Current State-of-Art in VAD Therapy for Heart Failure

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정 성호

History of mechanical circulatory support

Year	*Milestone*
1953	Cardiopulmonary bypass
1959	Demonstration of postcardiotomy shock support
1961	Development of intra-aortic counterpulsation
1962	First use roller pump for left ventricular assistance
1964	Artificial Heart Program established by the NHLBI
1966	First postcardiotomy mechanical bridge to recovery with assist pump
1967	First clinical application of IABP for cardiogenic shock
1967	First heart transplantation with human donor heart
1969	First total artificial heart as a bridge to transplantation
1974	Redirection of the Artificial Heart Program toward implantable devices
1978	Report of patients bridged to transplant with an abdominal LVAD
1978	Report of patients bridged to transplant with IABP
1980	NIH requests proposals for left heart assist systems
1982	First total artificial heart for permanent replacement
1984	First successful use of LVAD as bridge to transplant
1994	Heartmate LVAD FDA approved as bridge to transplant
2001	REMATCH trial published
2002	Heartmate XVE FDA approved for destination therapy

Classification of VAD

- LV vs RV vs Bi-ventricular
- Pulsatile flow vs Continuous flow
- Axial flow vs Centrifugal flow
- 1st vs 2nd vs 3rd Generation

Ventricular Assist Device Innovation

- Pulsatile Flow
- Valves
- Mechanical bearings

1st Generation

FDA Approved
BTT 1998
DT 2002

- Continuous Flow
- Axial Design
- Bearing with mechanical pivot

2nd Generation

FDA Approved
BTT 2008
DT 2010

- Continuous Flow
- Centrifugal Design
- Noncontact bearing design
- Hydrodynamic levitation

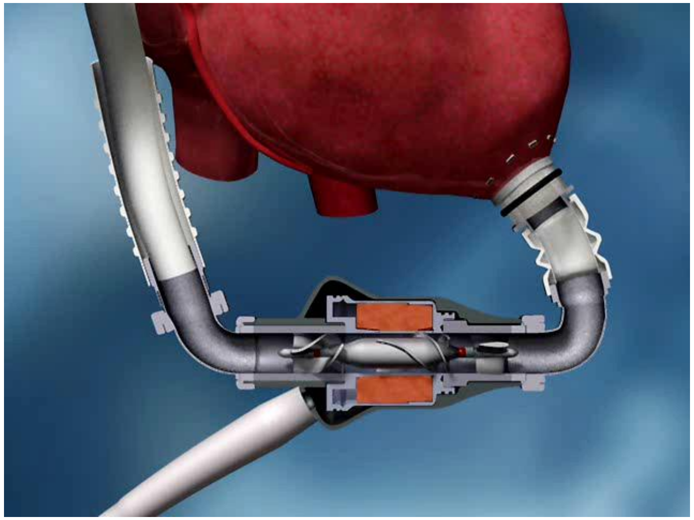
3rd Generation

FDA Approved
BTT 2012
DT Investigational

- **Minaturization**
- **Durability**

Pulsatile vs Continuous Flow VAD

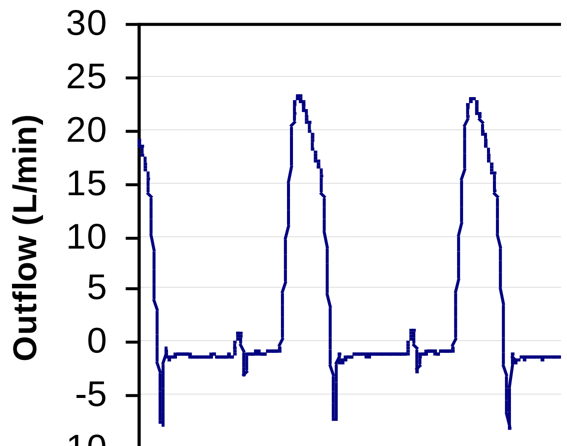
Attribute	Pulsatile-flow VAD	Continuous-flow VAD
Size	Large; intracorporeal devices limited to large patients; extracorporeal devices especially suited for smaller patients or for biventricular support	Smaller; accommodates most patients, excluding infants
Blood flow capacity	Up to 10 liters/min	Up to 10 liters/min
Type of pump	Sac or diaphragm	Centrifugal or axial flow by rotating impeller
Implantation	Extracorporeal or intracorporeal types: sub-diaphragmatic intraperitoneal or preperitoneal	Extracorporeal, intracardiac, pericardial, sub-diaphragmatic
Main hemodynamic characteristic	Intermittent unloading of ventricle; pulsatile arterial pressure; asynchronous with heart	Continuous unloading of ventricle
Physiologic flow variables	Pre-load dependant	Pre-load and after-load dependant
Mechanical flow variables	Automatic or fixed rate and stroke volume capacity	Set speed of the impeller rotation

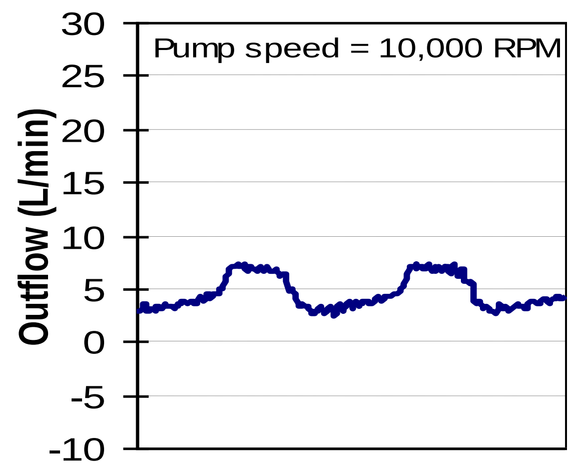


Volume Displacement vs Axial Flow

- Volume displacement pumps
  - Pulsed ("physiologic") flow based on device function of positive displacement
  - VAD flow = beat rate X stroke volume

- Axial flow pumps
  - pump flow follows native cardiac pulse
  - Flow increases & decreases in response to LV pressure
  - Sensitive to pressure differential across the pump ($P_{aortic} – P_{LV}$)
    : more residual function = bigger pulse
  - pump flow determined by pump speed & power





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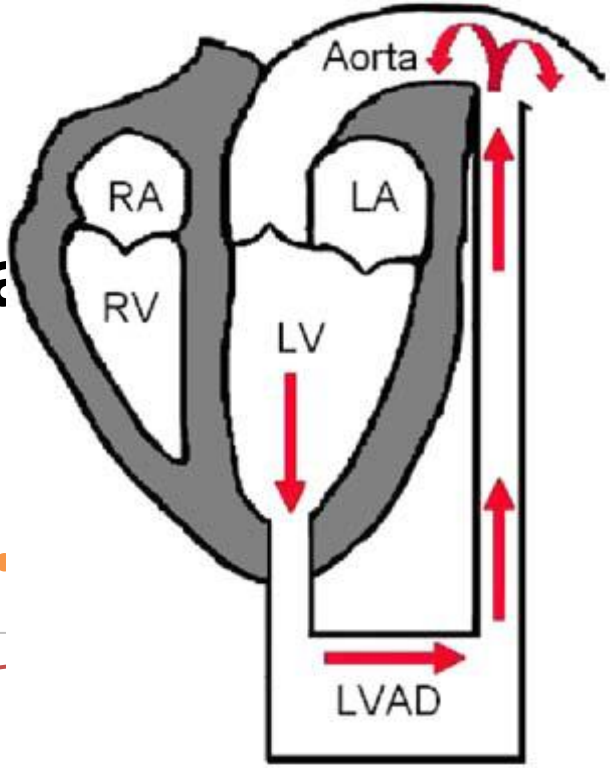
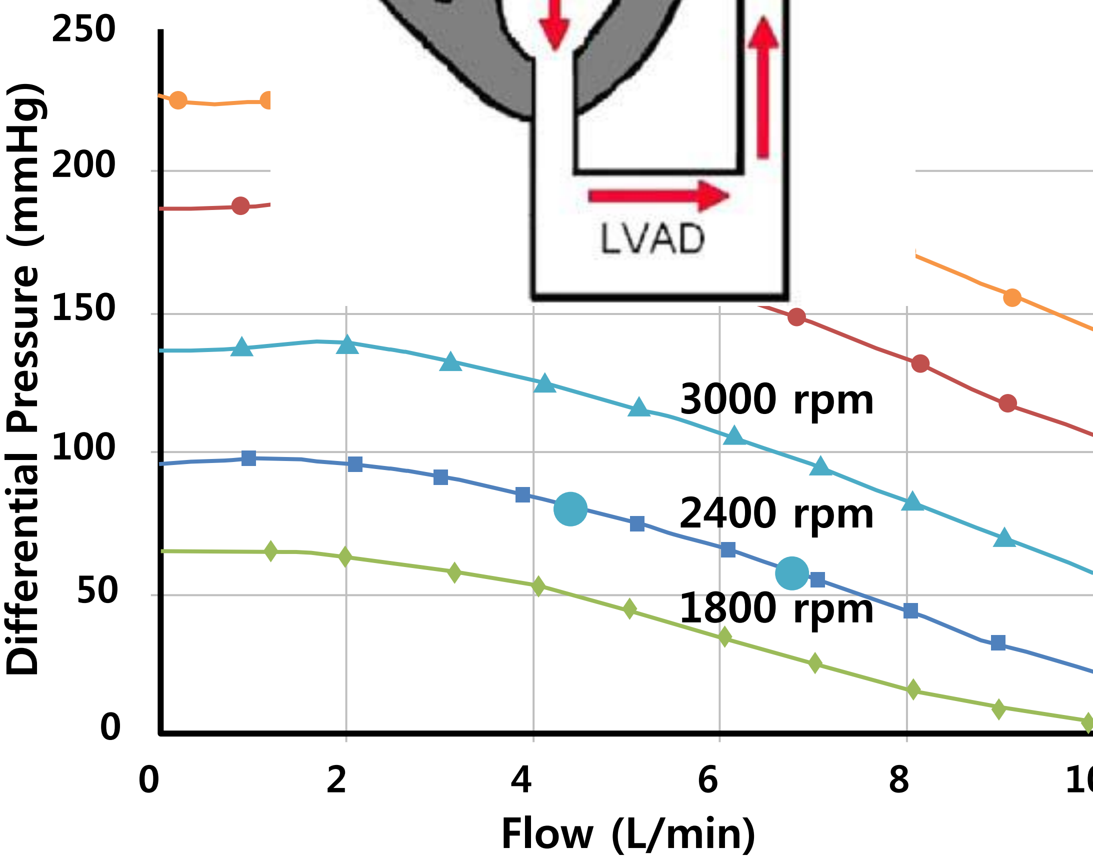
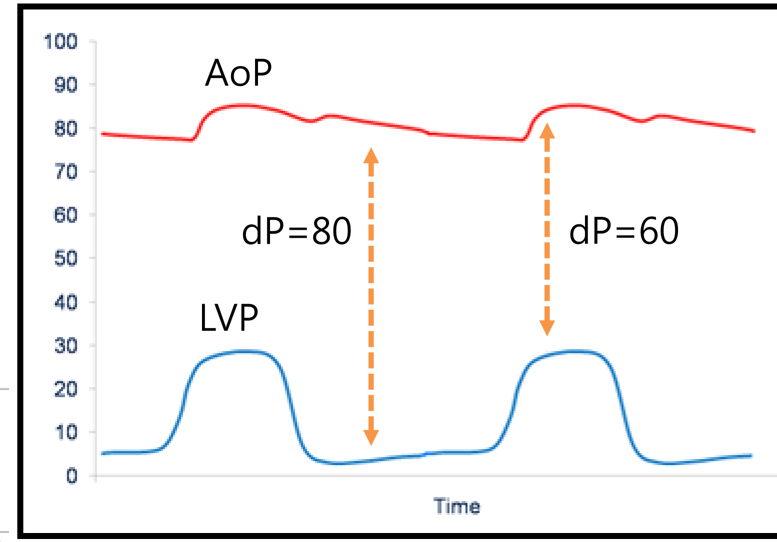
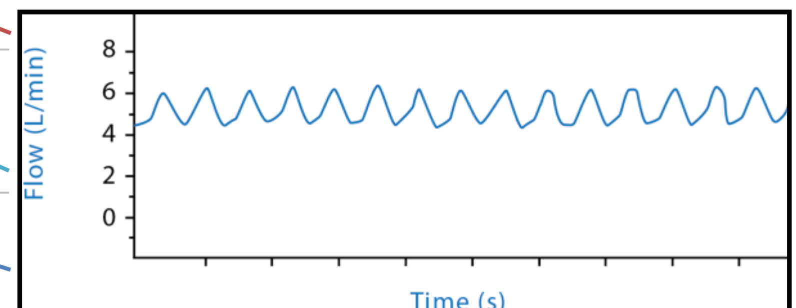
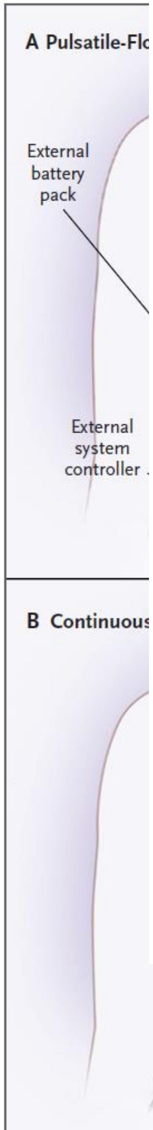

Aorta
RA
LA
RV
LV
LVAD


250
200
150
100
50
0
Differential Pressure (mmHg)
3000 rpm
2400 rpm
1800 rpm
0
2
4
6
8
10
Flow (L/min)

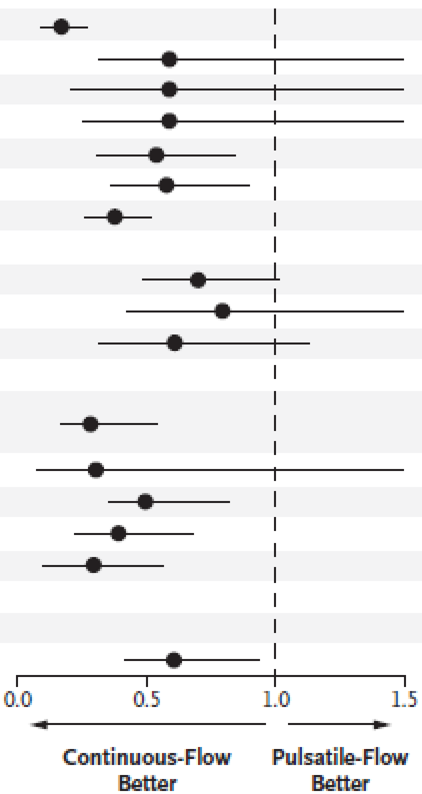

100
90
80
70
60
50
40
30
20
10
0
AoP
LVP
dP=80
dP=60
Time

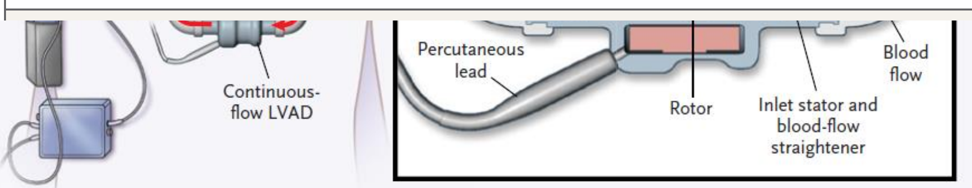

8
6
4
2
0
Flow (L/min)
Time (s)

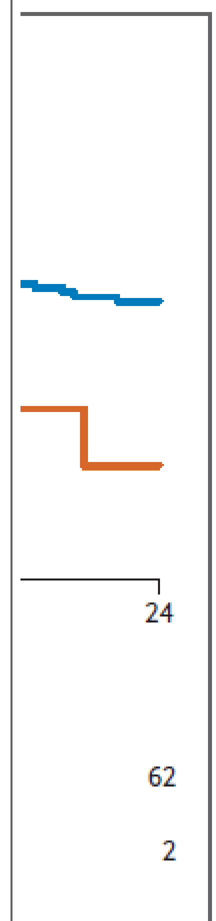
Advanced Heart Failure Treated with Continuous-Flow Left Ventricular Assist Device



Subgroup	Continuous-Flow LVAD (N=133) (211 patient-yr) no. (%)	Continuous-Flow LVAD no. of Events/Patient-Yr	Pulsatile-Flow LVAD (N=59) (41 patient-yr) no. (%)	Pulsatile-Flow LVAD no. of Events/Patient-Yr	P Value for Interaction
Pump replacement	12 (9)	0.06	20 (34)	0.51	<0.001
Stroke	24 (18)	0.13	8 (14)	0.22	0.21
Ischemic	11 (8)	0.06	4 (7)	0.10	0.38
Hemorrhagic	15 (11)	0.07	5 (8)	0.12	0.33
LVAD-related infection	47 (35)	0.48	21 (36)	0.90	0.01
Local non-LVAD infection	65 (49)	0.76	27 (46)	1.33	0.02
Sepsis	48 (36)	0.39	26 (44)	1.11	<0.001
Bleeding					
Bleeding requiring PRBC	108 (81)	1.66	45 (76)	2.45	0.06
Bleeding requiring surgery	40 (30)	0.23	9 (15)	0.29	0.57
Other neurologic event	29 (22)	0.17	10 (17)	0.29	0.14
Right heart failure					
Managed with extended use of inotropes	27 (20)	0.14	16 (27)	0.46	<0.001
Managed with RVAD	5 (4)	0.02	3 (5)	0.07	0.12
Cardiac arrhythmia	75 (56)	0.69	35 (59)	1.31	0.006
Respiratory failure	50 (38)	0.31	24 (41)	0.80	<0.001
Renal failure	21 (16)	0.10	14 (24)	0.34	<0.001
Hepatic dysfunction	3 (2)	0.01	0	0.00	
LVAD thrombosis	5 (4)	0.02	0	0.00	
Rehospitalization	107 (94)	2.64	42 (96)	4.25	0.02







NEJM 2009;361:2241-51

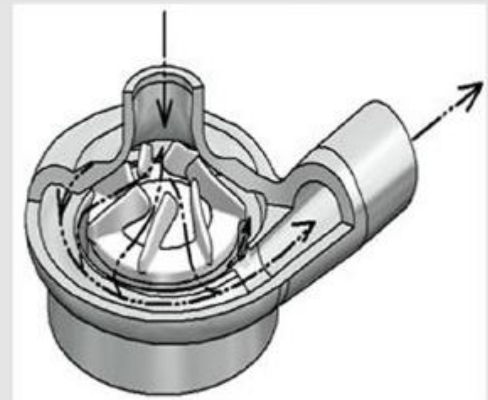
Centrifugal vs Axial

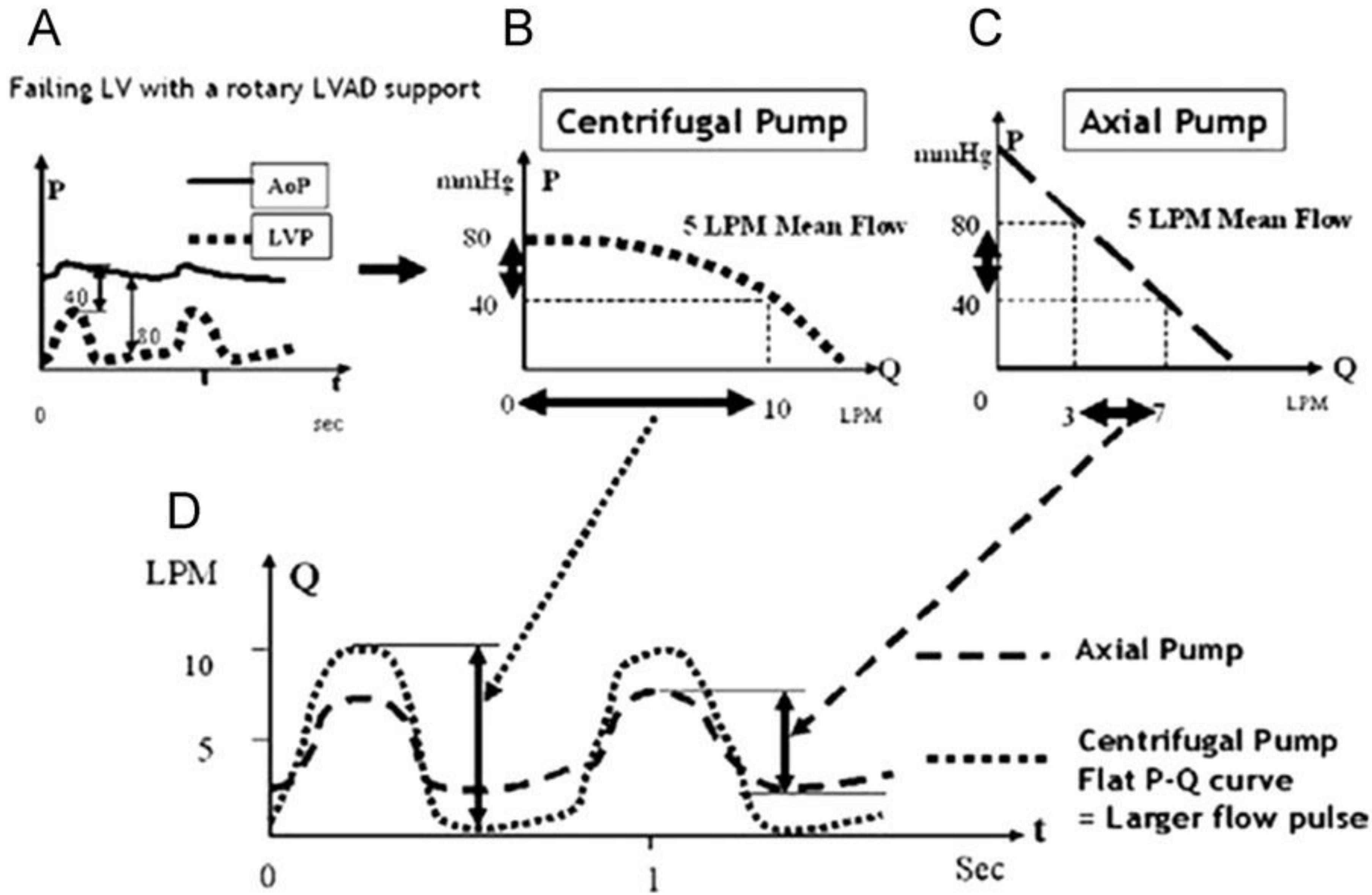
- **Centrifugal** (“radial”) pump has impeller outflow directed perpendicular form axis of rotation
- **Axial** pump has impeller outflow directed parallel to axis of rotation

Axial and centrifugal continuous-flow rotary pumps:
A t ... e

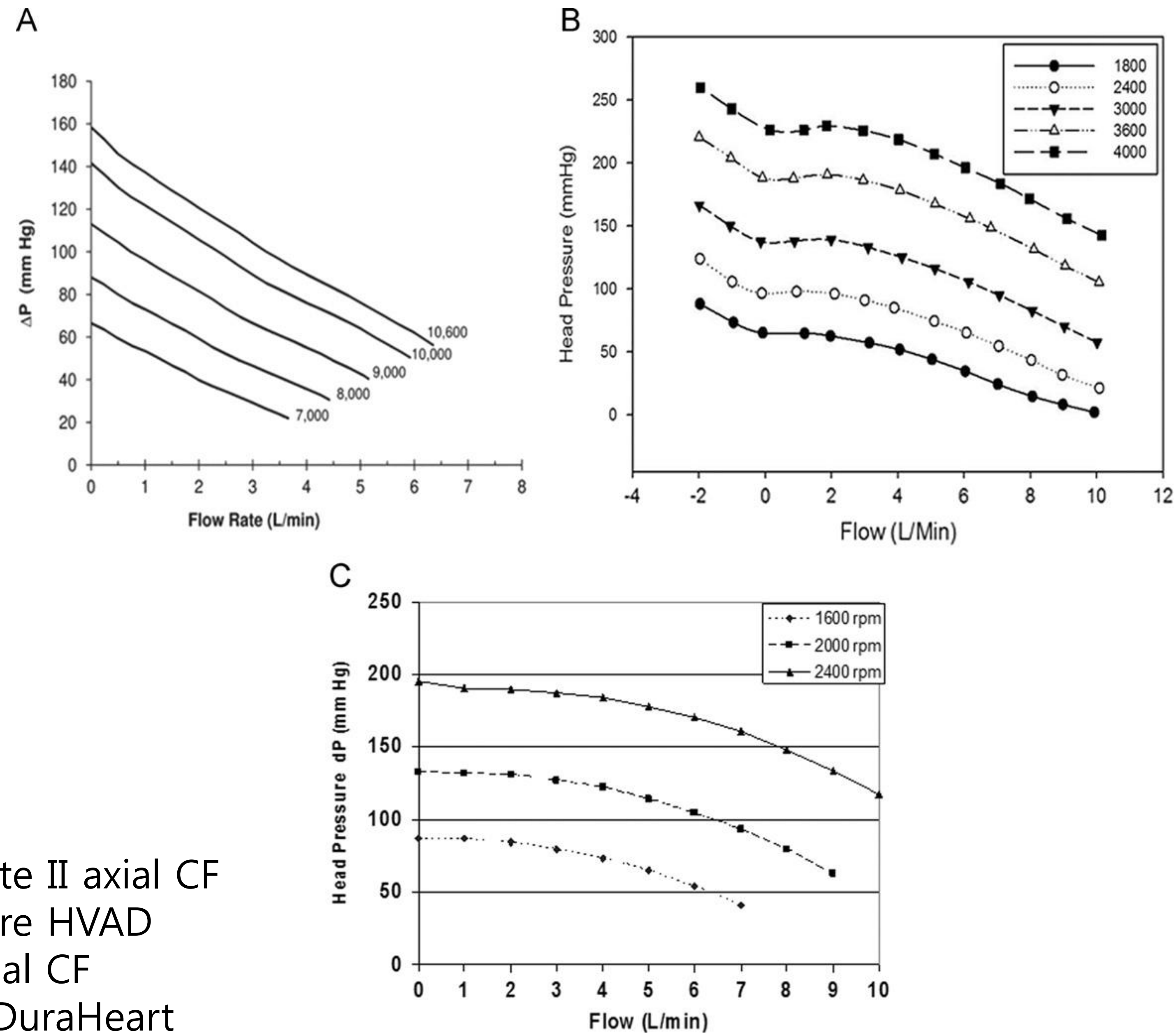
Nade
Nich
Sang ... PH[b,d]

Table 1 Comparison of Axial and Centrifugal Rotary Pump Response to Physiologic Conditions

Conditions	Axial pump			Centrifugal pump		
						
	Propeller in a pipe			Bladed disk spinning in a cavity		
Decreased pre-load ↓ CBV, RHF Restricted Inlet Suction	Propeller screws itself into inlet fluid and pushes it at the outlet to increase suction at the inlet.			Fluid revolves centrifugally with the blades vs little resistance rather than to the outlet, limiting suction & power.		
	Pump dP	Power	Flow	Pump dP	Power	Flow
	↑↑	↑ or ↓[a]	↓	---	↓↓	↓↓
Increased after-load ↑ SVR Restricted Outlet	Propeller pushes fluid harder into increased resistance causing high outlet pressures.			Fluid revolves centrifugally with the blades rather than to the outlet to limit power & outlet pressure increase.		
	Pump dP	Power	Flow	Pump dP	Power	Flow
	↑↑	↑ or ↓[a]	↓	---	↓↓	↓↓
Decreased after-load ↓ SVR	Propeller pushes against less resistance producing highest flow.			Fluid is pumped through to the outlet against systemic resistance producing highest flow but highest power.		
	Pump dP	Power	Flow	Pump dP	Power	Flow
	↓↓	↑ or ↓[a]	↑	↓	↑↑	↑↑



J Heart Lung Transplant 2013;32:1–11



A. HeartMate II axial CF
B. HeartWare HVAD centrifugal CF
C. Terumo DuraHeart centrifugal CF

J Heart Lung Transplant 2013;32:1–11

Axial vs Centrifugal pump

Table 2 Summary of Key Physiologic Differences in Axial and Centrifugal Continuous Flow Pumps

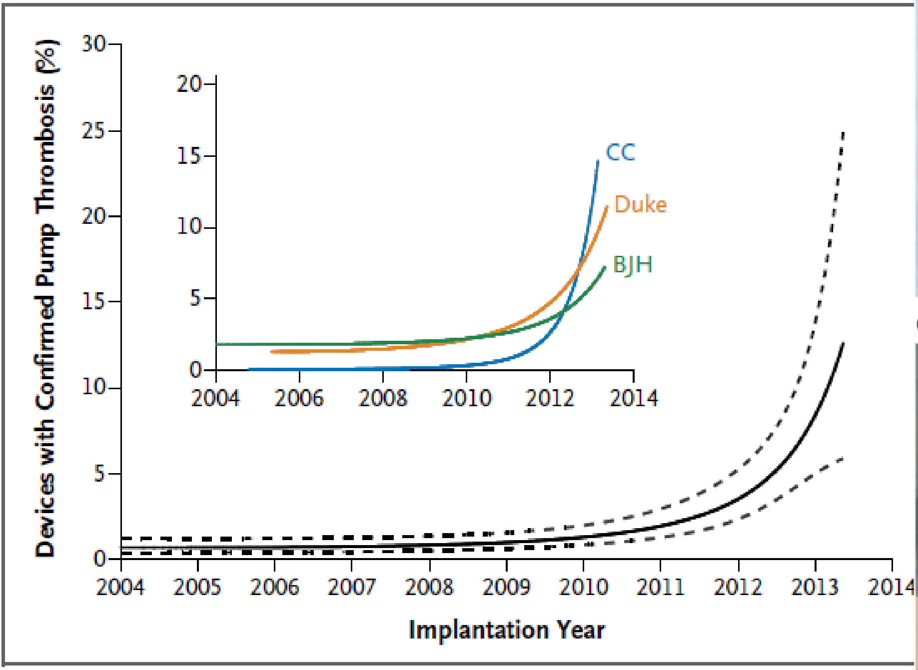
Pump characteristics	C vs A	Qualitative pump comparisons
Flow pulsatility	C > A	Centrifugal pumps have significantly higher flow pulsatility.
Estimated flow accuracy	C > A	Centrifugal pumps have significantly higher estimated flow accuracy.
Inlet suction	A > C	Centrifugal pumps have significantly lower inlet suction at low flow conditions.
Ability to scale size down	A > C	Axial pumps can be more easily scaled down to sizes sufficient to be implanted intravascularly.
Pre-load sensitivity	A = C	Axial and centrifugal continuous-flow pumps both have low preload sensitivity relative to the native ventricle and pulsatile VAD.
After-load sensitivity	C > A	Axial and centrifugal continuous flow pumps both have high after-load sensitivity relative to the native ventricle and pulsatile VAD; however, centrifugal pumps, by hydraulic performance characteristics, have higher after-load sensitivity.
Susceptibility to infection	A = C	No difference.
Biocompatibility	A = C	No difference.
Hemolysis	A = C	Not enough clinical data to suggest one is superior over the other.
Anti-coagulation	A = C	Not enough clinical data to suggest one is superior over the other.
Ability to wean the pump	A = C	Not enough clinical data to suggest one is superior over the other.

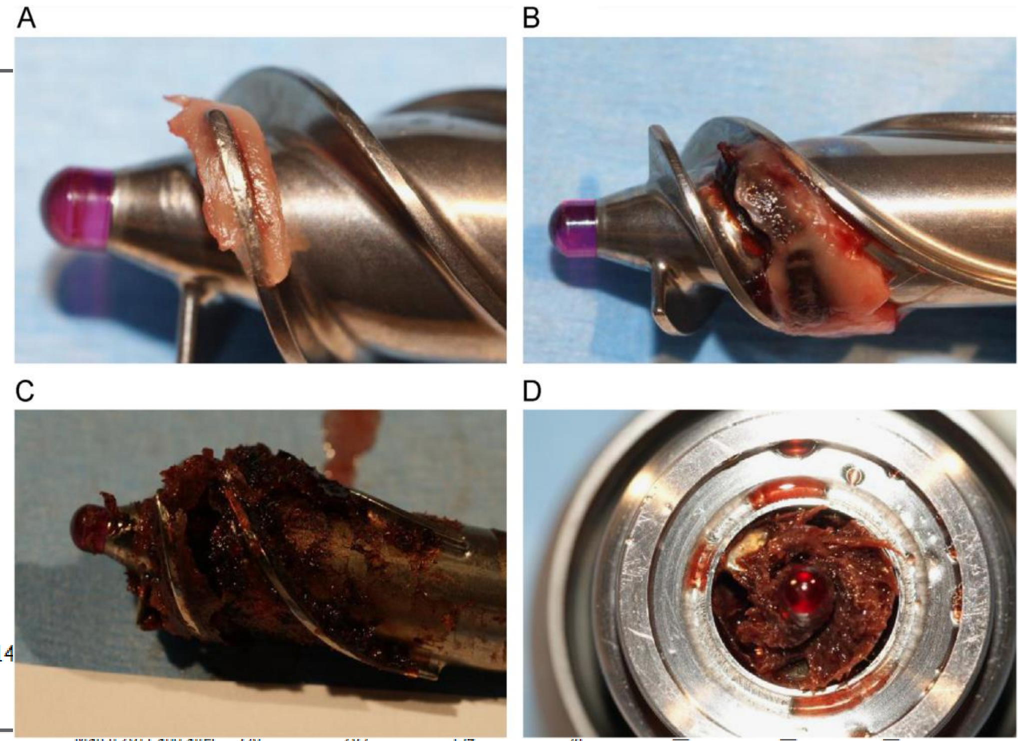
A, axial; C, centrifugal; VAD, ventricular assist device.

Late complications of LVAD

- Infection
- Bleeding: GI bleeding due to AVM
- Device thrombosis
- De novo Aortic regurgitation

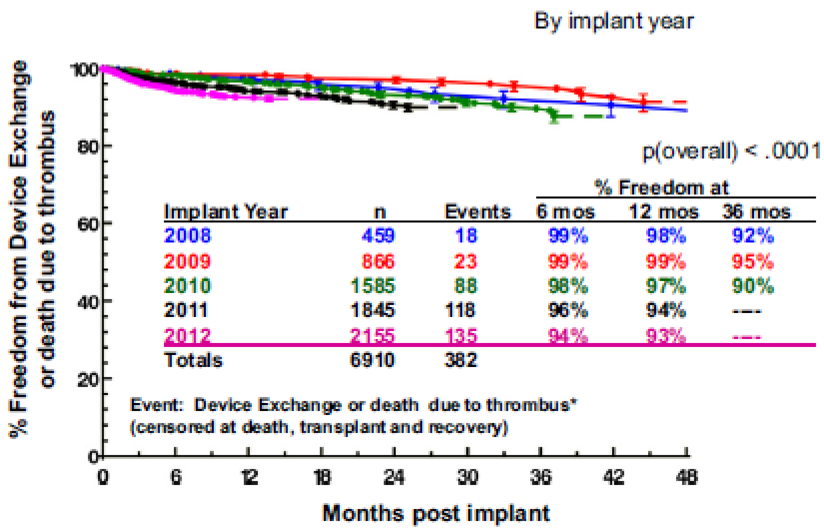
Unexpected Abrupt Increase in Left Ventricular Assist Device Thrombosis





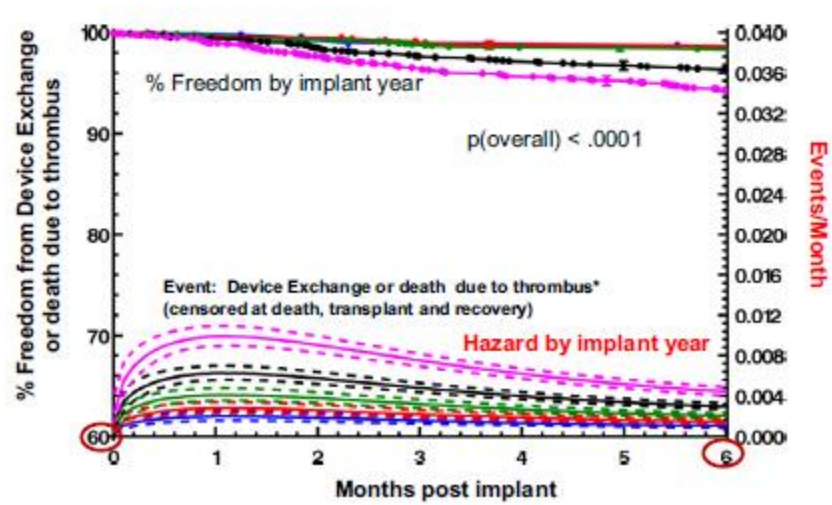
- Confirmed pump thrombosis: 2.2% → 8.4%
- Median time from implantation to thrombosis
  : 18.6 months → 2.7 months
- Actuarial mortality in the ensuing 6 mo after pump thrombosis: 48.2%

NEJM 2014;370:33-40



Implant Year	n	Events	% Freedom at 6 mos	12 mos	36 mos
2008	459	18	99%	98%	92%
2009	866	23	99%	99%	95%
2010	1585	88	98%	97%	90%
2011	1845	118	96%	94%	----
2012	2155	135	94%	93%	----
Totals	6910	382			

*Thrombus events include 'probable' thrombus events



*Thrombus events include 'probable' thrombus events

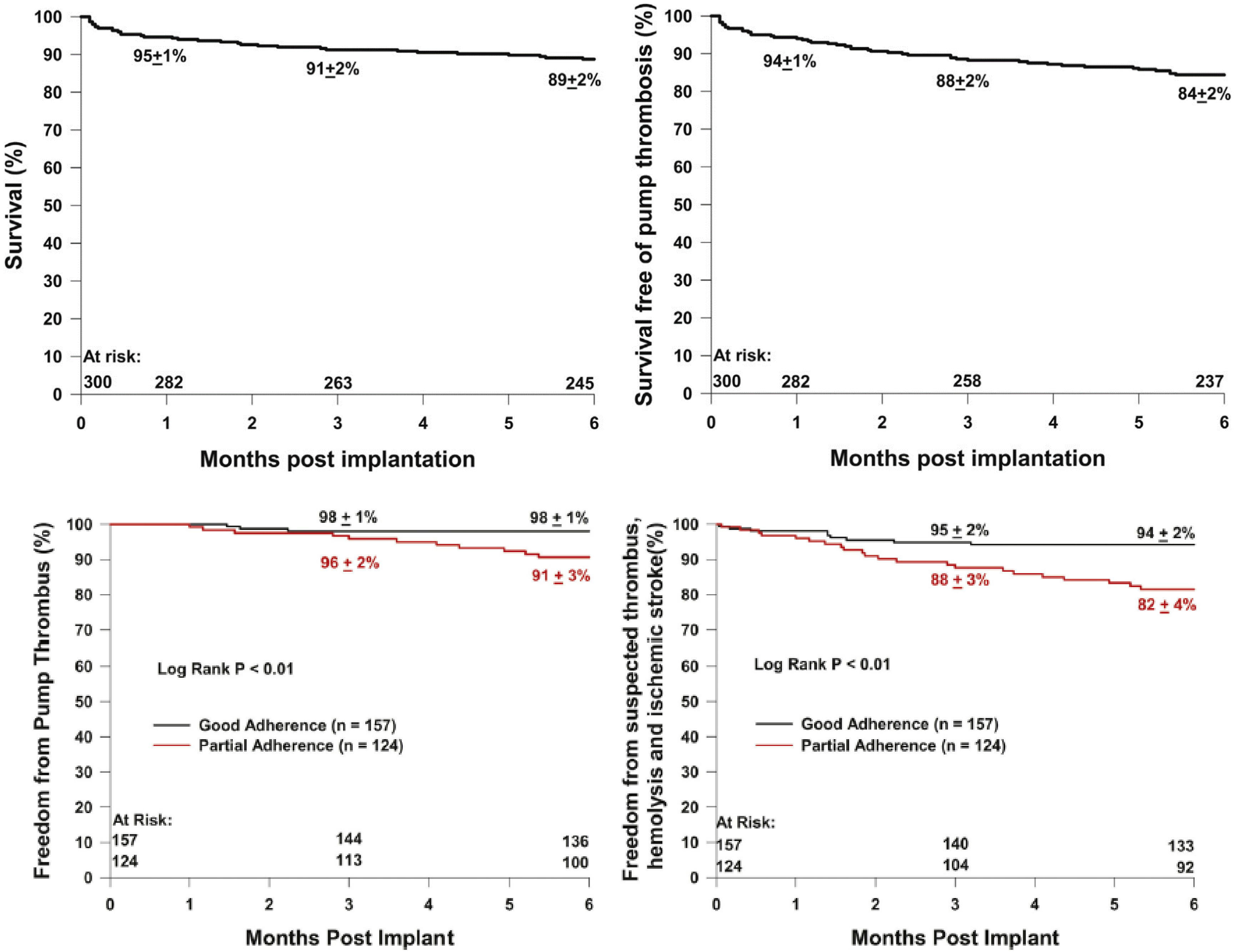
2014 INTEMACS analysis of pump thrombosis in HM II

*PREVEN*tion of HeartMate II Pump *T*hrombosis Through Clinical Management: The PREVENT multi-center study

Table 1 Overview of PREVENT Surgical Recommendations

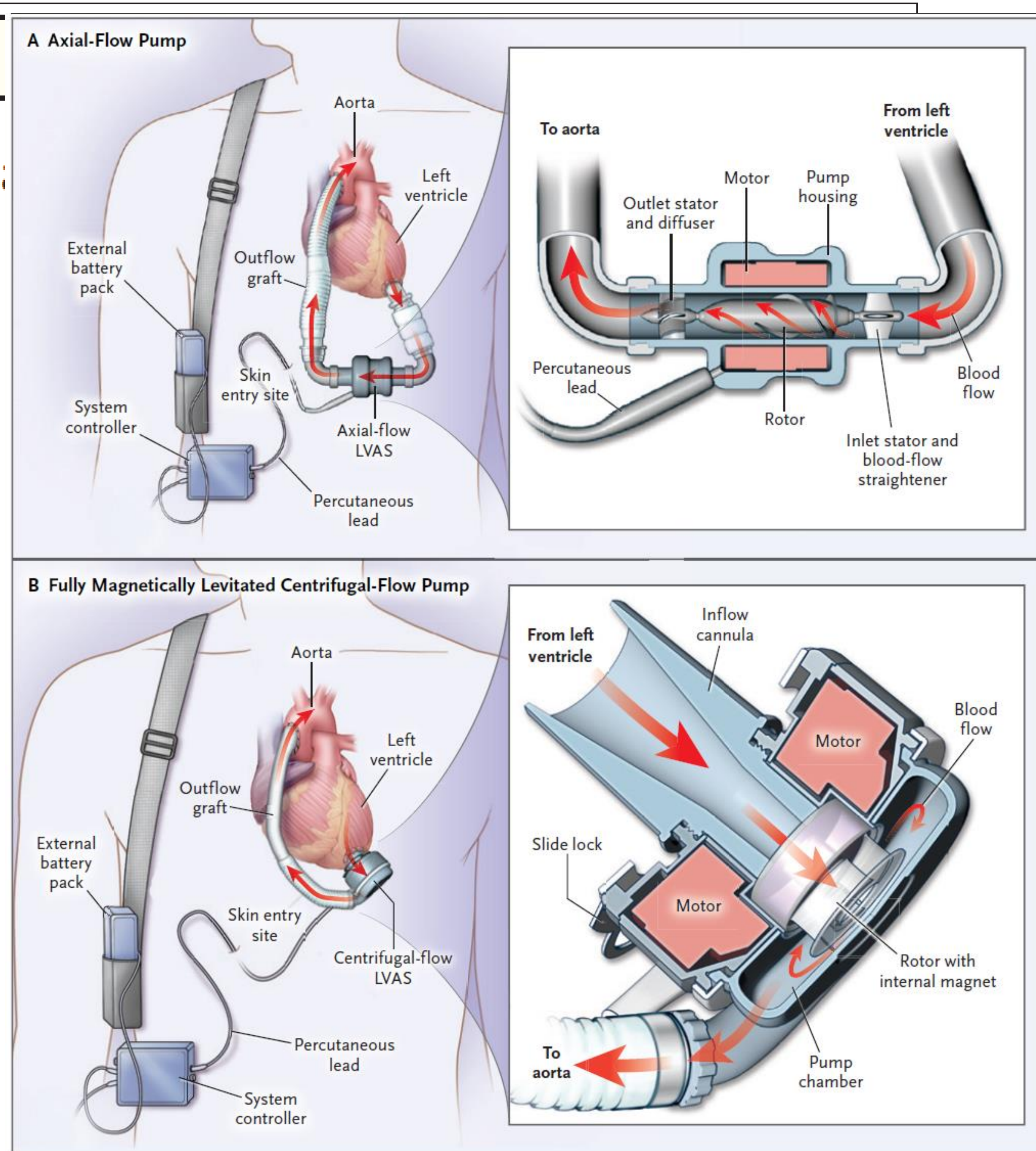
Surgical recommendations
1. Create an adequately sized pump pocket, located inferiorly deep and lateral.
2. Position the inflow cannula parallel to the septum, oriented to the central left ventricle.
3. Position the outflow graft right of the sternal midline to avoid compression of the right ventricle.
4. Position the pump below the diaphragm.
5. Fixate the pump (e.g., to the diaphragm or the chest wall) to prevent migration.
Anti-coagulation and anti-platelet management
1. In patients without persistent bleeding, begin bridging with unfractionated heparin or LMWH within 48 hours of device implantation with a goal PTT of 40–45 seconds in the first 48 hours, followed by titration up to PTT of 50–60 seconds by 96 hours. If heparin is contraindicated, consider other alternatives, including argatroban, intravenous warfarin, and bivalirudin.
2. Initiate warfarin within 48 hours to obtain goal INR of 2.0–2.5 by post-operative days 5–7, at which time heparin therapy may be discontinued.
3. When there is no evidence of bleeding, initiate aspirin therapy (81–325 mg daily) 2–5 days after HMII implantation.
4. Maintain the patient throughout LVAD support on aspirin and warfarin with goal INR of 2.0–2.5.
Pump speed management
1. Run pump speeds $>$9,000 RPM, and avoid speeds $<$8,600 RPM.
2. Adjust pump speed to permit intermittent aortic valve opening only after above goals are achieved.
Blood pressure management
1. Maintain a MAP $<$90 mm Hg.

HMII, HeartMate II; INR, international normalized ratio; LMWH, low-molecular-weight heparin; LVAD, left ventricular assist device; MAP, mean arterial pressure; PTT, partial thromboplastin time.



J Heart Lung Transplant 2017;36:1–12

A Fully M
Pump



HeatMate 3

- **Intrinsic artificial pulse**
- **Wide blood-flow passage**
- **No mechanical bearing**

Table 2. Noninferiority and Superiority Analyses in the Intention-to-Treat Population.*

Variable	Centrifugal-Flow Pump Group (N=152)		Axial-Flow Pump Group (N=142)		Absolute Difference	Hazard Ratio (95% CI)	P Value†
	no. of patients	*% (95% CI)*	*no. of patients*	*% (95% CI)*	*percentage points (95% LCB)*		
Noninferiority analysis							
Primary end point	131	86.2 (79.7–91.2)	109	76.8 (68.9–83.4)	9.4 (−2.1)		<0.001
Superiority analyses							
Primary end point	131	86.2 (79.7–91.2)	109	76.8 (68.9–83.4)		0.55 (0.32–0.95)	0.04
First event that resulted in failure to reach the primary end point							
Did not receive the assigned implant	1	0.7 (0–3.6)	4	2.8 (0.8–7.1)		0.23 (0.03–2.09)	0.15
Had disabling stroke	6	3.9 (1.5–8.4)	4	2.8 (0.8–7.1)		1.31 (0.37–4.64)	0.59
Underwent reoperation to replace or remove pump‡	1	0.7 (0–3.6)	11	7.7 (3.9–13.4)		0.08 (0.01–0.60)	0.002
Died within 6 months after implantation	13	8.6 (4.6–14.2)	14	9.9 (5.5–16.0)		0.82 (0.38–1.73)	0.70

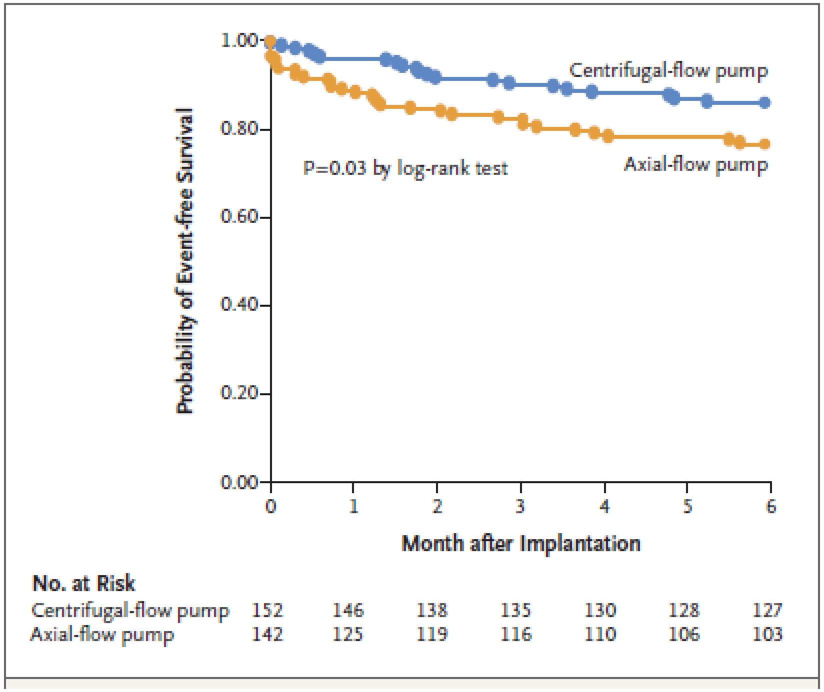


Table 3. Major Adverse Events in the Per-Protocol Population.*

Event	Centrifugal-Flow Pump Group (N=151)		Axial-Flow Pump Group (N=138)		Relative Risk (95% CI)	P Value
	no. of patients with events (%)	*no. of events*	*no. of patients with events (%)*	*no. of events*		
Suspected or confirmed pump thrombosis	0	0	14 (10.1)	18	NA	<0.001
Stroke						
Any stroke	12 (7.9)	12	15 (10.9)	17	0.73 (0.35–1.51)	0.39
Hemorrhagic stroke	4 (2.6)	4	8 (5.8)	8	0.46 (0.14–1.48)	0.18
Ischemic stroke	8 (5.3)	8	9 (6.5)	9	0.81 (0.32–2.05)	0.66
Disabling stroke	9 (6.0)	9	5 (3.6)	5	1.65 (0.57–4.79)	0.36
Other neurologic event†	9 (6.0)	9	8 (5.8)	8	1.03 (0.41–2.59)	0.95
Bleeding						
Any bleeding	50 (33.1)	100	54 (39.1)	98	0.85 (0.62–1.15)	0.29
Bleeding requiring surgery	15 (9.9)	15	19 (13.8)	21	0.72 (0.38–1.36)	0.31
Gastrointestinal bleeding	24 (15.9)	47	21 (15.2)	36	1.04 (0.61–1.79)	0.87
Sepsis	14 (9.3)	19	9 (6.5)	10	1.42 (0.64–3.18)	0.39
LVAS drive-line infection	18 (11.9)	21	9 (6.5)	11	1.83 (0.85–3.93)	0.12
Local infection not associated with LVAS	46 (30.5)	57	36 (26.1)	58	1.17 (0.81–1.69)	0.41
Right heart failure						
Any right heart failure	45 (29.8)	49	34 (24.6)	36	1.21 (0.83–1.77)	0.33
Right heart failure managed with RVAS	4 (2.6)	4	8 (5.8)	8	0.46 (0.14–1.48)	0.18
Cardiac arrhythmia						
Any cardiac arrhythmia	47 (31.1)	61	52 (37.7)	68	0.83 (0.60–1.14)	0.24
Ventricular arrhythmia	27 (17.9)	33	27 (19.6)	37	0.91 (0.57–1.48)	0.71
Supraventricular arrhythmia	23 (15.2)	27	30 (21.7)	31	0.70 (0.43–1.15)	0.15
Respiratory failure	33 (21.9)	44	24 (17.4)	27	1.26 (0.78–2.02)	0.34
Renal dysfunction	17 (11.3)	18	12 (8.7)	12	1.29 (0.64–2.61)	0.47
Hepatic dysfunction	7 (4.6)	7	3 (2.2)	3	2.13 (0.56–8.08)	0.34
Hemolysis not associated with pump thrombosis	1 (0.7)	1	2 (1.4)	2	0.46 (0.04–4.98)	0.61

* The per-protocol population included patients who underwent implantation of the assigned device. LVAS denotes left ventricular assist system, NA not available, and RVAS right ventricular assist system.
† Other neurologic events included transient ischemic attack and neurologic events other than stroke.

ORIGINAL ARTICLE

Intrapericardial Left Ventricular Assist Device for Advanced Heart Failure

Joseph G. Rogers, M.D., Francis D. Pagani, M.D., Ph.D., Antone J. Tatooles, M.D., Geetha Bhat, M.D., Mark S. Slaughter, M.D., Emma J. Birks, M.B., B.S., Ph.D., Steven W. Boyce, M.D., Samer S. Najjar, M.D., Valluvan Jeevanandam, M.D., Allen S. Anderson, M.D., Igor D. Gregoric, M.D., Hari Mallidi, M.D., Katrin Leadley, M.D., Keith D. Aaronson, M.D., O.H. Frazier, M.D., and Carmelo A. Milano, M.D.

ENDURANCE trial

N Engl J Med 2017;376:451-60.

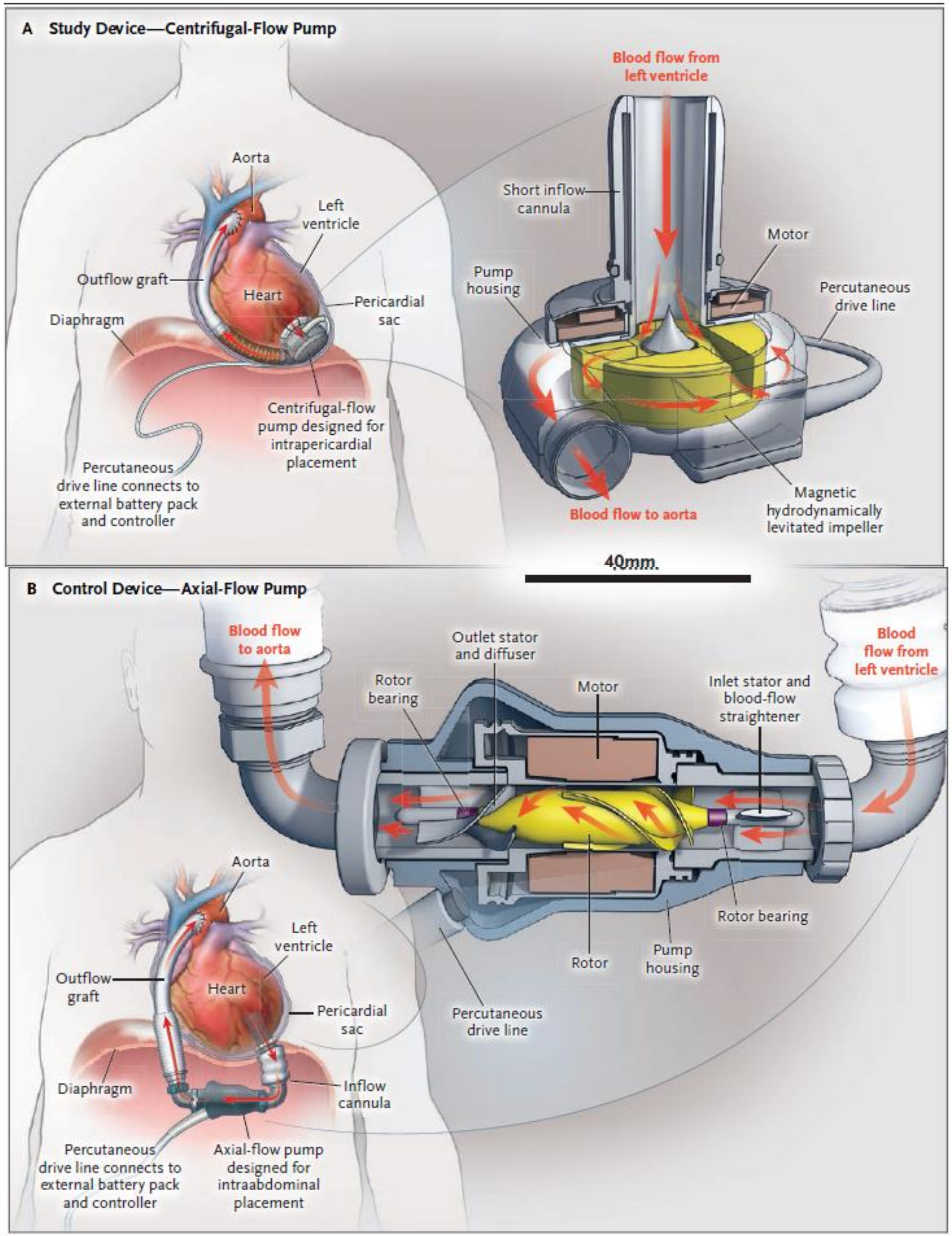
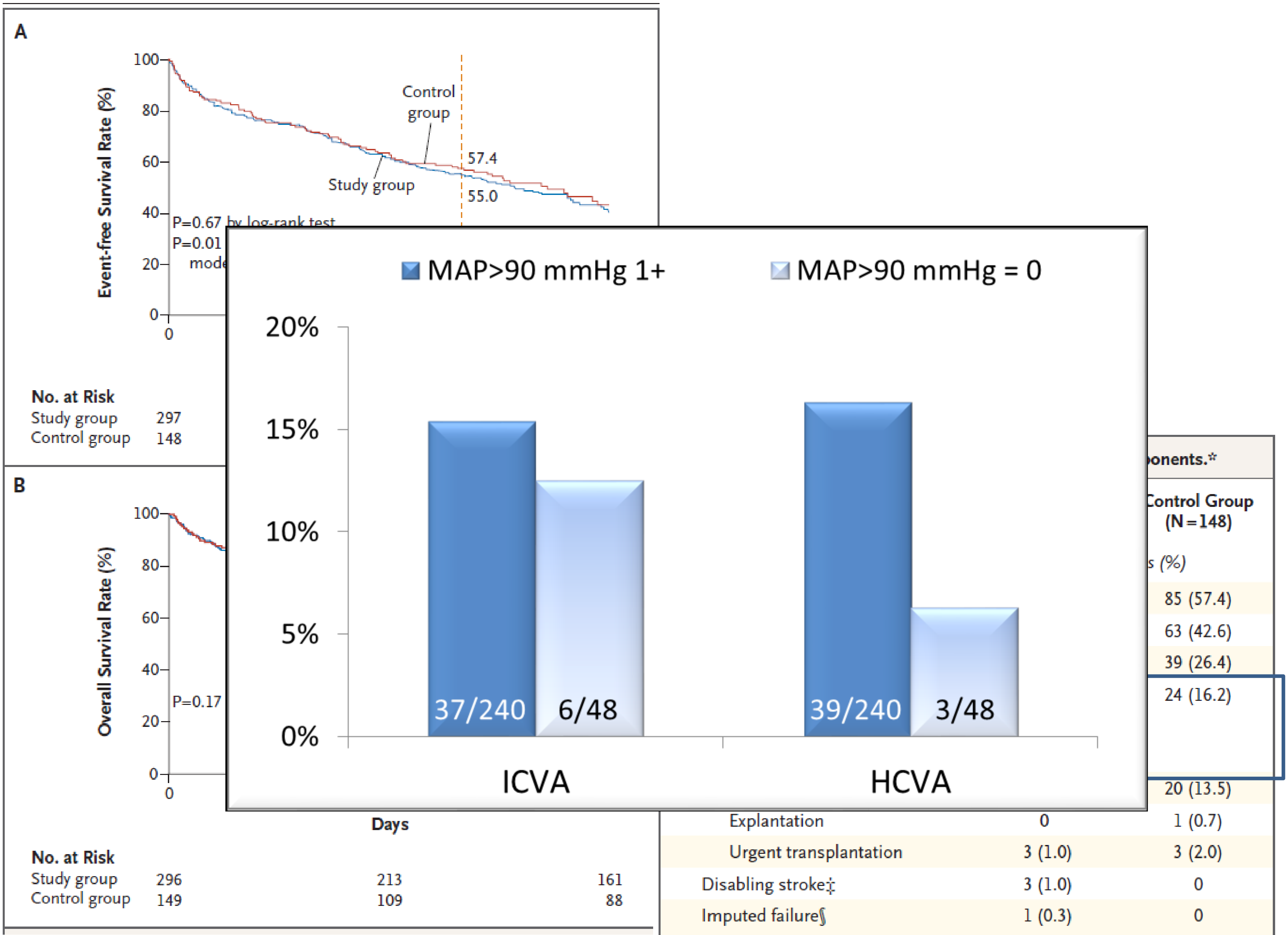

A Study Device—Centrifugal-Flow Pump
Blood flow from left ventricle
Aorta
Left ventricle
Short inflow cannula
Motor
Pump housing
Percutaneous drive line
Outflow graft
Heart
Pericardial sac
Diaphragm
Centrifugal-flow pump designed for intrapericardial placement
Percutaneous drive line connects to external battery pack and controller
Blood flow to aorta
Magnetic hydrodynamically levitated impeller
40mm
B Control Device—Axial-Flow Pump
Blood flow to aorta
Outlet stator and diffuser
Rotor bearing
Motor
Inlet stator and blood-flow straightener
Blood flow from left ventricle
Aorta
Rotor bearing
Left ventricle
Rotor
Pump housing
Outflow graft
Heart
Pericardial sac
Percutaneous drive line
Diaphragm
Inflow cannula
Percutaneous drive line connects to external battery pack and controller
Axial-flow pump designed for intraabdominal placement

Table 3. Adverse Events in the As-Treated Population.*

Event	Study Group (N=296)			Control Group (N=149)			P Value†
	no. of patients (%)	*no. of events*	*events/patient-yr*	*no. of patients (%)*	*no. of events*	*events/patient-yr*	
Bleeding events	178 (60.1)	410	1.00	90 (60.4)	199	0.98	>0.99
Requiring reoperation‡	45 (15.2)	52	0.13	27 (18.1)	28	0.14	0.52
Requiring transfusion of >4 units of packed red cells within 7 days‡	45 (15.2)	47	0.11	33 (22.1)	36	0.18	0.09
Gastrointestinal bleeding	104 (35.1)	230	0.56	51 (34.2)	91	0.45	0.92
Cardiac arrhythmia	112 (37.8)	178	0.43	61 (40.9)	83	0.41	0.54
Hepatic dysfunction	14 (4.7)	14	0.03	12 (8.1)	12	0.06	0.20
Hypertension	47 (15.9)	62	0.15	25 (16.8)	29	0.14	0.79
Sepsis	70 (23.6)	84	0.20	23 (15.4)	28	0.14	0.048
Drive-line exit-site infection	58 (19.6)	752	0.18	23 (15.4)	27	0.13	0.30
Stroke	88 (29.7)	117	0.29	18 (12.1)	19	0.09	<0.001
Ischemic cerebrovascular event	52 (17.6)	70	0.17	12 (8.1)	12	0.06	0.007
Hemorrhagic cerebrovascular event	44 (14.9)	47	0.11	6 (4.0)	7	0.03	<0.001
Transient ischemic attack§	25 (8.4)	28	0.07	7 (4.7)	7	0.03	0.18
Renal dysfunction	44 (14.9)	53	0.13	18 (12.1)	20	0.10	0.47
Respiratory dysfunction	86 (29.1)	116	0.28	38 (25.5)	49	0.24	0.502
Right heart failure	114 (38.5)	133	0.32	40 (26.8)	46	0.23	0.02
Need for RVAD‡	8 (2.7)	8	0.02	5 (3.4)	6	0.03	0.77
Pump replacement¶	23 (7.8)	NA	NA	20 (13.4)	NA	NA	0.06
Exchange owing to pump thrombosis	19 (6.4)	NA	NA	16 (10.7)	NA	NA	0.12
Device malfunction or failure	93 (31.4)	124	0.30	38 (25.5)	43	0.21	0.23
Rehospitalization	249 (84.1)	1167	2.85	118 (79.2)	478	2.34	0.23
Death	116 (39.2)	NA	NA	48 (32.2)	NA	NA	0.18

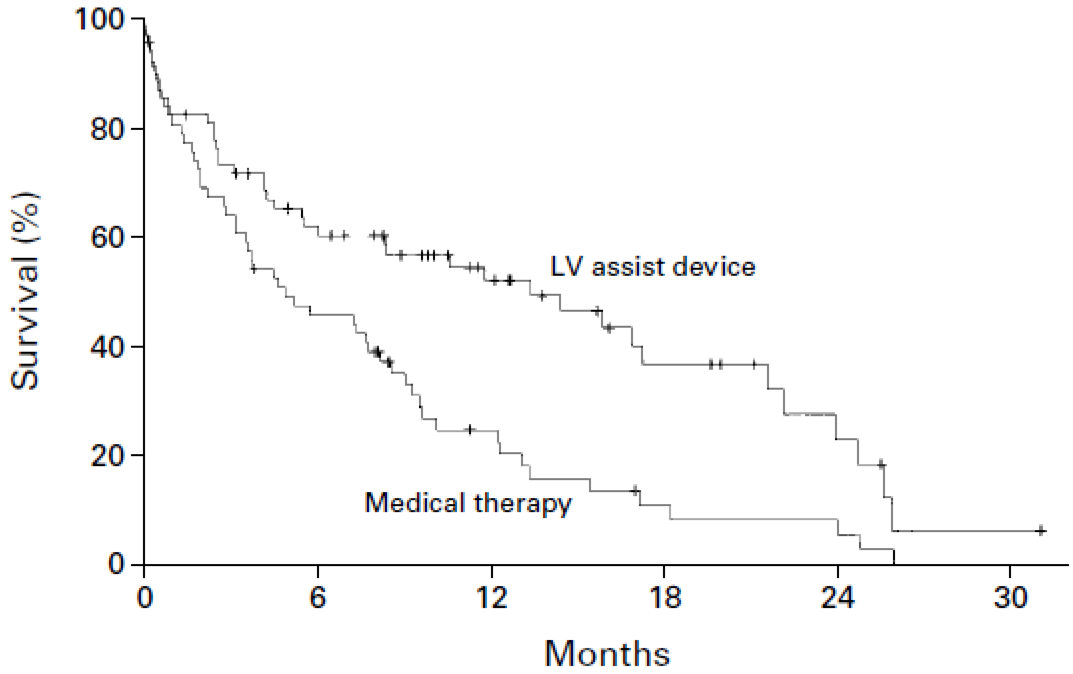

A
Event-free Survival Rate (%)
100
80
60
40
20
0
Control group
Study group
57.4
55.0
P=0.67 by log-rank test
P=0.01
mode
No. at Risk
Study group 297
Control group 148
B
Overall Survival Rate (%)
P=0.17
Days
No. at Risk
Study group 296 213 161
Control group 149 109 88
MAP>90 mmHg 1+
MAP>90 mmHg = 0
20%
15%
10%
5%
0%
37/240
6/48
39/240
3/48
ICVA
HCVA
ponents.*
Control Group (N=148)
s (%)
85 (57.4)
63 (42.6)
39 (26.4)
24 (16.2)
20 (13.5)
Explantation 0 1 (0.7)
Urgent transplantation 3 (1.0) 3 (2.0)
Disabling stroke‡ 3 (1.0) 0
Imputed failure§ 1 (0.3) 0

Summary

- VAD: smaller, more durable
- Non-physiologic
- Continuous flow: axial vs centrifugal type
- Pump thrombosis: increase ?
- Guideline-based management

  - perfect surgical technique, BP control, anti-coagulation
- Driveline problems

LONG-TERM USE OF A LEFT VENTRICULAR ASSIST DEVICE FOR END-STAGE HEART FAILURE



No. at Risk

LV assist device	68	38	22	11	5	1
Medical therapy	61	27	11	4	3	0

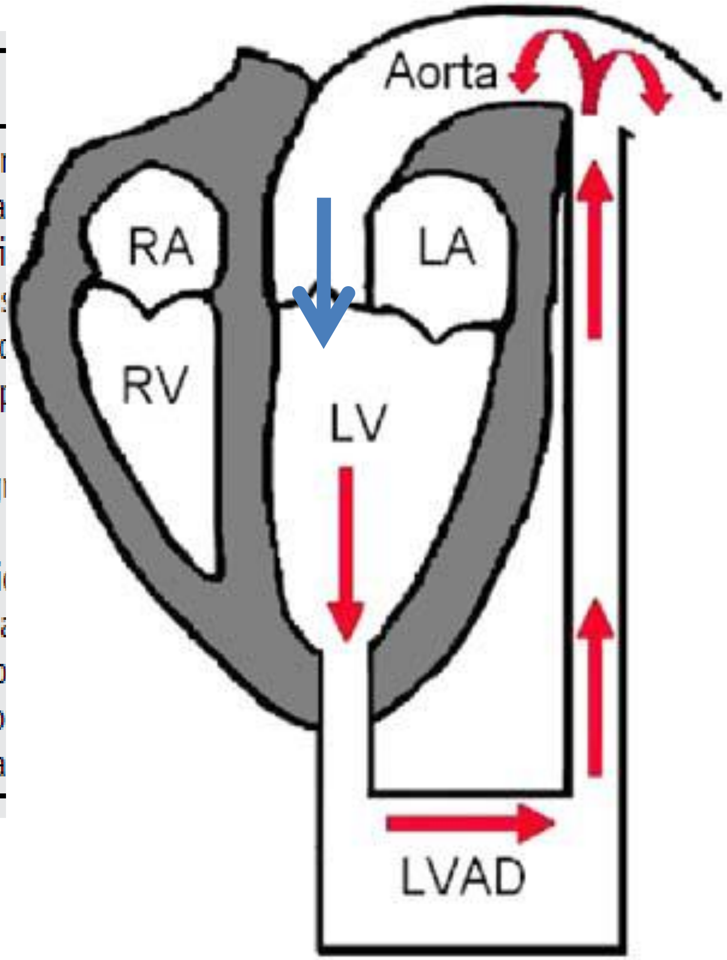
REMATCH study group NEJM 2001;345:1435-43

ISHLT Guidelines for Speed and Medical Management

- Adjust RPMs to adequately unload the LV while maintaining midline interventricular septum and minimizing mitral regurgitation
  - (Class of Recommendation: I; Level of Evidence: C)
- Adjust RPMs low enough to allow intermittent aortic valve opening
  - (Class of Recommendation: IIb; Level of Evidence: B)
- Diuretics, ACE-inhibitors, ARBs, b-blockers and mineralocorticoids are considered useful for managing volume status, blood pressure, arrhythmias and myocardial fibrosis
  - (Class of Recommendation: I; Level of Evidence: C)

Valve issues at implantation

Issue	Possible solution and comments	
Aortic insufficiency	Aortic insufficiency that is greater be partially over-sewn or the va expected post-operative aortic i high left ventricular filling press pressures, reassessment of the c weaning of cardiopulmonary byp	valve leaflets can ne amount of the presence of ar filling iately after
Mitral regurgitation	Generally does not require repair.	
Mitral stenosis	Mitral stenosis to a moderate deg bioprosthetic valve.	cement with a
Tricuspid insufficiency	Moderate to severe tricuspid insuffi This is especially important for pa performed using annuloplasty rep	ntricular function. r can be
Mechanical prosthetic valves	A mechanical prosthesis in the ao closure. The mitral valve genera	e or patch coagulation.

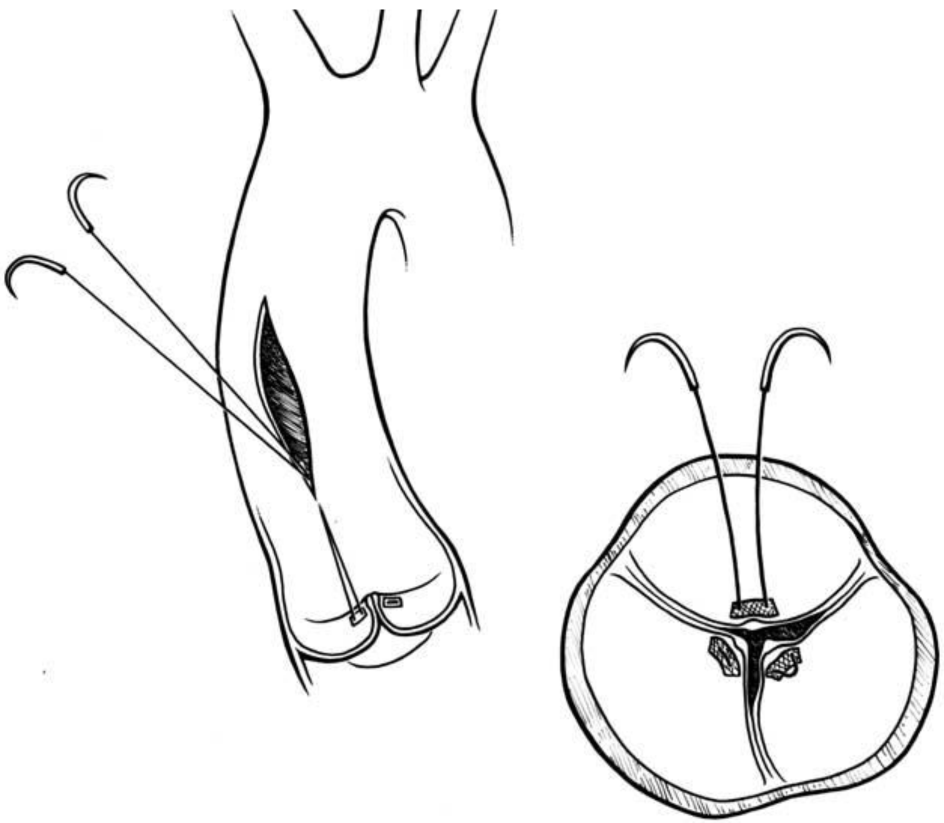


S39

Surgical technique of AV management

Management of aortic insufficiency in patients with left ventricular assist devices: A simple coaptation stitch method (Park's stitch)

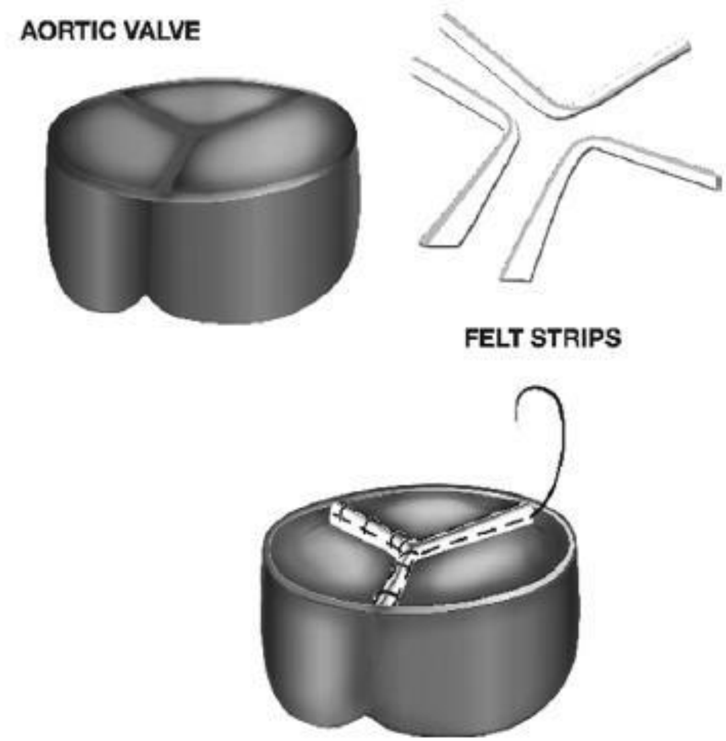
Soon J. Park, MD,[a] Kenneth K. Liao, MD,[a] Romualdo Segurola, MD,[a] K. P. Madhu, MD,[b] and Leslie W. Miller, MD,[b] Minneapolis, Minn



ORIGINAL CLINICAL SCIENCE

Aortic valve closure associated with HeartMate left ventricular device support: Technical considerations and long-term results

Robert M. Adamson, MD,[a] Walter P. Dembitsky, MD,[a] Sam Baradarian, MD,[a] Joseph Chammas, MD,[a] Karen May-Newman, PhD,[b] Suzanne Chillcott, RN,[c] Marcia Stahovich, RN,[c] Vicki McCalmont, NP,[c] Kristi Ortiz, NP,[c] Peter Hoagland, MD,[d] and Brian Jaski, MD[d]



Late complications of LVAD

- Infection
- Bleeding: GI bleeding due to AVM
- Device thrombosis
- De novo Aortic regurgitation

Aortic Regurgitation: Incidence

- AI (mild to moderate or greater) in 6% of HM I and 14.3% of HM II. Median time t o AI development were 48 days for HMI and 90 days for HMII

Pak SW et al. JHLT 2010;29:1172-6

- Mild AI in 52%. Median time to AI devel opment was 187 day. No severe AI

Aggarwal A et al. Ann Thorac Surg 2013;95:493–9

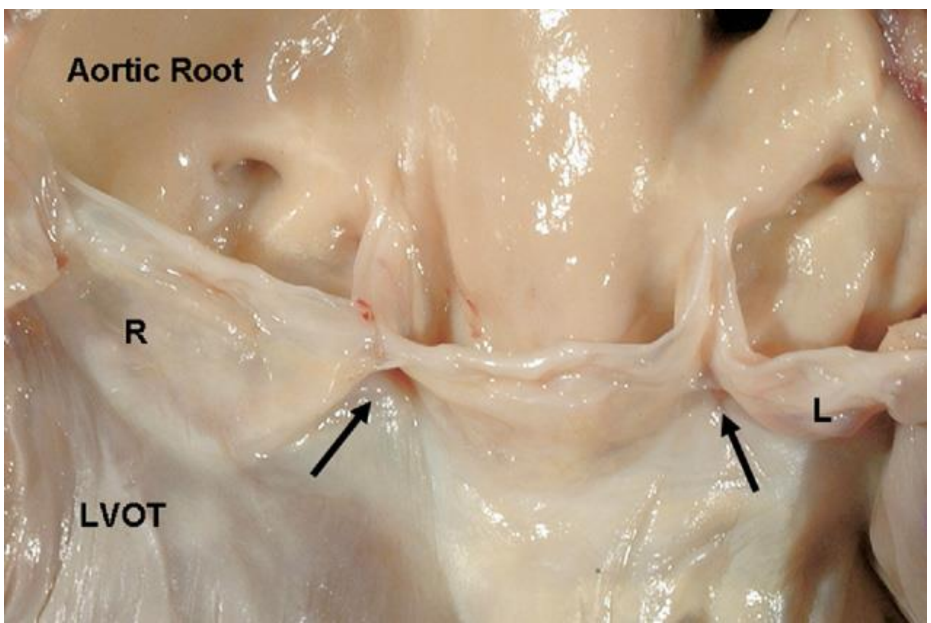
AR_ Risk factors

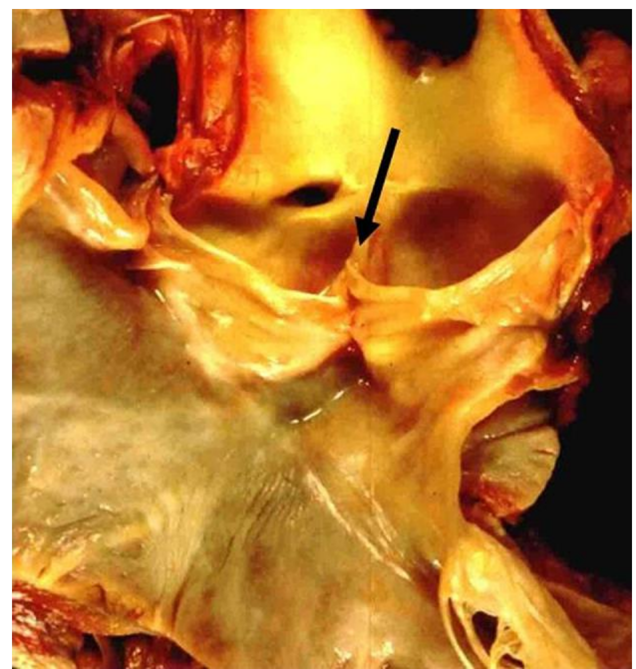
- Closure of AV
- Older age
- Duration of support
- Continuous flow type
- Aortic root size (?)

Aortic valve pathology

- 9 patients, HM II BT trial
- All but 1 explant had evidence of commissural fusion of the native aortic valve leaflets

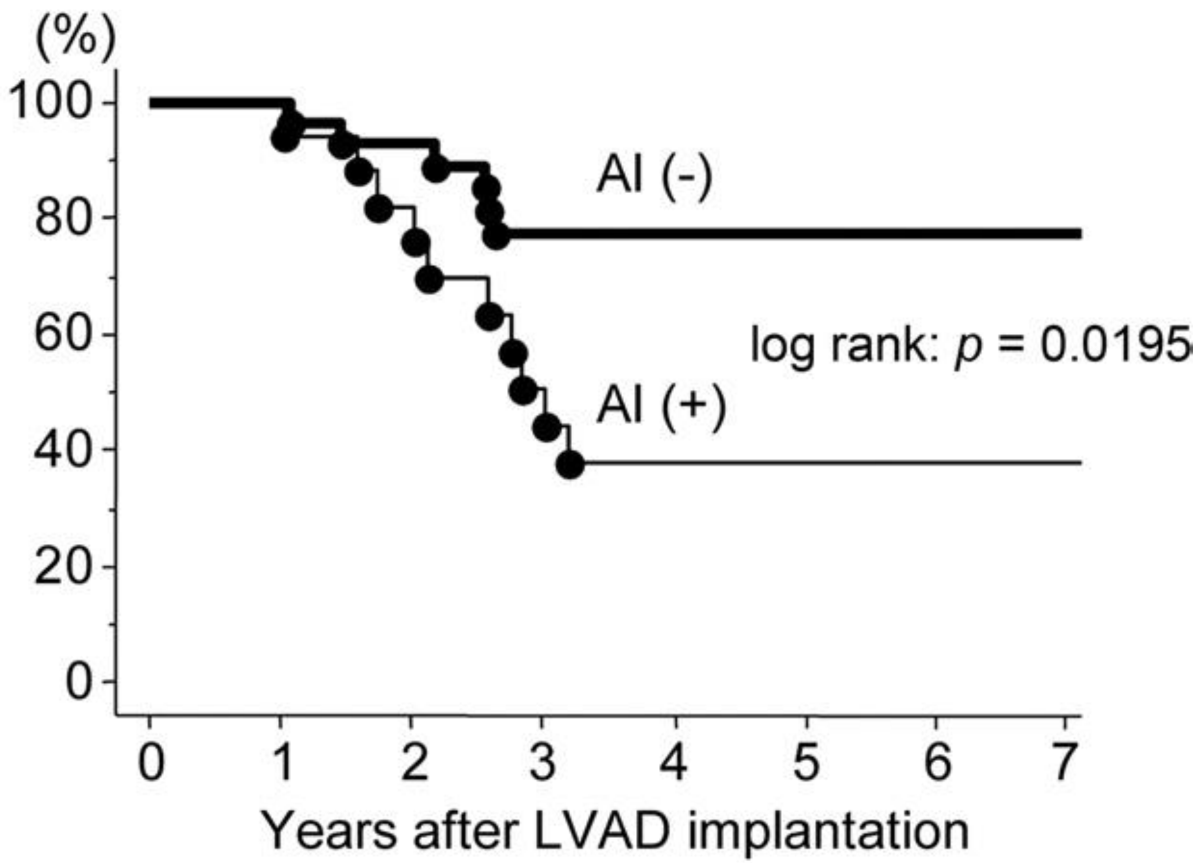
Mudd JO, et al. JHLT 2008;27:1269-74





Late Aortic Insufficiency Related to Poor Prognosis During Left Ventricular Assist Device Support

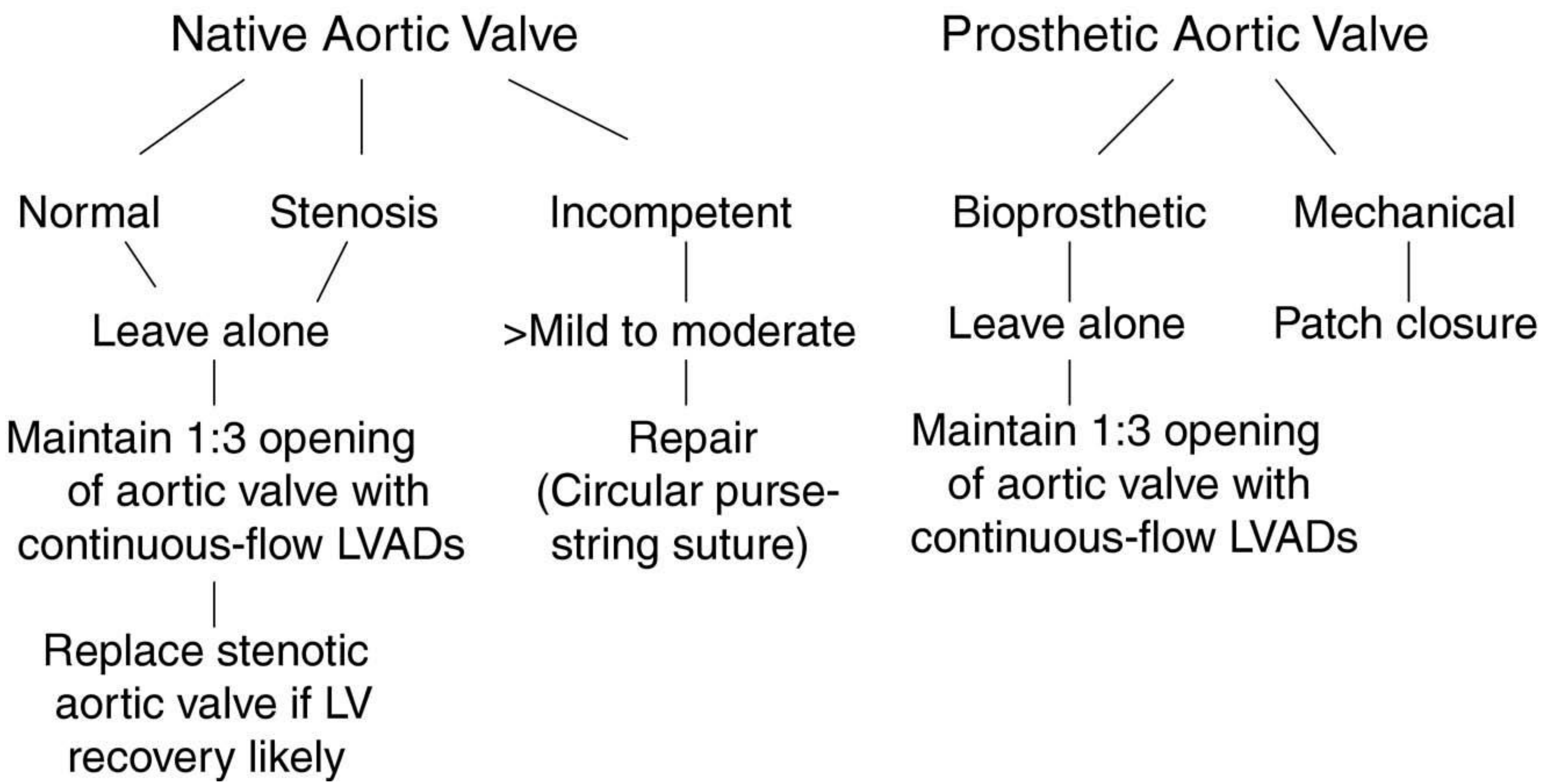
Koichi Toda, MD, PhD, Tomoyuki Fujita, MD, Keitaro Domae, MD,
Yusuke Shimahara, MD, Junjiro Kobayashi, MD, PhD, and Takeshi Nakatani, MD, PhD
Department of Cardiovascular Surgery, National Cerebral and Cardiovascular Center, Osaka, Japan



Number of patients at risk

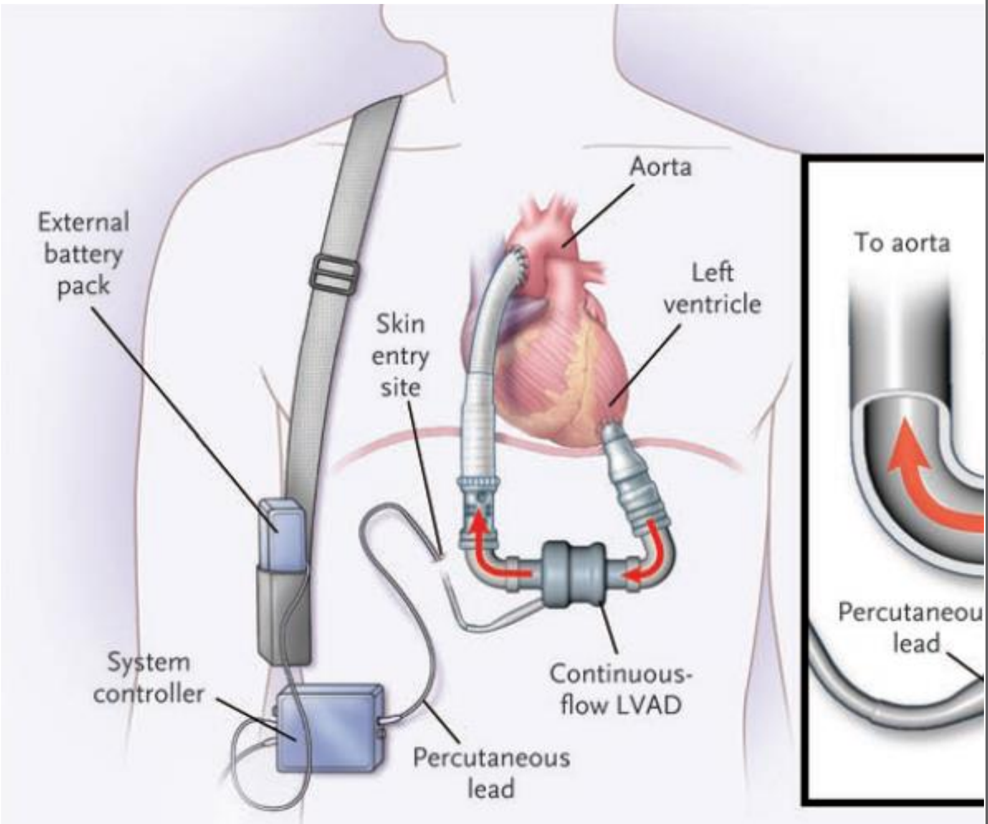
AI (-)	29	29	24	16	15	12	11	9
AI (+)	18	18	13	8	6	6	2	2

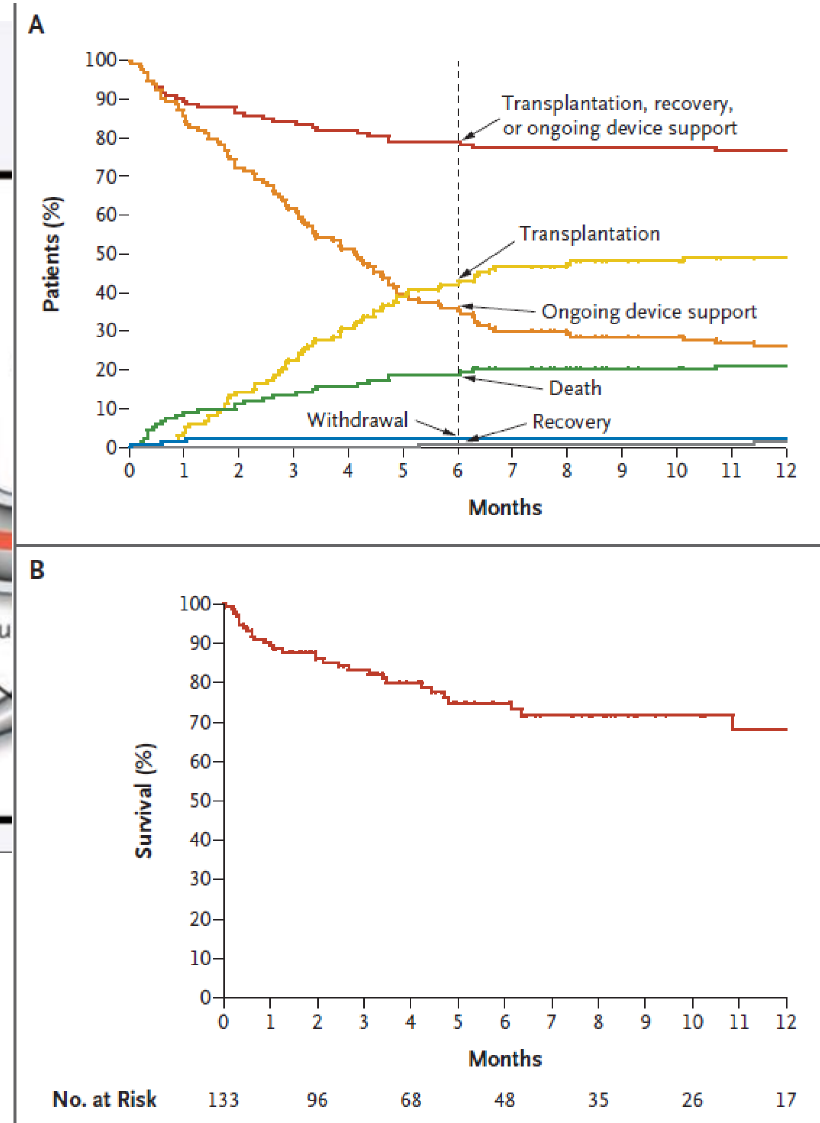
Recommendation of aortic valve in patients with LVAD



John R, et al. JHLT 2010;29:1321-9

Use of a Continuous-Flow Device in Patients Awaiting Heart Transplantation





NEJM 2007;357:885-96

Centrifugal vs Axial type summary

- Pump type difference is based on how the blood leaves the impeller, i.e., radially outward for centrifugal pumps and axially outward for axial pumps
- Both pump types can utilize mechanical bearings, passive impeller suspension systems, and active impeller suspension systems
- All blood pumps require small gaps (0.001 to 0.01) for suspension and for hydraulic efficiency

Pump flow principles

- The relationship between differential pressure head (H) and delivered flow (Q) is typically:

  H = Ho – k*Q2

- Pump flow is a function of:

  - the speed of the rotor

  - the difference in pressure across the pump