Hospices Civils de Lyon

Chirurgie Cardiovasculaire de l'Adulte

Université de Lyon

Lyon 1

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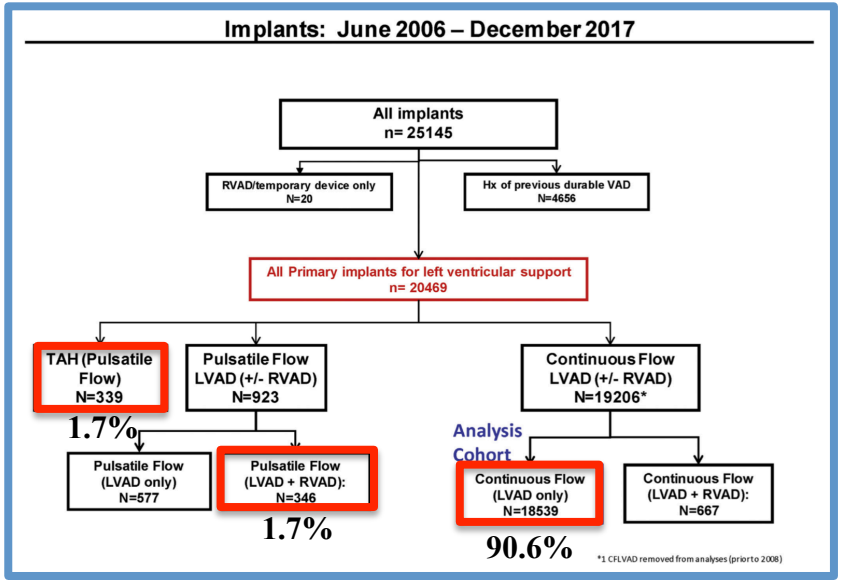
MOMENTUM 3

CONFLICTS OF INTEREST

No conflict of interest to disclose

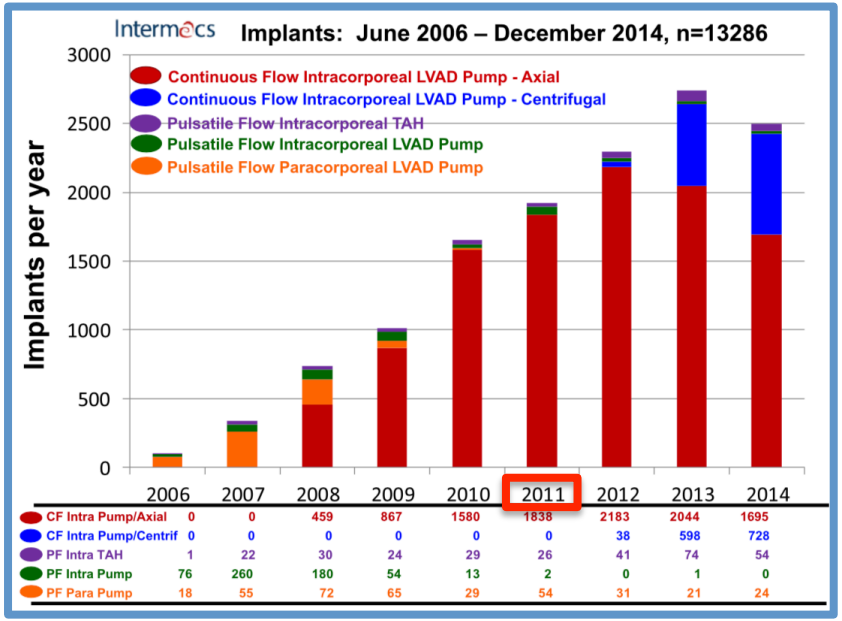
INTRODUCTION

Intermacs

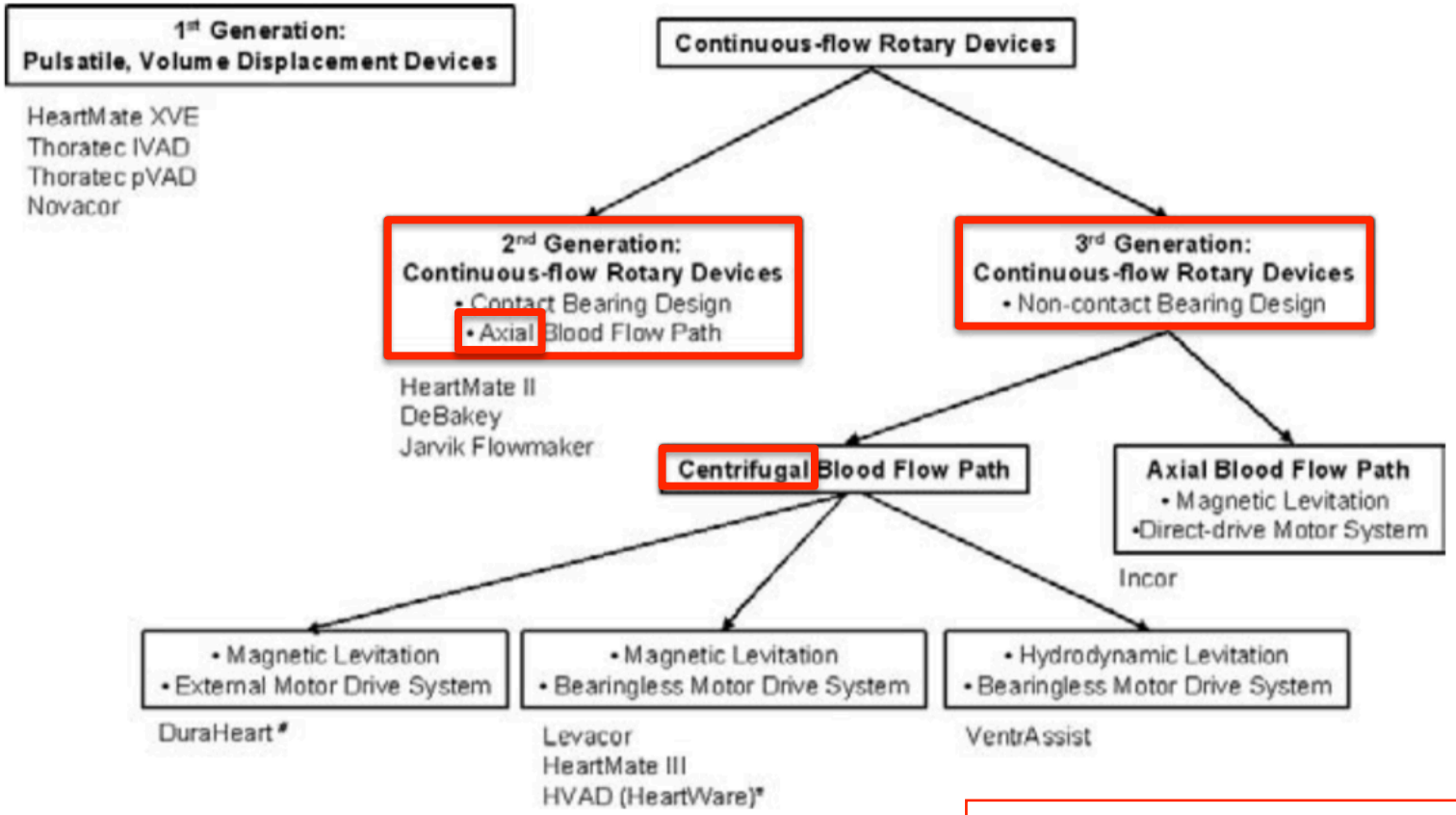


Ann Thorac Surg 2019;107:341-354

J Heart Lung Transplant 2015;34:1495-504



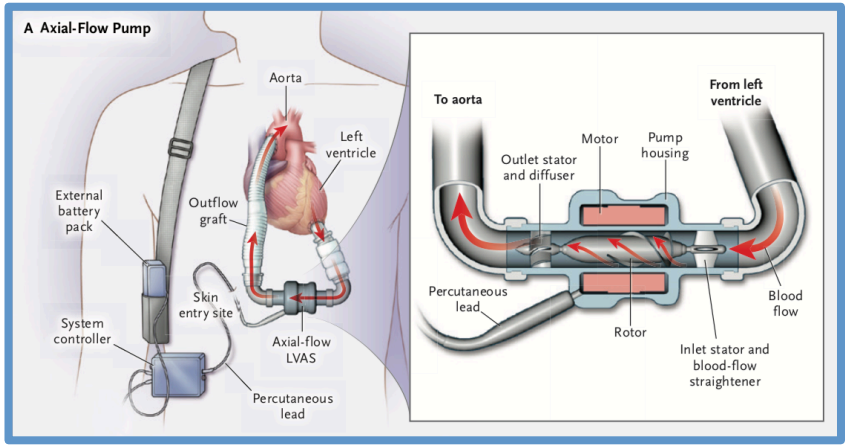
INTRODUCTION



Semin Thorac Cardiovasc Surg 2008;20:255-263

MOMENTUM 3

The Multicenter Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Therapy with HeartMate 3



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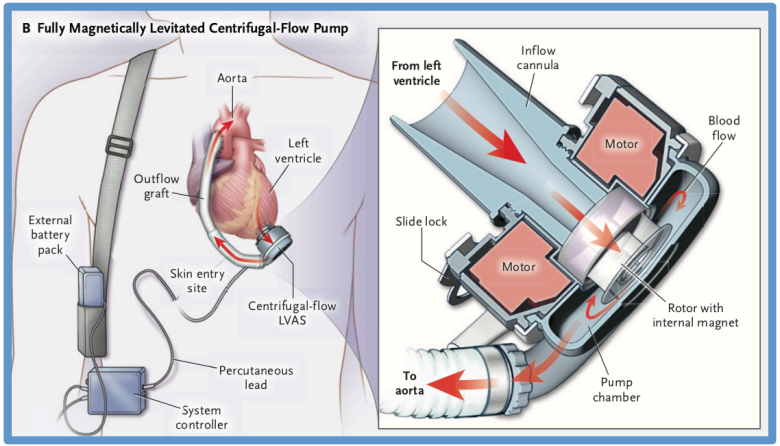


HeartMate II **HeartMate 3**

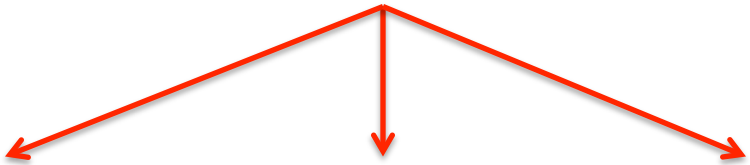
MOMENTUM 3

STUDY POPULATION

Inclusion criteria

Age ≥18 years

End-stage heart failure (BTT or DT strategy)
NYHA III-IV *LVEF ≤25%*



Refractory to OMM

Inotrope Dependent

IABP support
(at least 7 days)

MOMENTUM 3

STUDY POPULATION

Exclusion criteria

1) Etiology of heart failure due to or associated with uncorrected thyroid disease, obstructive cardiomyopathy, pericardial disease, amy
2) Technical obstacles whi
3) Existence of ongoing me
4) Positive pregnancy test
5) Presence of mechanical at the time of LVAD imp
8) Psychiatric disease/diso compliance with the stu
9) History of confirmed, u enrollment
10) Presence of an active, u
11) Intolerance to anticoag investigator will require

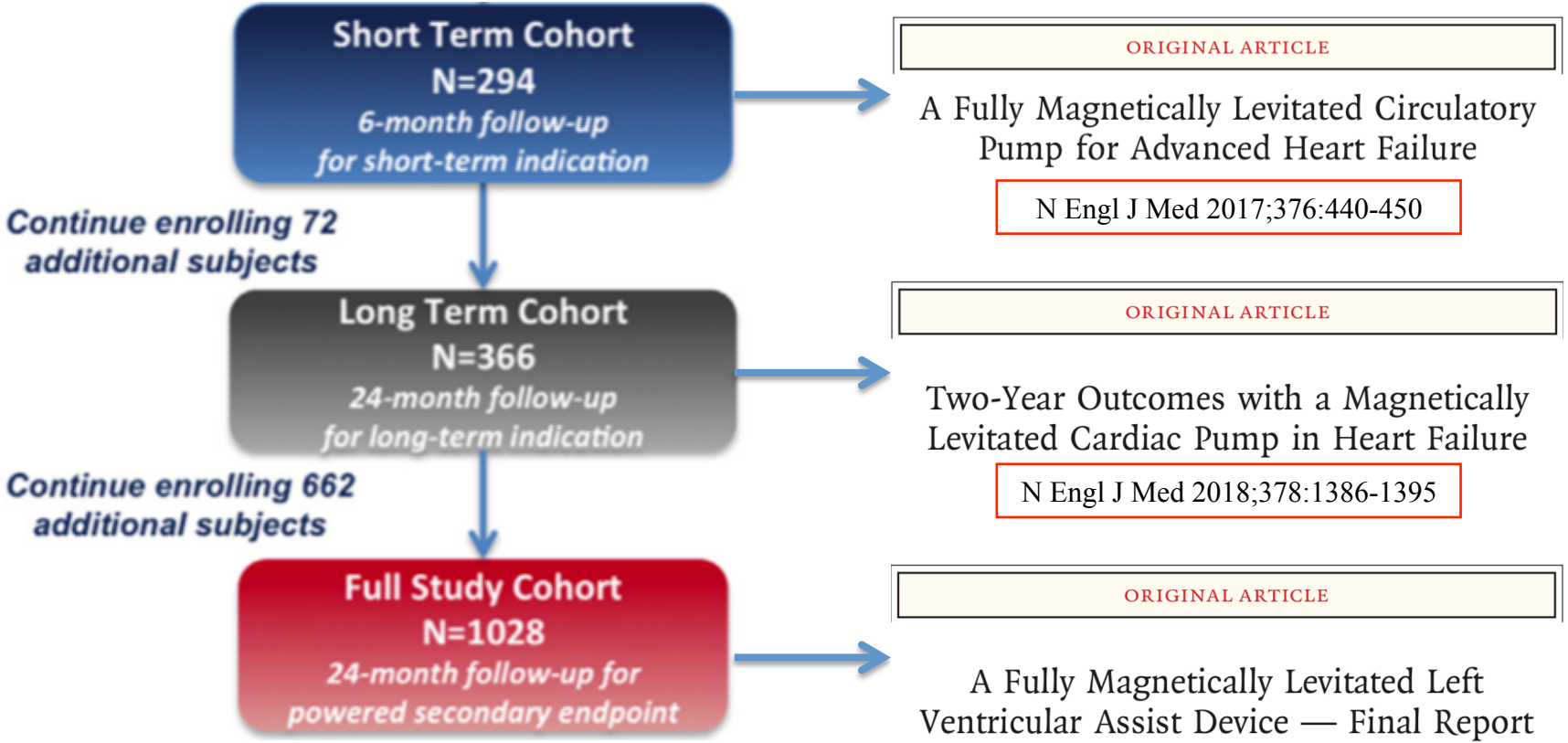
12) Presence of any one of the following risk factors for indications of severe end organ dysfunction or failure:
    a) An international normalized ratio (INR) ≥ 2.0 not due to anticoagulation therapy
    b) Total bilirubin > 43 µmol/L (2.5 mg/dl), shock liver, or biopsy proven liver cirrhosis
    c) History of severe chronic obstructive pulmonary disease (COPD) defined as the ratio of forced expiratory volume in one second to forced vital capacity (FEV_1/FVC) < 0.7, and FEV_1 < 50% predicted
    d) Fixed pulmonary hypertension with a most recent pulmonary vascular resistance (PVR) ≥ 8 Wood units that is unresponsive to pharmacologic intervention

3) Existence of ongoing mechanical circulatory support (MCS) other than IABP

    g) Significant peripheral vascular disease (PVD) accompanied by rest pain or extremity ulceration
13) Patient has moderate to severe aortic insufficiency without plans for correction during pump implant
14) Pre albumin < 150 mg/L (15mg/dL) or Albumin < 30g/L (3 g/dL) (if only one available); pre albumin < 150 mg/L (15mg/dL) and Albumin < 30g/L (3 g/dL) (if both available)
15) Planned Bi-VAD support prior to enrollment
16) Patient has known hypo- or hyper coagulable state such as disseminated intravascular coagulation and heparin induced thrombocytopenia (HIT)
17) Participation in any other clinical investigation that is likely to confound study results or affect the study
18) Any condition other than heart failure that could limit survival to less than 24 months

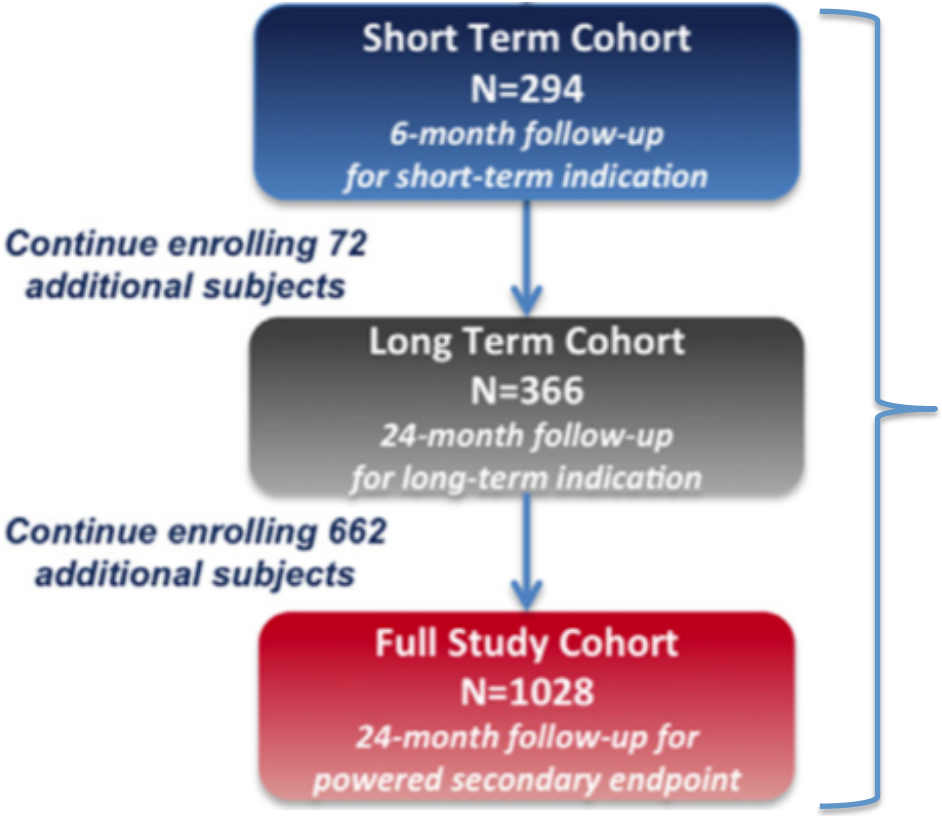
MOMENTUM 3

STUDY DESIGN



MOMENTUM 3

STUDY DESIGN



PRIMARY ENDPOINT

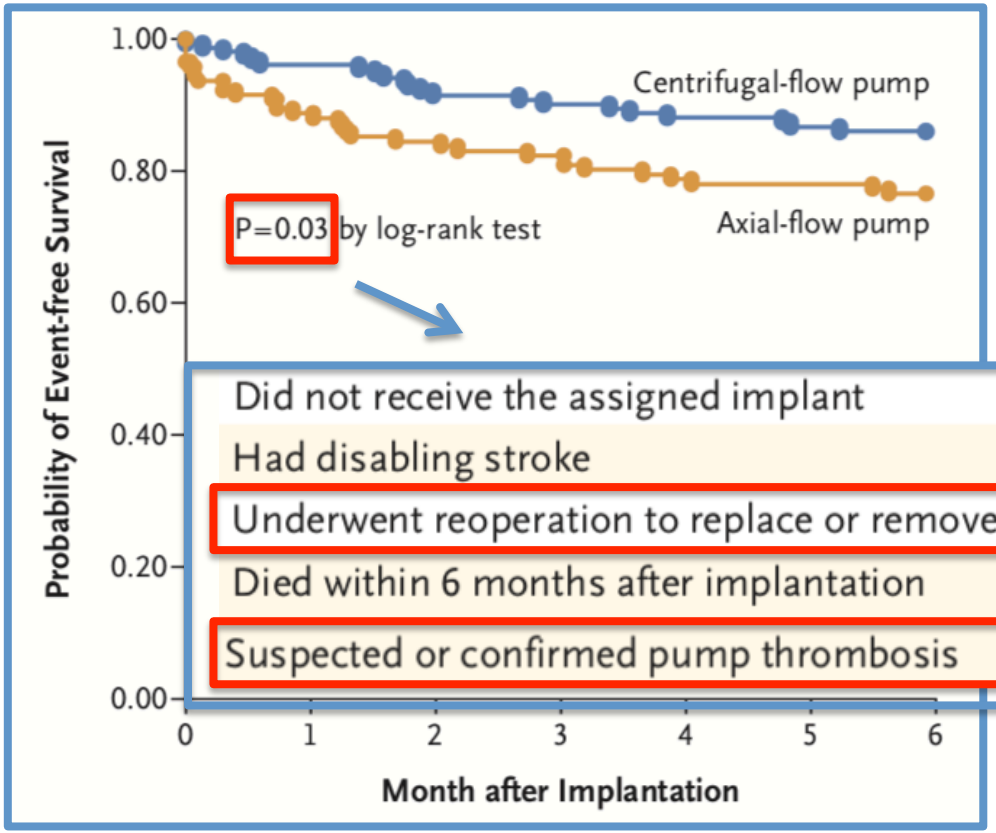
Composite of survival free of disabling stroke (with disabling stroke indicated by a modified Rankin score >3; scores range from 0 to 6, with higher scores indicating more severe disability) or survival free of reoperation to replace or remove the device (for reasons other than recovery)

MOMENTUM 3 - SHORT TERM COHORT

Characteristic	Centrifugal-Flow Pump Group (N=152)	Axial-Flow Pump Group (N=142)
Age — yr		
Mean	60.3±12.3	58.9±12.0
Intended goal of pump support — no. (%)		
Bridge to transplantation	41 (27.0)	37 (26.1)
Bridge to candidacy for transplantation	27 (17.8)	27 (19.0)
Destination therapy	84 (55.3)	78 (54.9)
INTERMACS profile — no. (%)‡		
1	1 (0.7)	4 (2.8)
2	50 (32.9)	44 (31.0)
3	76 (50.0)	69 (48.6)
4	22 (14.5)	23 (16.2)
5	2 (1.3)	2 (1.4)
6 or 7	0	0
Not provided	1 (0.7)	0

N Engl J Med 2017;376:440-450

MOMENTUM 3 - SHORT TERM COHORT

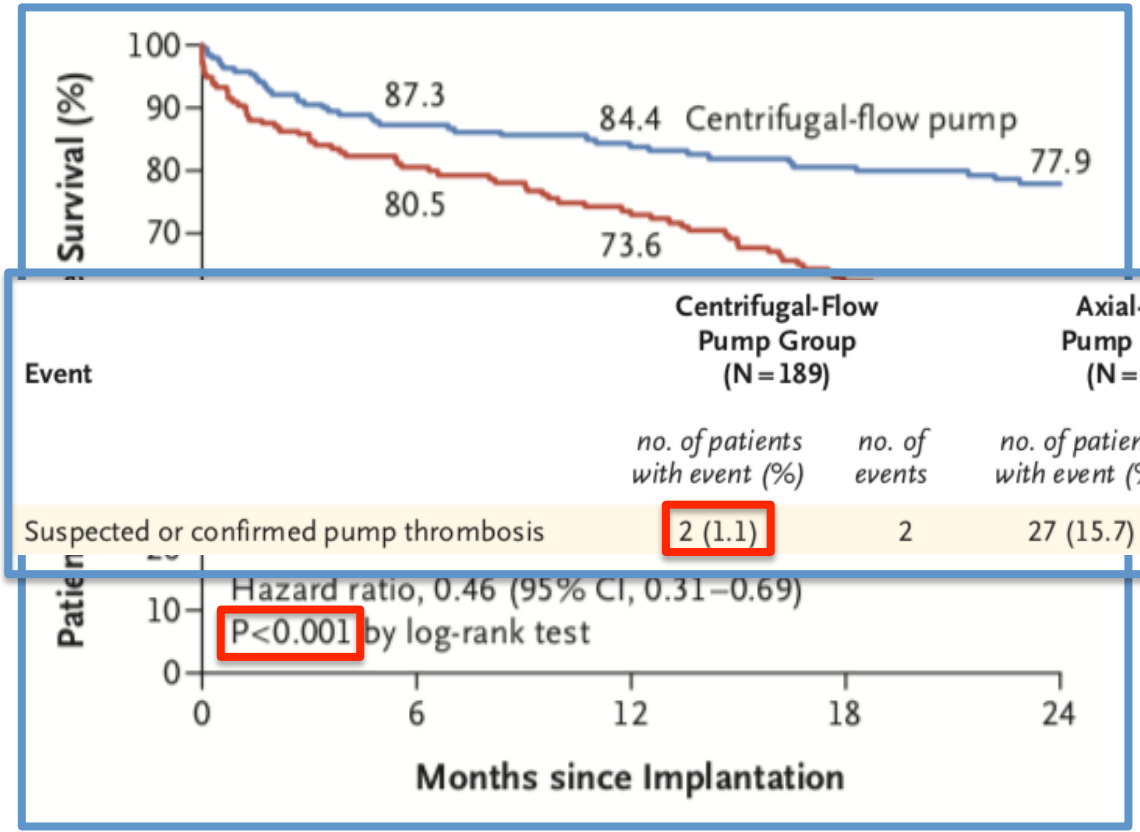


Intention-to-Treat Population

	HM3	HM II	*p*
Did not receive the assigned implant	1	4	0.15
Had disabling stroke	6	4	0.59
Underwent reoperation to replace or remove pump‡	1	11	0.002
Died within 6 months after implantation	13	14	0.70
Suspected or confirmed pump thrombosis	0	14	<0.001

N Engl J Med 2017;376:440-450

MOMENTUM 3 - LONG TERM COHORT

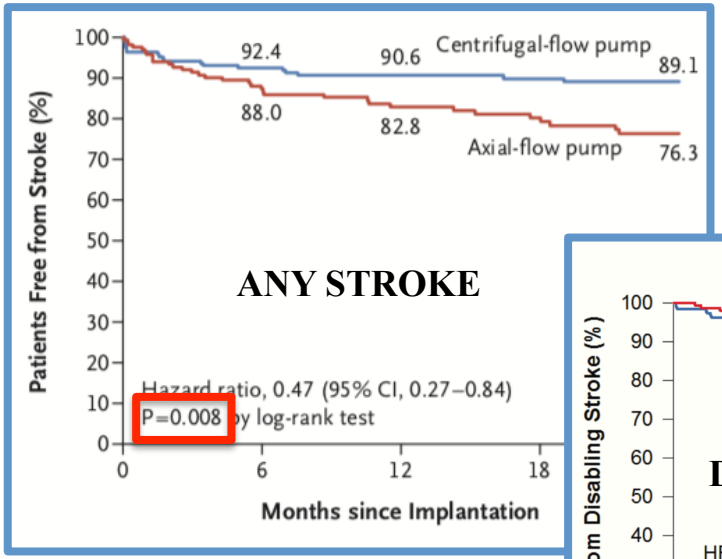


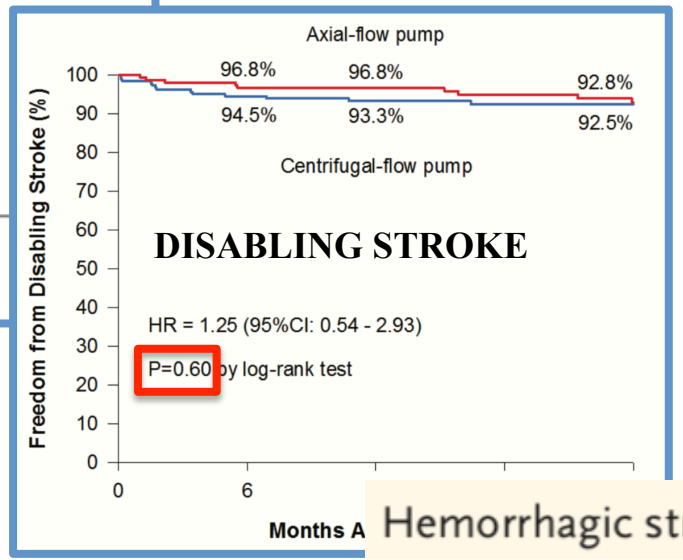
Intention-to-Treat Population

Event	Centrifugal-Flow Pump Group (N=189)		Axial-Flow Pump Group (N=172)		Hazard Ratio (95% CI)	P Value†
	no. of patients with event (%)	*no. of events*	*no. of patients with event (%)*	*no. of events*		
Suspected or confirmed pump thrombosis	2 (1.1)	2	27 (15.7)	33	0.06 (0.01–0.26)	<0.001

N Engl J Med 2018;378:1386-1395

MOMENTUM 3 - LONG TERM COHORT



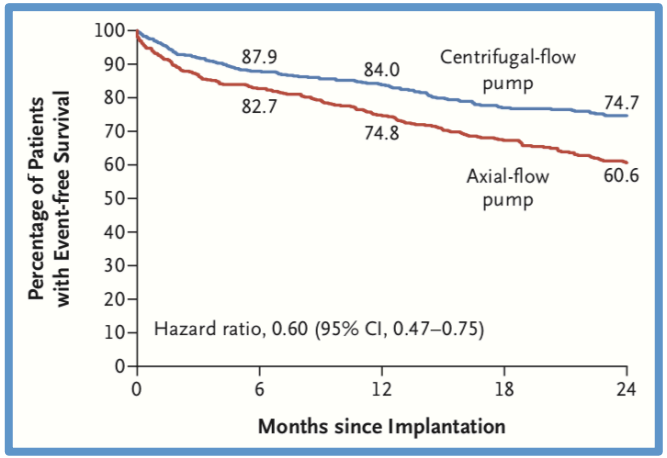


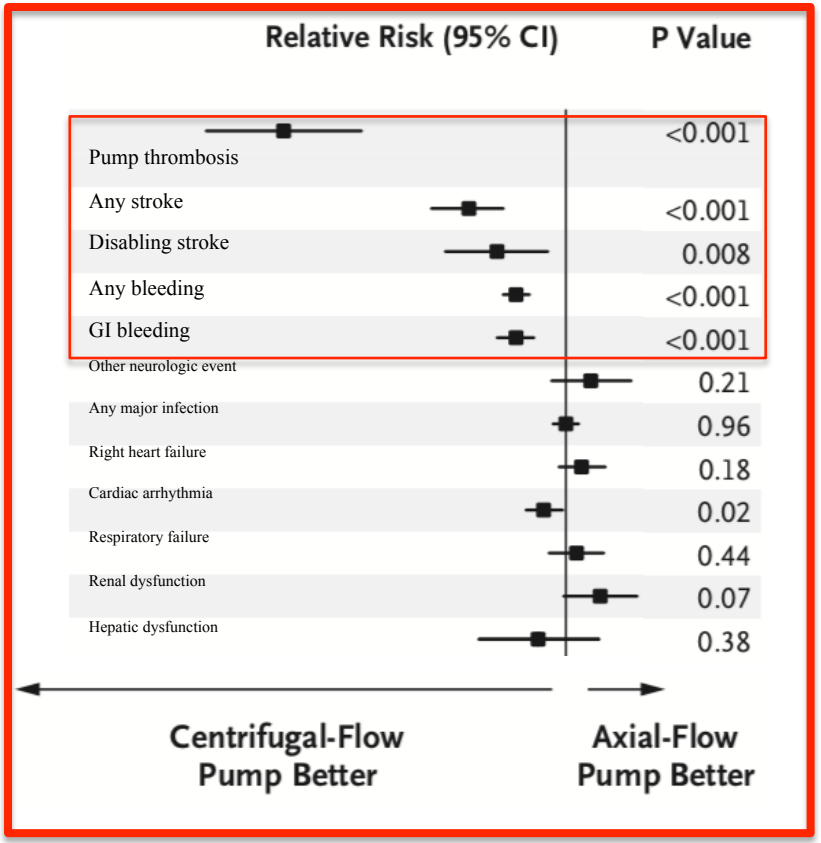
Per-Protocol Population

	HM3	HM II	*p*
Hemorrhagic stroke	8 (4.2)	16 (9.3)	0.06
Ischemic stroke	12 (6.3)	23 (13.4)	0.03

N Engl J Med 2018;378:1386-1395

MOMENTUM 3 - FULL STUDY COHORT





N Engl J Med 2019;380:1618-1627

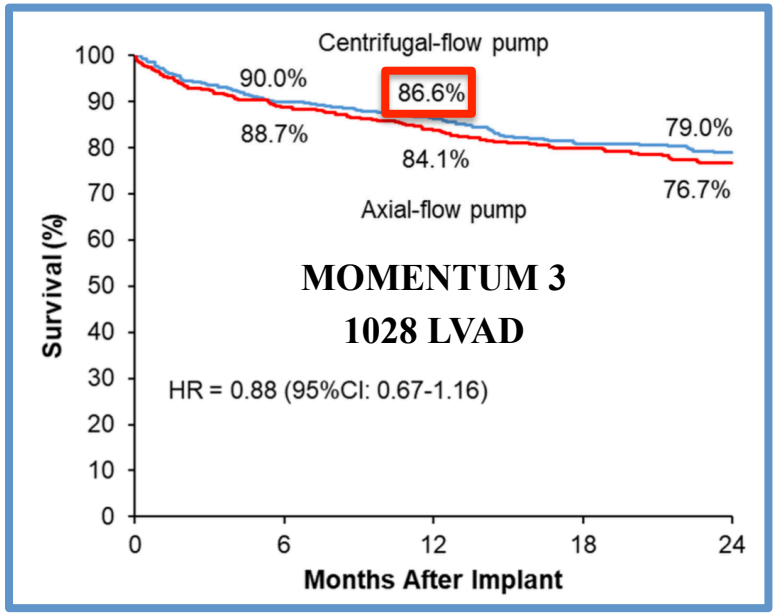
MOMENTUM 3

vs.

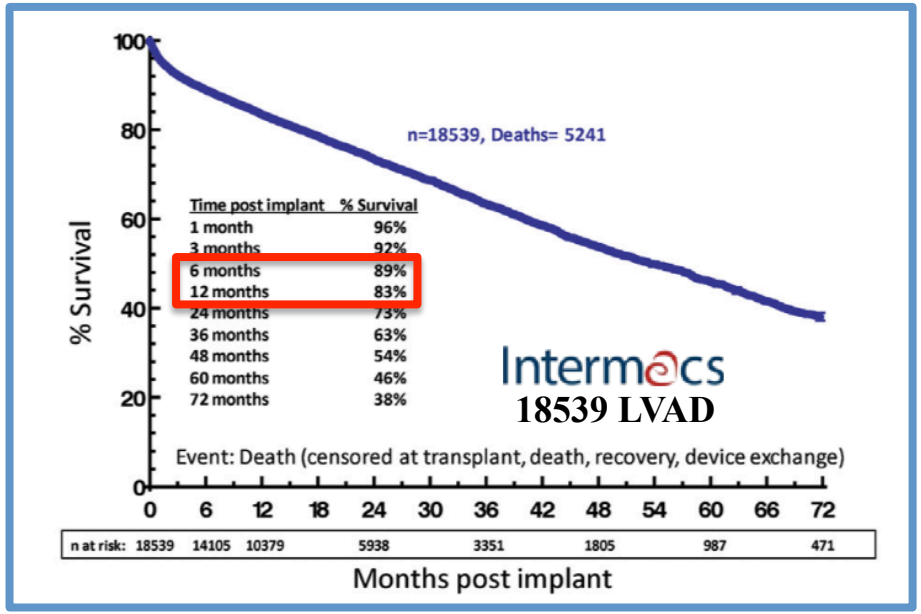
REAL LIFE DATA

DISCUSSION

OVERALL SURVIVAL



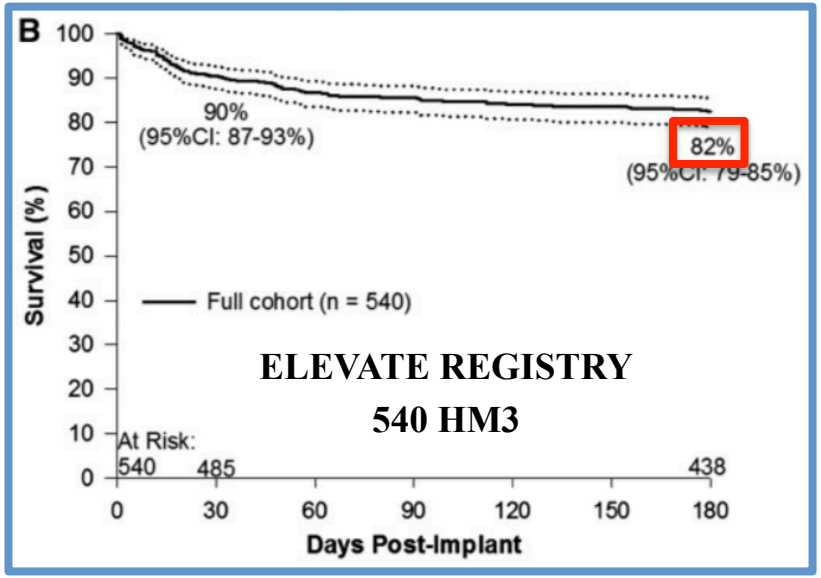
N Engl J Med 2019;380:1618-1627



Ann Thorac Surg 2019;107:341-354

DISCUSSION

OVERALL SURVIVAL



Eur Heart J 2018;39:3454-3460

ASSIST-ICD REGISTRY

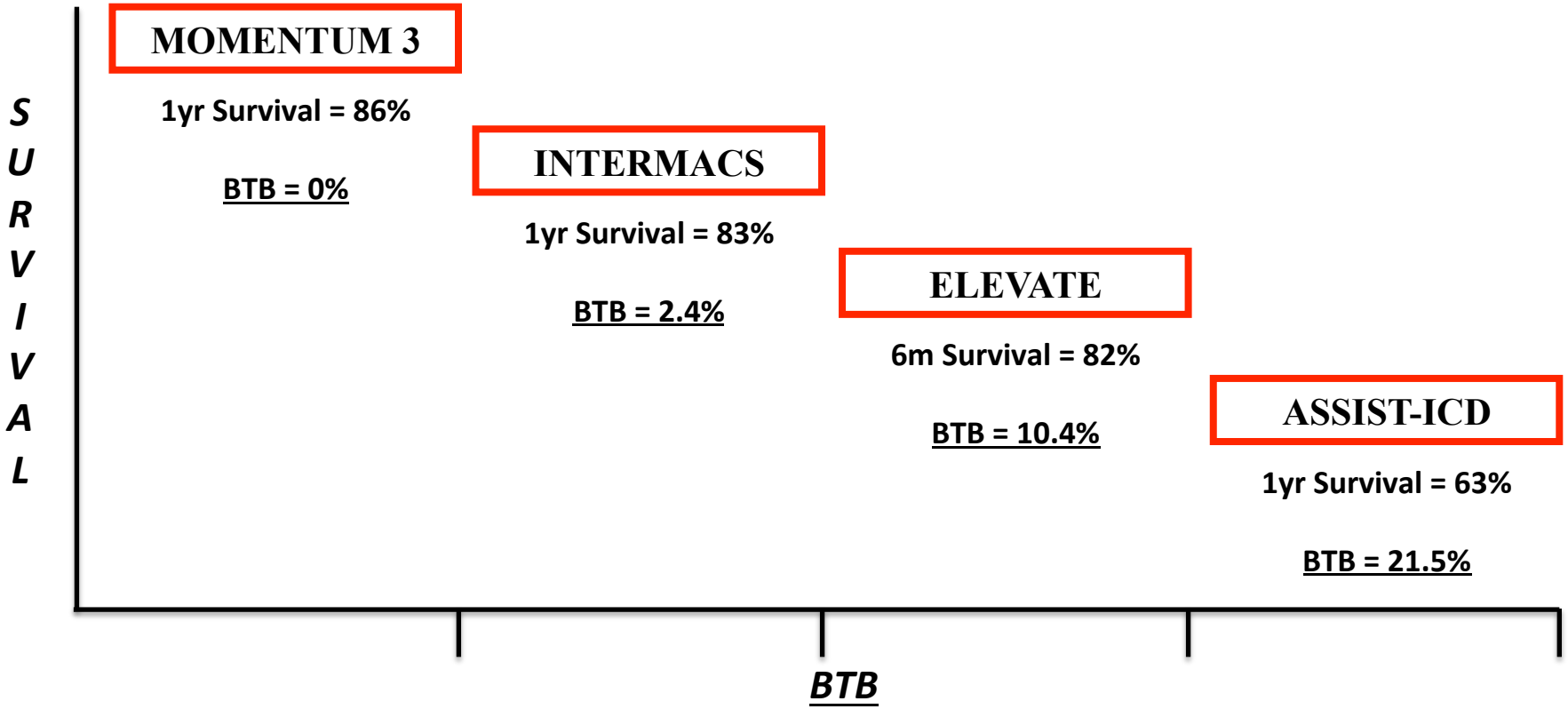
671 LVAD

1yr Survival = 63.2%

Eur J Cardiothorac Surg
Paper under review

DISCUSSION

BRIDGE-TO-BRIDGE STRATEGY



DISCUSSION

BRIDGE-TO-BRIDGE STRATEGY

The Use of Extracorporeal Life Support in Adult Patients With Primary Cardiac Failure as a Bridge to Implantable Left Ventricular Assist Device

Ann Thorac Surg 2001;71:S77-S81

Outcome Evaluation of the Bridge to Bridge Concept in Patients With Cardiogenic Shock

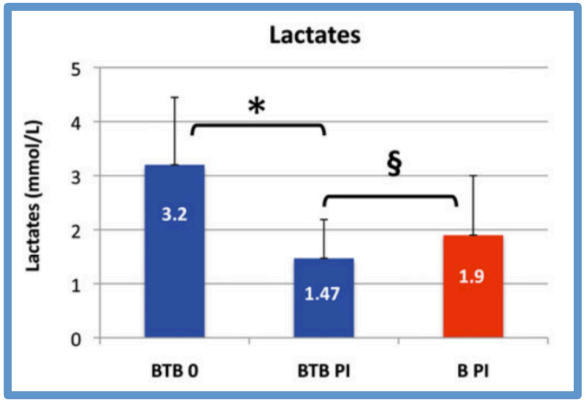
Ann Thorac Surg 2006;82:28-33

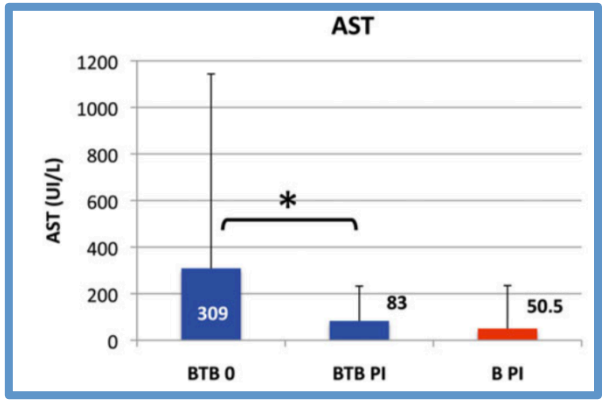
DISCUSSION

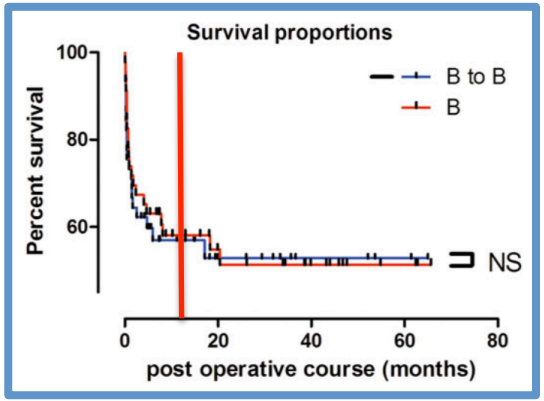
BRIDGE-TO-BRIDGE STRATEGY

Extracorporeal life support as a bridge to bridge: a strategy to optimize ventricular assist device results

Guillaume Lebreton[a,*], Matteo Pozzi[a,b], Ciro Mastroianni[a], Philippe Léger[a], Alain Pavie[a] and Pascal Leprince[a]





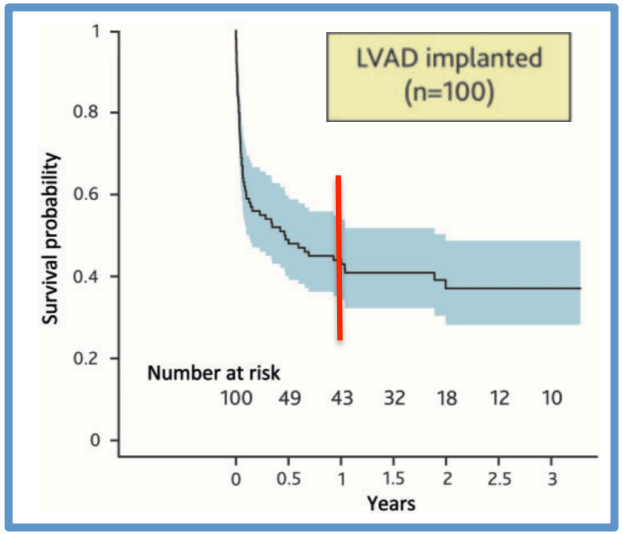


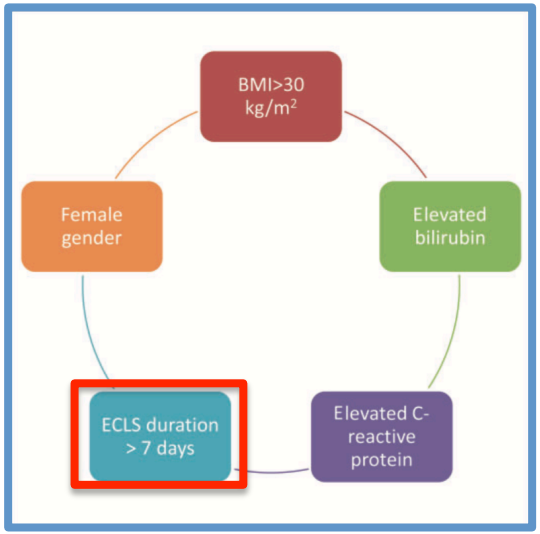
Eur J Cardiothorac Surg 2015;48:785-791

DISCUSSION

BRIDGE-TO-BRIDGE STRATEGY

Predictors of mid-term outcomes in patients undergoing implantation of a ventricular assist device directly after extracorporeal life support

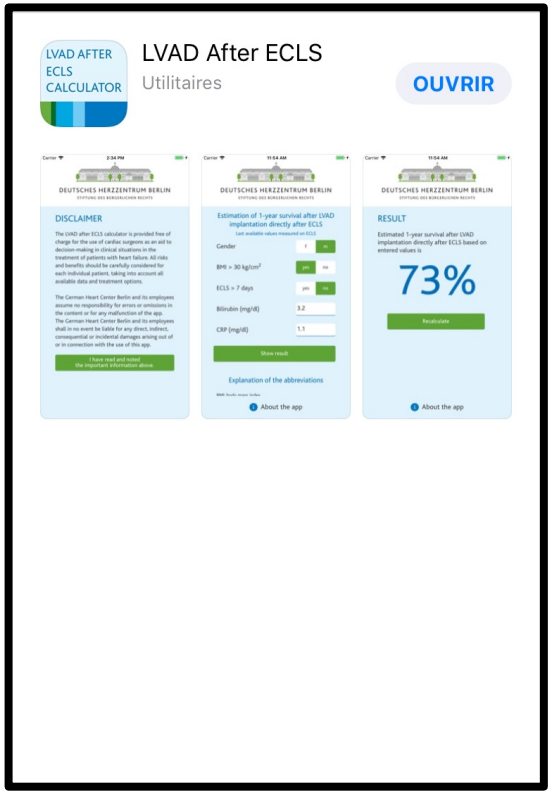


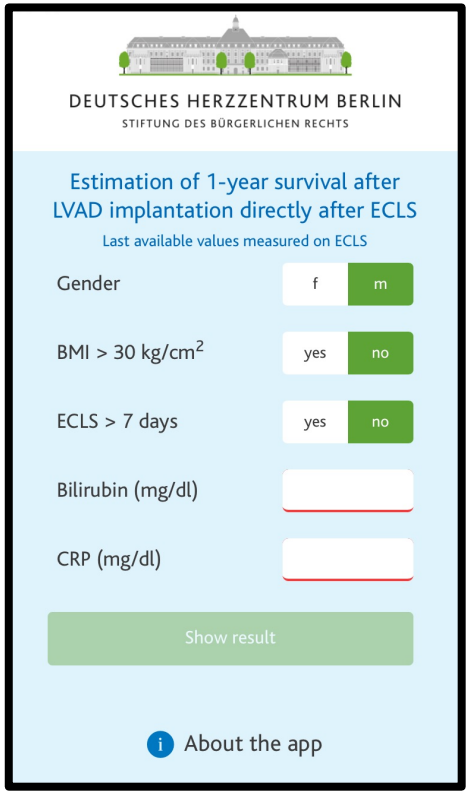


Eur J Cardiothorac Surg 2019;55:773-779

DISCUSSION

BRIDGE-TO-BRIDGE STRATEGY





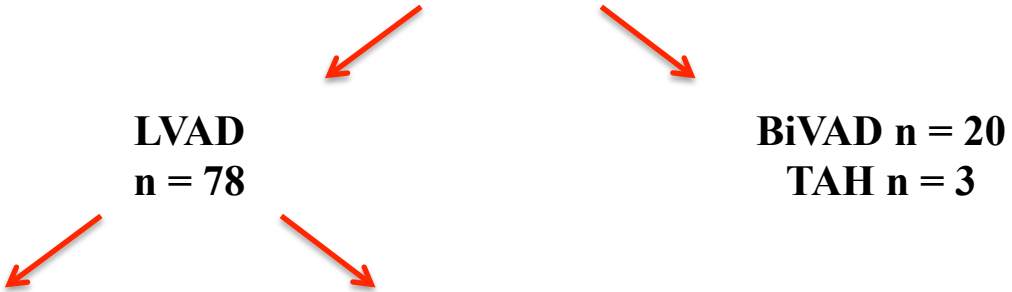
DISCUSSION

BRIDGE-TO-BRIDGE STRATEGY

Lyon Experience

01/01/2010 – 17/10/2019

101 long-term MCS



1m Survival	**80.6%**	*p=0.125*	**62.5%**
1yr Survival	**62.9%**	*p=0.108*	**38.4%**

CONCLUSIONS

- Les résultats de l'étude MOMENTUM 3 sont très encourageants et résumés par une meilleure hémocompatibilité de l'HeartMate 3

- L'étude MOMENTUM 3 concerne une population plutôt sélectionnée de patients insuffisants cardiaques

- La comparaison de ces résultats avec notre activité clinique quotidienne nécessite une certaine prudence