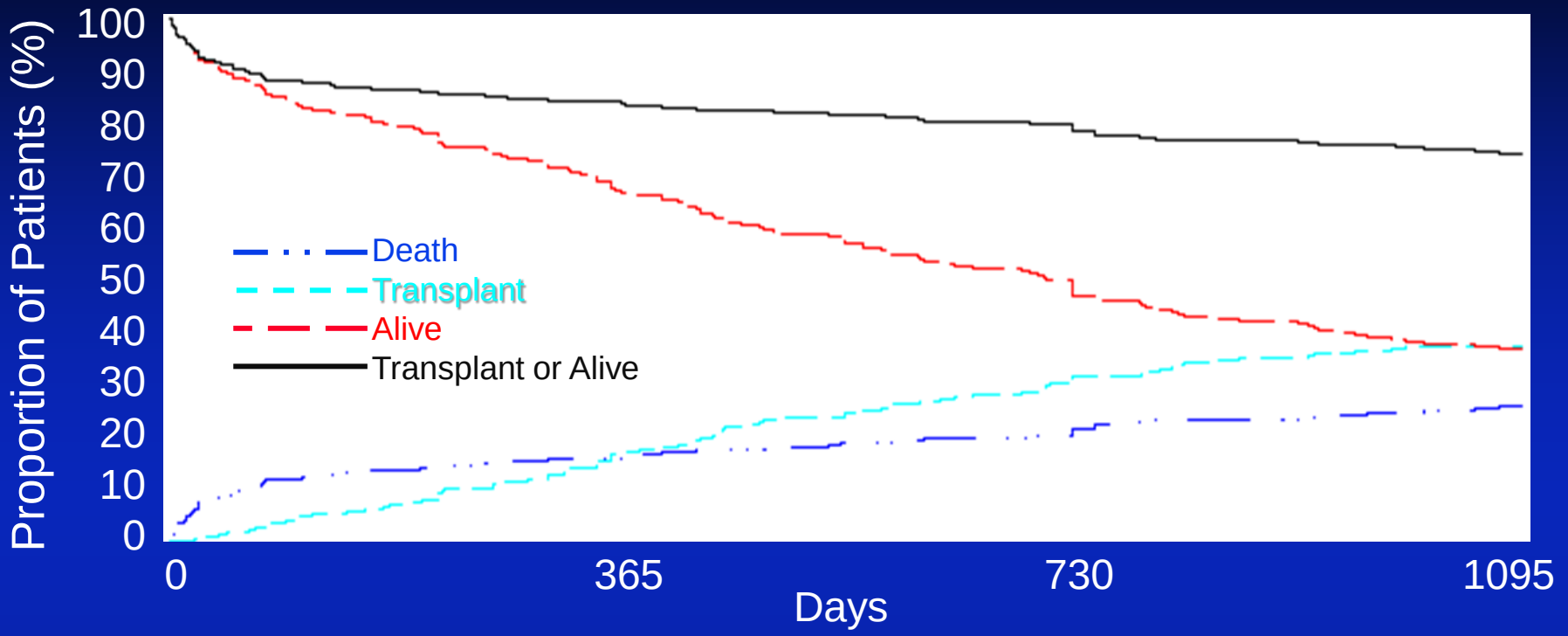
- Objective: To collect post CE-Mark data after HVAD implantation.
- Multi-center, prospective, single arm registry
- Results of the 254 patients receiving an HVAD with labeled indications previously presented at ISHLT 2013 (Montreal) and published (J Heart Lung Transplant 2014; 33:486–491)
- N=248 commercial HVAD implants in this subgroup analysis of long term support (6 patients lost to extended follow up)
- Mean time on support in this analysis: 789.9 $\pm$ 594 days

Long-Term Survival Results



- 8 patients exceed 5 years of support, 7 on the original pump

Competing Outcomes



Days:	0	180	365	730	1095
At Risk	248	197	167	123	90
Death	0.0%	13.7%	15.7%	20.2%	25.0%
Transplant	0.0%	6.9%	17.0%	30.0%	37.4%
Alive on Device	100.0%	79.4%	67.3%	49.8%	36.7%
Transplant or Alive on Device	100.0%	86.3%	84.3%	79.8%	74.1%

Adverse Events

INTERMACS Adverse Event	No. of Patients % (N)	No. of Events	Event Rate (EPPY*)
Bleeding	33% (79)	109	0.20
Gastrointestinal Bleeding	7% (17)	22	0.04
Right Heart Failure	10% (23)	23	0.04
Stroke (HCVA + ICVA)	14% (34)	37	0.07
Driveline Infection	17% (41)	45	0.08
Sepsis	9% (22)	22	0.04
Renal Failure	5% (12)	12	0.02
Pump Thrombus (requiring pump replacement)	6% (16)	19	0.04

* EPPY = events per patient year

Note: Bleeding includes all post operative (including tamponade) and follow-up bleeding events, except GI bleeding. Gastrointestinal Bleeding includes any documented bleeding of the GI tracts. Stroke includes ischemic and hemorrhagic strokes, but not TIAs.

Low Real World Complication Rates

- Driveline exit site infections were infrequent at 0.08 events/pt yr.
- The most common event was bleeding at 0.20 events/pt yr.
- Strokes occurred at a rate of only 0.07 events/pt yr.
- Exchange for pump thrombus remained low at 0.04 events/pt yr.

The HeartWare HVAD Pump in Clinical Practice - Results From 1,035 Patients Analyzed in a Retrospective European Multi-Center Study

T. Krabatsch[1], M. Morshuis[2], J. Garbade[3], D. Zimpfer[4], E. Potapov[1], G. Laufer[4], F. Mohr[3], V. Falk[1], J. Gummert[5].

[1]Cardiothoracic and Vascular Surgery, Deutsches Herzzentrum Berlin, Berlin, Germany, [2]Cardiothoracic and Vascular Surgery, Herzund Diabeteszentrum Nordrhein-Westfalen, Bad Oeynhausen, Germany, [3]Herzzentrum Leipzig, Leipzig, Germany, [4]Medizinische Universität Wien, Vienna, Austria, [5]Herzund Diabeteszentrum Nordrhein-Westfalen, Bad Oeynhausen, Germany

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Anticoagulation and MAP Protocols

	Hospital B	Hospital O	Hospital L	Hospital V
INR target	2.5 – 3.0	2.3 – 2.8	2.0 – 2.5	2.0 – 2.5
Aspirin	100 mg, tailored	100 mg	no	100 mg, now 200 mg
Clopidogrel	not for VAD		75 mg 3x/w	not for VAD
Bridging to oral anticoagulation	5 – 10 days i.v. Heparin	i.v. Heparin until drains out	5 – 7 days i.v. Heparin	LMWH
TAT	2-1x/week in hospital	yes	once before discharge	no
TEG	2-1x/week in hospital	no	no	intraoperative
INR self-management	yes telemed. monitoring	yes	yes telemed. monitoring	yes
Advanced MAP control	yes	yes	yes	yes

Summary

		HeartMate II	Heartware HVAD
	Intermacs 1 + 2	48.4 %	61.0 %
survival	30 day	87.2 %	86.6 %
	6 months	75.1 %	73.3 %
	1 year	68.2 %	67.2 %
	2 year	61.9 %	58.5 %
	3 years	50.8 %	50.8 %
	4 years	46.3 %	41.6 %
	5 years	42.0 %	33.2 %
	6 years	39.2 %	-
complications	driveline infections	0.095 EPPY	0.115 EPPY
	pump thrombosis	0.075 EPPY	0.078 EPPY
	cerebral events	0.114 EPPY	0.108 EPPY
	major bleeding	0.096 EPPY	0.176 EPPY
outcome	explantation for recovery	4.8 %	1.2 %
	transplanted	18.2 %	15.9 %

The impact of patient management on adverse events

JEFFREY TEUTEBERG, MD

MEDICAL DIRECTOR, ADVANCED HEART FAILURE

UNIVERSITY OF PITTSBURGH MEDICAL CENTER

Bleeding and Anticoagulation Survey

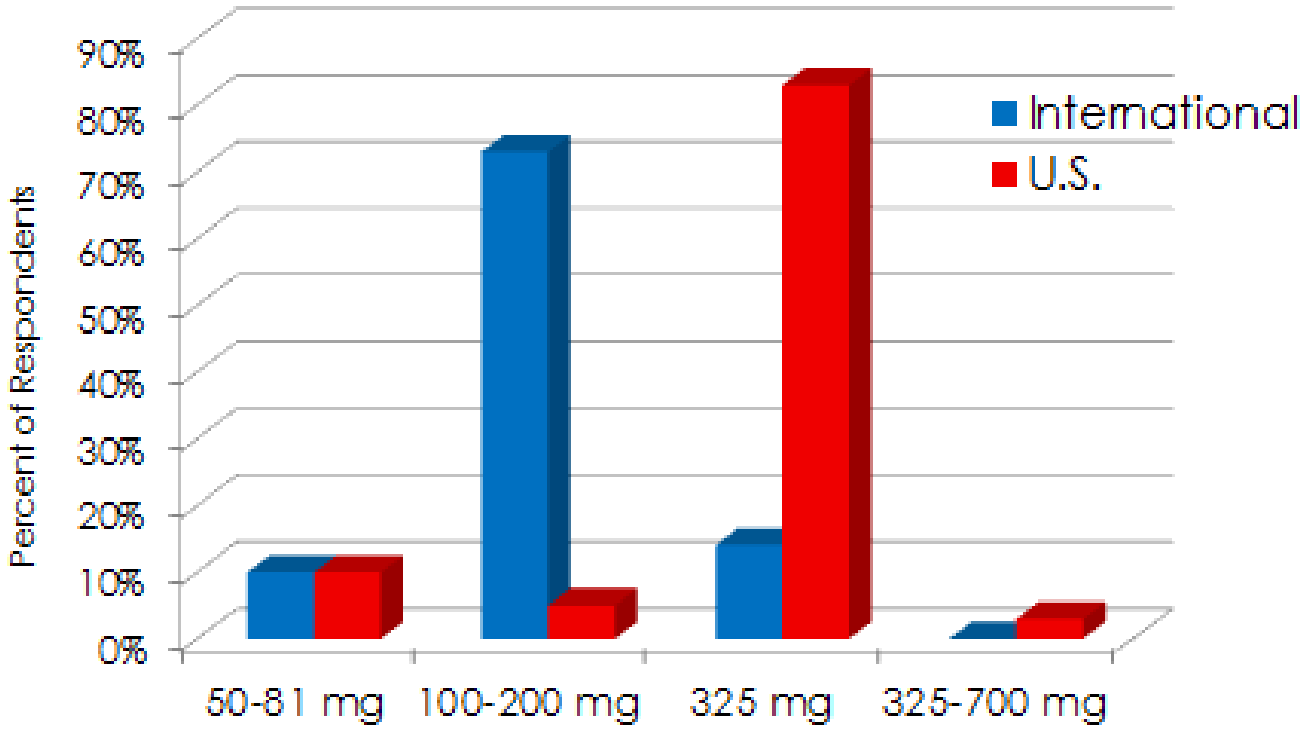
- **International Participation:**
- 59 centers representing 18 countries

- **US Participation:**
- 63 centers throughout the continental US

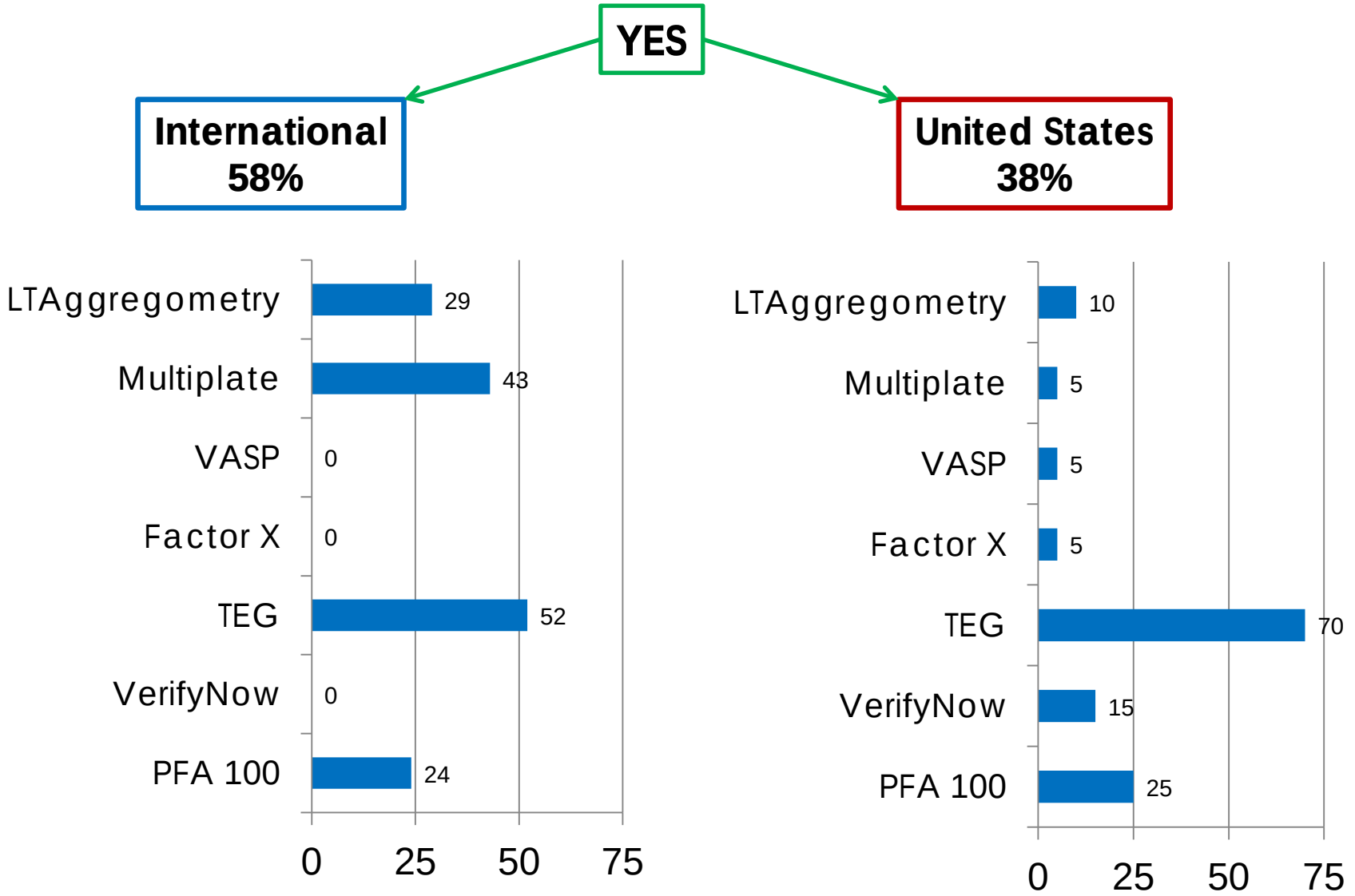
- 21 questions in an initial survey covering topics related to anticoagulation, antiplatelet therapy, and management of these medications during surgical procedures as well as bleeding events. A follow-up survey of 12 questions was also completed by 73% of the original participating sites.
- Comparisons are presented here of treatment and management strategies between international and US centers.

Aspirin Dosing

Median dose prescribed among International Centers is 100 mg, compared to 325 mg prescribed among U.S. Centers.

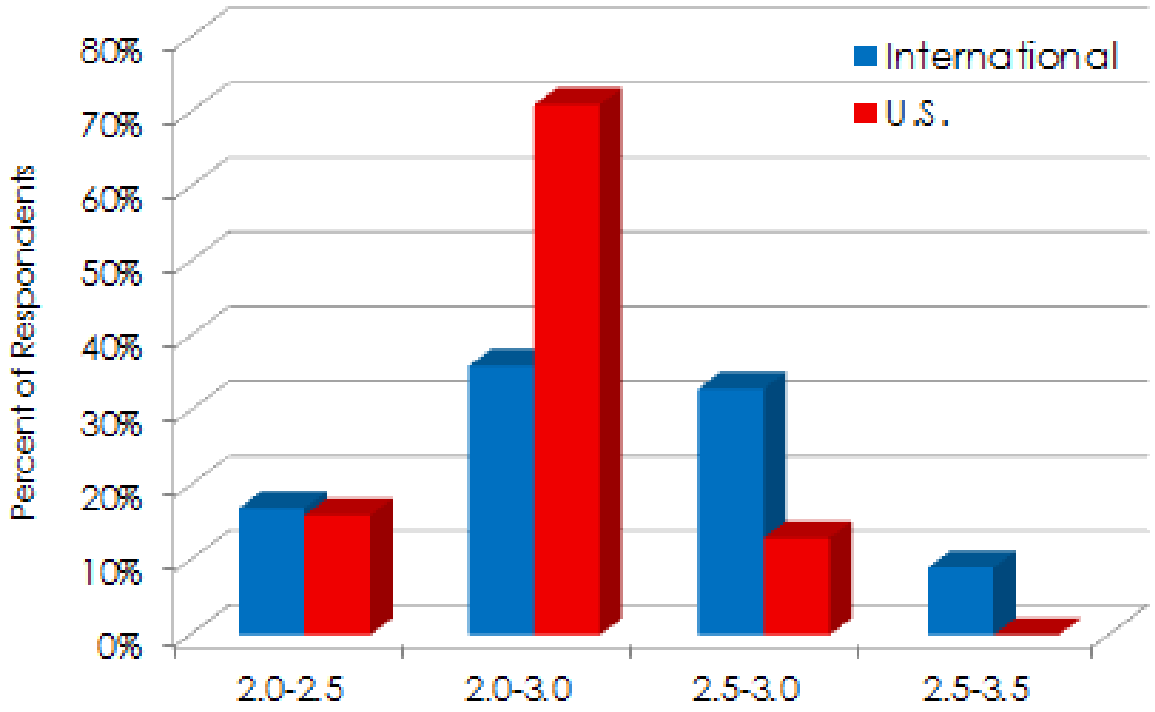


Do you perform additional testing to evaluate antiplatelet or anticoagulant effectiveness?



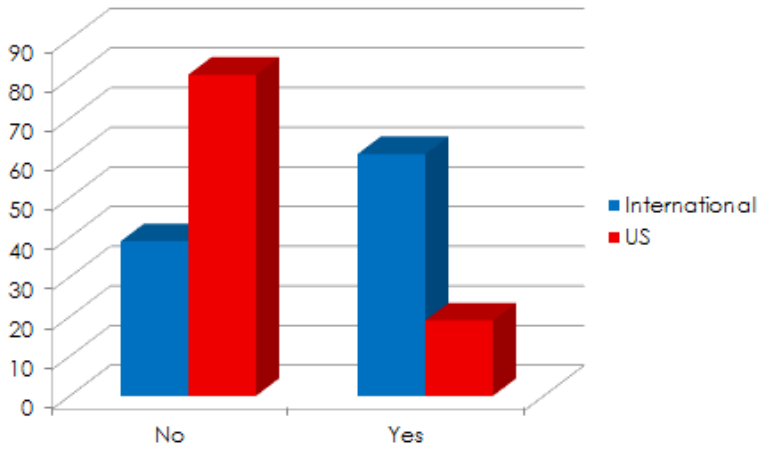
INR Targets

International centers were more likely to have a higher INR goal

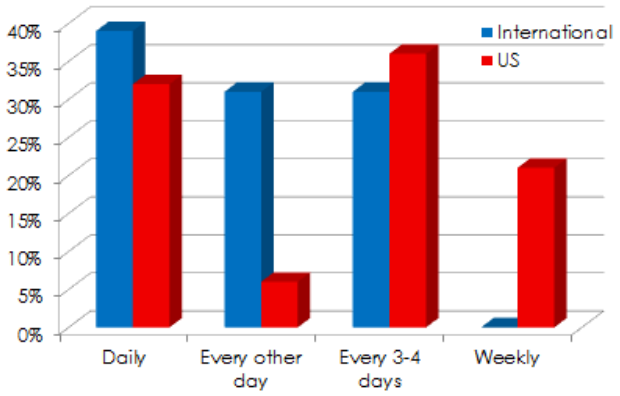


INR Monitoring

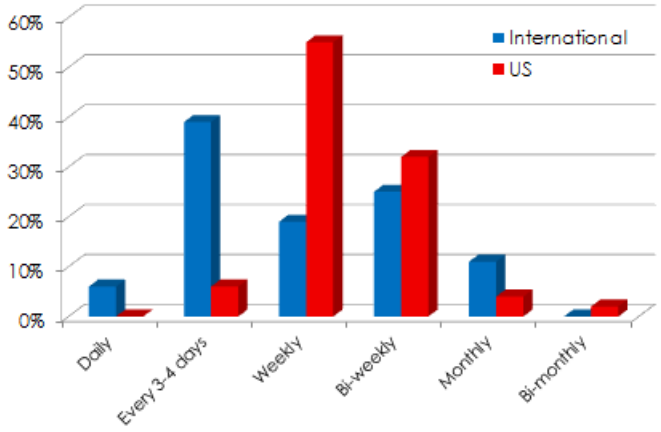
Utilization of home INR monitoring



Frequency @1 month



Frequency @ 3 months



More International centers provide home INR monitors to patients, which may explain the more frequent INR measures

Thank You

HeartWare