2017 CST-Astellas Canadian Transplant Fellows Symposium

Case Study: Heart Transplantation

Kim Anderson, MD, FRCPC

Dr. Anderson is an adult cardiologist specialized in advanced heart failure, transplantation and mechanical circulatory support. She obtained her medical diploma in 2007 at the Université de Montréal. She trained in internal medicine and adult cardiology also in Université de Montréal. She then completed a 2 years clinical fellowship in Heart Failure and Transplantation in Toronto at University Health Network, followed by a Master in Clinical Epidemiology and Health Care Research at University of Toronto. She is now an Assistant Professor at the Halifax Infirmary Hospital affiliated with Dalhousie University here in Halifax, in the Heart Failure and Transplantation group.

References:

1-Kobashigawa J. et al. Report from a consensus conference on primary graft dysfunction after cardiac transplantation. J Heart Lung Transplant 2014;33:327–340.

2- Chou H.-W. et al, Steroid Pulse Therapy Combined with Plasmapheresis for Clinically Compromised Patients after Heart Transplantation. Transplantation Proceedings, 44, 900–902 (2012)

3- Cosio Carmena M. D. G. et al. Primary graft failure after heart transplantation: Characteristics in a contemporary cohort and performance of the RADIAL risk score. J Heart Lung Transplant 2013;32:1187–1195

4-Segovia J. et al. RADIAL: A novel primary graft failure risk score in heart transplantation. J Heart Lung Transplant 2011;30:644–51.

5-Shahzad K. et al. New-onset graft dysfunction after heart transplantation—incidence and mechanism-related outcomes. J Heart Lung Transplant 2011;30:194–203

Disclosure

Kim Anderson, MD, FRCPC

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- Novartis

Heart Transplant Case

2017 CST-Astellas Canadian Transplant Fellows Symposium

Kim Anderson, MD FRCPC

QEII-Halifax Infirmary Hospital, Dalhousie University

Nova Scotia

Clinical case: Mrs. H

- 56 yo W. BG B, 68 kg
- Dilated cmp with biV failure, most likely post-myocarditis. Dx 2005
- Embolic myocardial infarction (LV thrombus) 08-2010
- Appropriate choc for VF May 2013
- RHC 1 month pre-Tx: RA 2, RV 18/0, PA 19/2/9, wedge 1, MVO2 66%
- cPRA 2013: 99/54%-Listed status 4s
- No end organ significant dysfunction

Heart transplant 2014

- Virtual cross-match negative
- OR at 7h00, CVICU at 13h40 same day
- Ischemic time: 164 minutes
- Solumedrol 1g on call to OR then 0.5g at cross-clamp
- Thymoglobulin 75 mg IV started at 15h30

Mrs. H Donor

- 50 yo, 65 kg, 165 cm
- Risk factors for coronary artery disease +
- Angiogram: very minor OM origin disease, not palpable at time of Tx
- « Good looking donor heart »
- Small area LAD with some plaque seen by surgeon at time of Tx (but lumen OK on angio)

- Surgery and immediate post-op:
  - Intra-op TEE: BiV function OK
  - Bleeding + and vasoplegia
  - Milrinone 0.25, epi 0.07 to 0.09, levo 0.06
  - AV pace 100 bpm
  - PA 24/10, RA 5-10, CO 2.7/CI 1.8, MAP 65 (90/60), urine output 30 cc/h, lactate 6.7 (17h00)
  - Extubated at 16h00 same day then on 5L O2

gnosis
TGH CCU LAB20
M4S-RS
MI 1.3
25/02/2014 18:53:37
USR
Echo_V
TIS:1.6
V
5
10
15

TGH CCU LAB20
M4S-RS
MI 1.3
25/02/2014 18:57:34
USR
Echo_V
TIS:1.6
V
5
10
15

The retrospective cross-match

FLOW XM Auto:

T Flow -, B Flow –

FLOW XM Allo:

T Flow -, B Flow +

No, there is no DSA (ouf!)

STAT typing of her HLA antibodies with serum post-transplant

comparison to HLA typing of donor:

<u>NO DSA</u>

Acute rejection… or what else?

- Acute RV dysfunction?
- Pulmonary hypertension?
- Bradyarhythmia/ sinus node dysfunction?
- Surgical complication?
- Myocardial infarction?
  - Underestimated CAD of donor?
  - Air or thrombi emboli?
  - Plaque rupture?
- Marginal donor (a « bad heart »)?

Primary graft dysfunction (heart)

ISHLT CONSENSUS

Report from a consensus conference on primary graft dysfunction after cardiac transplantation

- No discernable cause for graft dysfunction
- LV or RV or BiV dysfunction
- ≤ 24 h after the transplant surgery

Kobashigawa. JHLT 2014;33.

Pre-concensus survey[1]:

Table 1 Primary Graft Dysfunction in Heart Transplantation, Results of Pre-conference Online Survey (47 centers participating) January 2013–March 2013

- Total number of transplant patients at all participating centers was 9,901 with 733 patients thought to have PGD—rate 7.4%
- 30-day mortality was 30% and 1-year mortality was 34.6%
- Most common causes of death for 30-day mortality: Multiorgan failure (70%), graft failure (20%), and sepsis (10%)
- Definition parameters for PGD:
  - 79% of centers felt that LVEF $\leq$ 40% was a criteria of PGD
  - 68% of centers felt that a time frame of within 24 hours should be used to define PGD
  - 70% of participating centers felt that mechanical support is a mandatory criteria for the definition of PGD

- Death or reTx: 2.5%
- 23.4% of all deaths 90 days post-Tx[2]

1-Kobashigawa. JHLT 2014;33. 2-Mark. Transplantation 2010;90

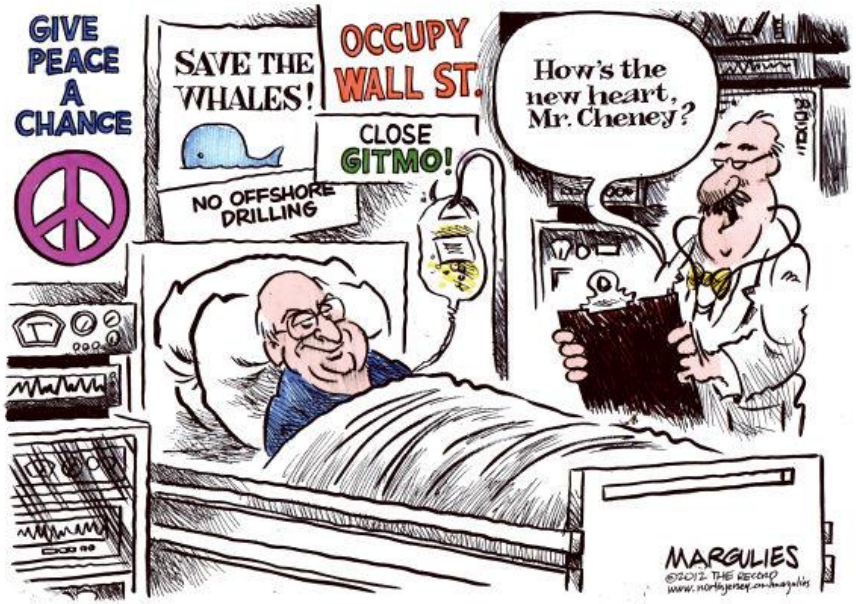
Definitions - severity

Table 6 Definition of Severity Scale for Primary Graft Dysfunction (PGD)

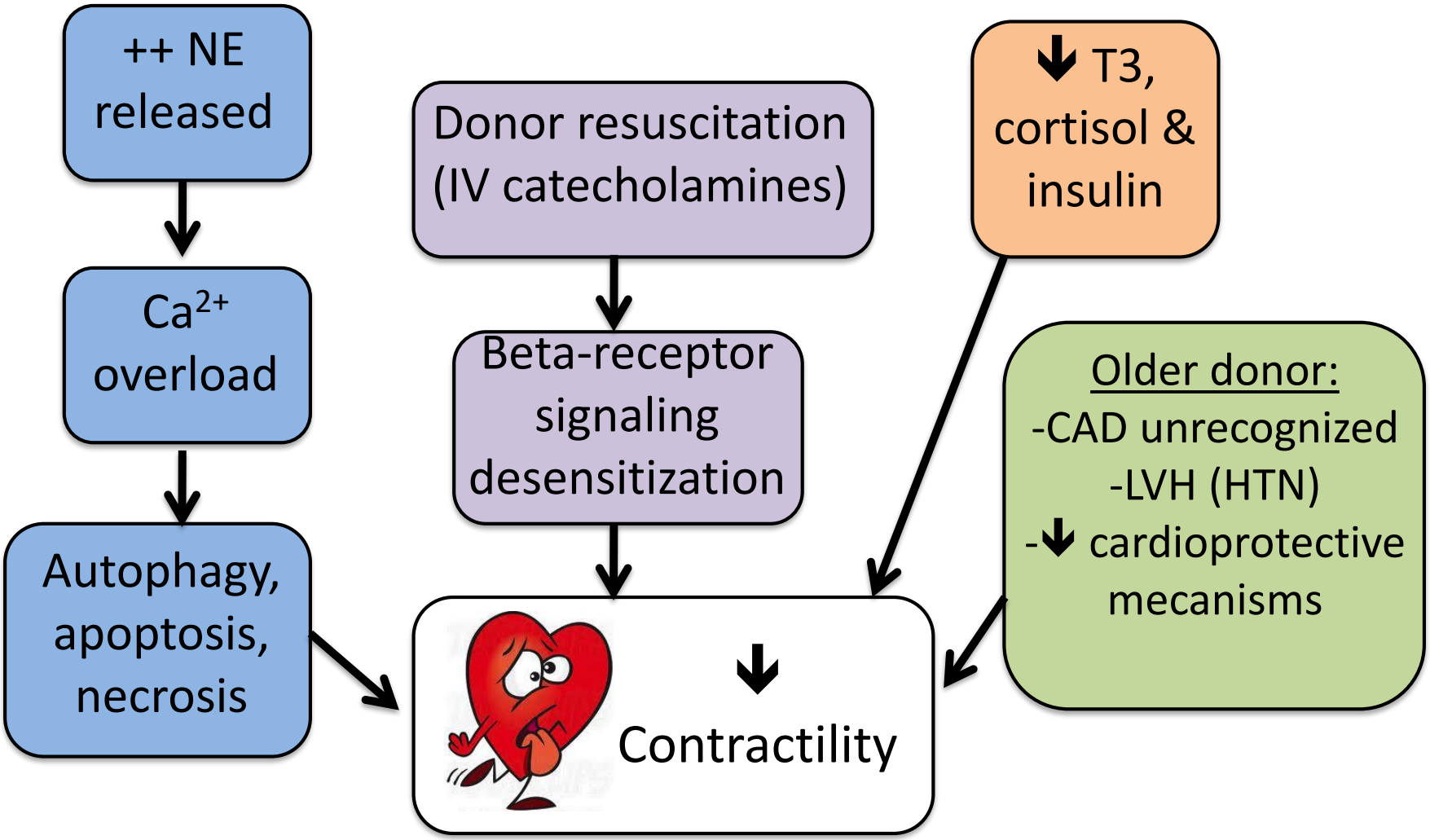
1. **PGD-Left ventricle (PGD-LV):**	*Mild PGD–LV*: *One* of the following criteria must be met:	LVEF $\leq$ 40% by echocardiography, *or* Hemodynamics with RAP $>$ 15 mm Hg, PCWP $>$ 20 mm Hg, CI $<$ 2.0 L/min/m^2 (lasting more than 1 hour) requiring low-dose inotropes
	Moderate PGD-LV: Must meet one criterion from I *and* another criterion from II:	I. *One* criteria from the following: Left ventricular ejection fraction $\leq$ 40%, *or* Hemodynamic compromise with RAP $>$ 15 mm Hg, PCWP $>$ 20 mm Hg, CI $<$ 2.0 L/min/m^2, hypotension with MAP $<$ 70 mm Hg (lasting more than 1 hour) II. *One* criteria from the following: i. High-dose inotropes—Inotrope score $>$ 10[a] *or* ii. Newly placed IABP (regardless of inotropes)
	Severe PGD–LV	Dependence on left or biventricular mechanical support including ECMO, LVAD, BiVAD, or percutaneous LVAD. Excludes requirement for IABP.
2. **PGD-right ventricle (PGD-RV):**	Diagnosis requires either both i and ii, or iii alone:	i. Hemodynamics with RAP $>$ 15 mm Hg, PCWP $<$ 15 mm Hg, CI $<$ 2.0 L/min/m^2 ii. TPG $<$15 mm Hg and/or pulmonary artery systolic pressure $<$ 50 mm Hg, *or* iii. Need for RVAD

Kobashigawa. JHLT 2014;33.

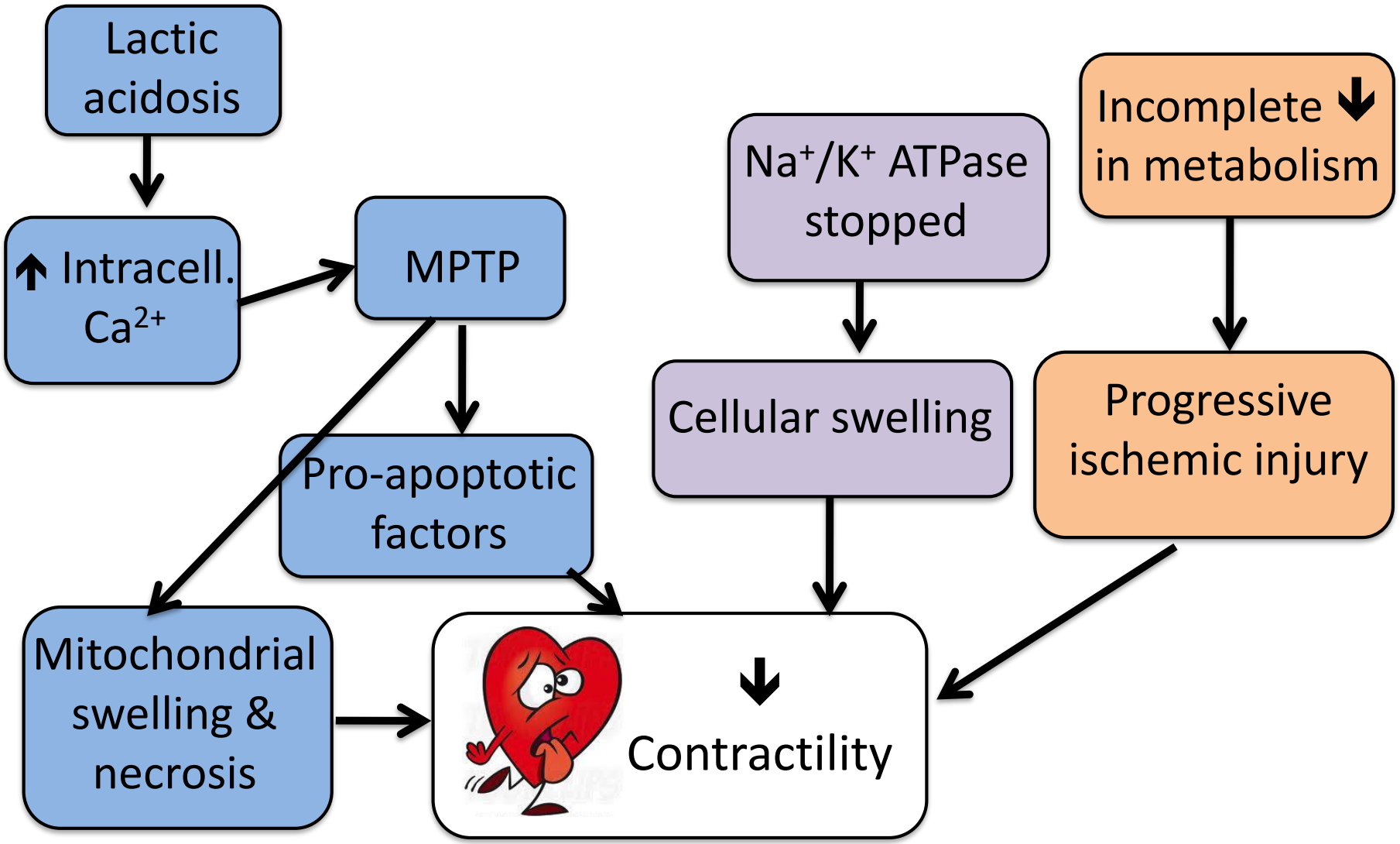
Pathogenesis - from donor to recipient



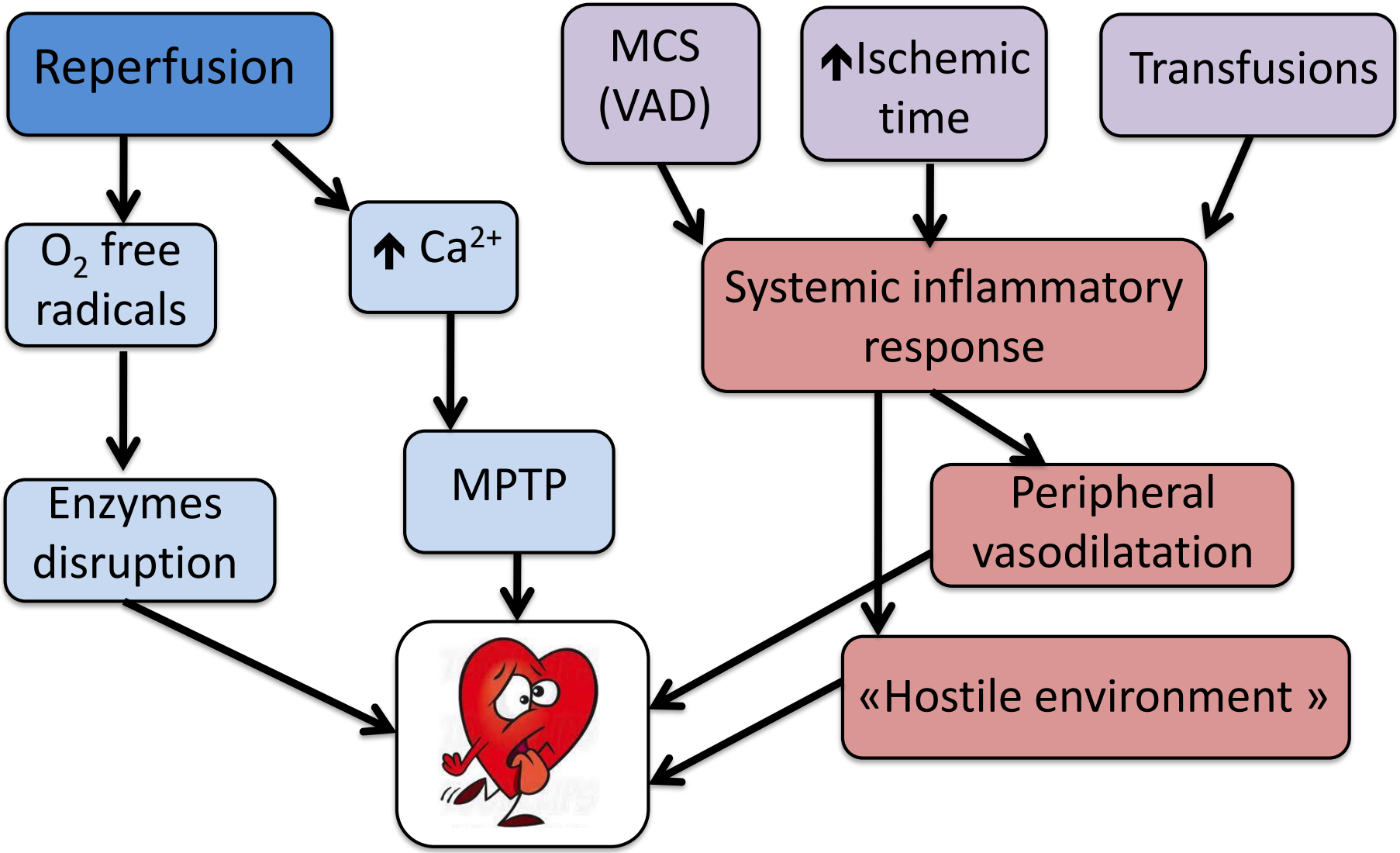
Brain death of the donor:



Hypothermic organ preservation:



In the recipient:



Autopsy evaluation

Table B1

Pathologic diagnosis	Autopsy results (%)
Rejection	7
Reperfusion injury/ischemia	48
Possible freeze injury	7
Pulmonary embolus	3.4
Myocyte necrosis	28
Antibody-mediated rejection (C4D staining; CD68)	3.4
Multifocal edema and/or hemorrhage	14
Aortic tear	3.4
Infection	3.4

Kobashigawa. JHLT 2014;33.

Mrs. H:
Hemodynamic support and IS

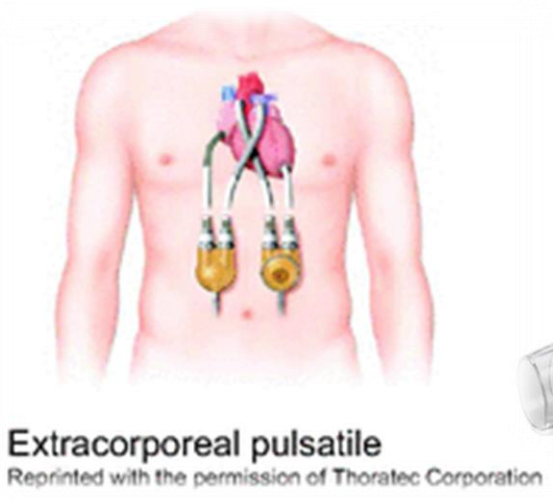
- Epi, norepi and isoproterenol 48h
- Milrinone 7 days

- Plex x 5
- Thymoglobuline 225
- Solumedrol 1.5g total then pred 40mg OD
- Cellcept 1g bid+ Tac 2g bid

Pharmacologic management of PGD

- Low-dose inotropes
- Pulmonary vascular vasodilators
- Nitric oxide
- Specific treatment for PGD ? or standard of care after cardiac transplantation ?

Mechanical management of PGD



Extracorporeal pulsatile

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Percutaneous

Right, Left or Both ventricles?

With oxygenator or not?

Central or peripheral cannulation?

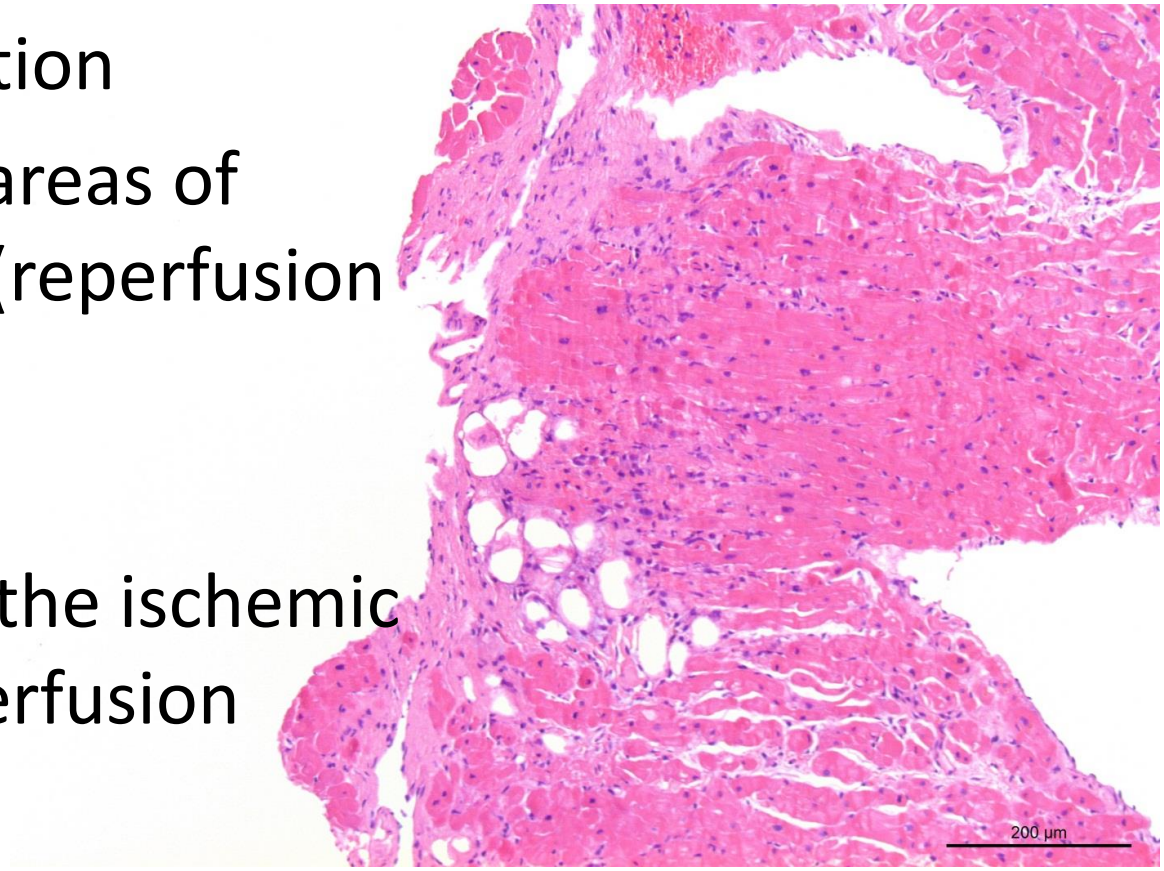
Mrs. H:
Graft function evolution (Echo)

Days post-Tx	LV function	RV function
1	<20%	Mild to moderate dysfct
3	40-59%	Mild to moderate dysfct
7	40-59%	Low normal
10	Normal	Low normal

Biopsy #1 (1 week post-Tx)

- No cellular rejection
- Subendocardial areas of recent ischemic (reperfusion injury) damage

➢ Likely related to the ischemic interval and reperfusion



Conclusions

- Recognize primary graft dysfunction in heart transplant recipient
  - Uni or BiV dysfunction
  - ≤ 24h post-Tx
  - No other discernable cause

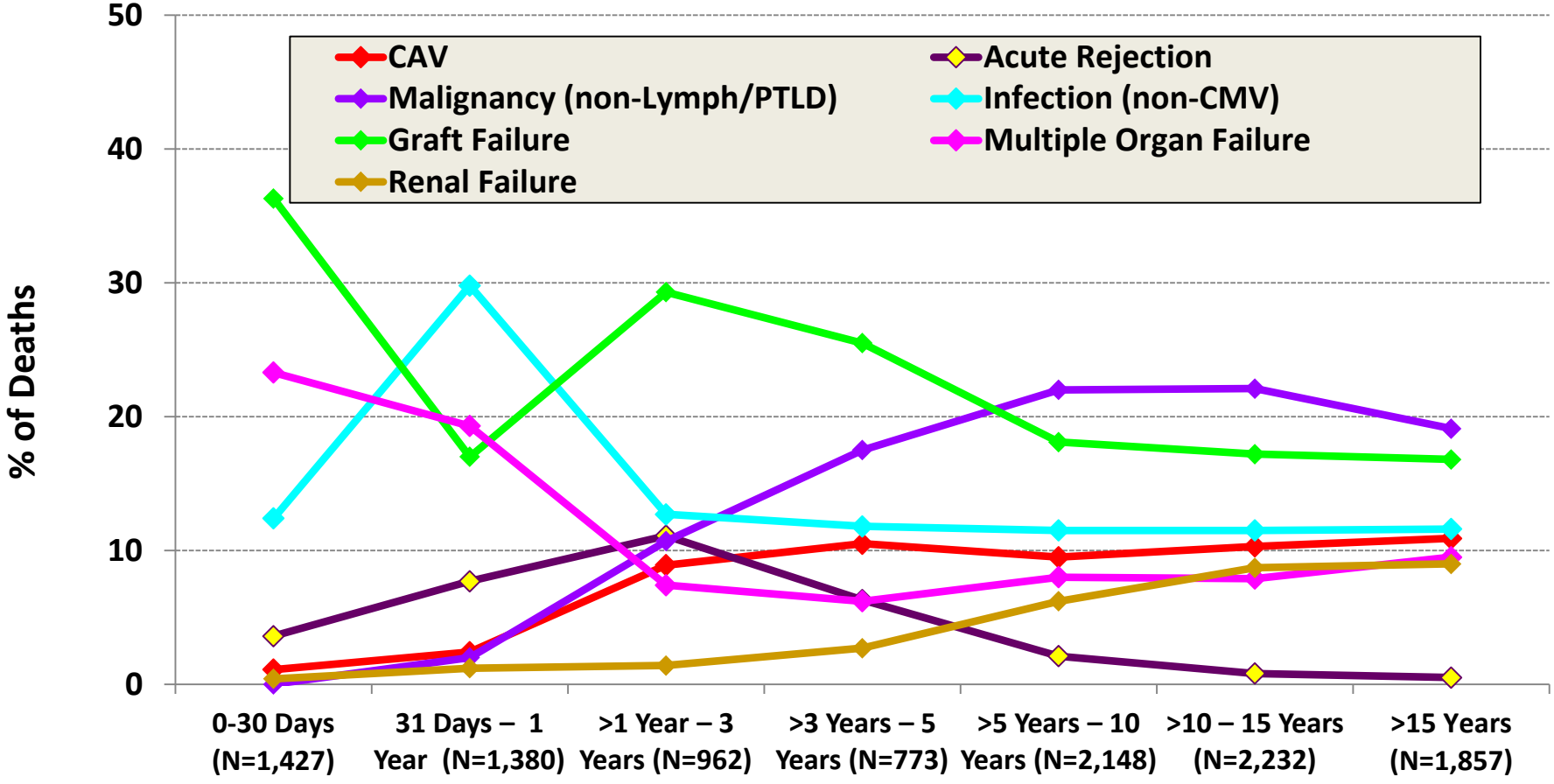
  - Rate ± 7% (2.5-25%), mortality ± 30%

- Understand the pathophysiology of this entity
  - Ischemic-reperfusion
  - Multiple risk factors
    (donor, recipient, surgery and organ preservation)

BACK-UP SLIDES

Adult Heart Transplants
Relative Incidence of Leading Causes of Death

(Deaths: January 2006 – June 2012)



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Since only leading causes of death are shown, sum of percentages for each time period is less than 100%

CME

Cardiac Size and Sex-Matching in Heart Transplantation

Size Matters in Matters of Sex and the Heart

Robert M. Reed, MD,* Giora Netzer, MD, MSCE,*† Lawrence Hunsicker, MD,‡
Braxton D. Mitchell, PHD,§|| Keshava Rajagopal, MD, PHD,¶ Steven Scharf, MD, PHD,*
Michael Eberlein, MD, PHD#

Baltimore, Maryland; and Iowa City, Iowa

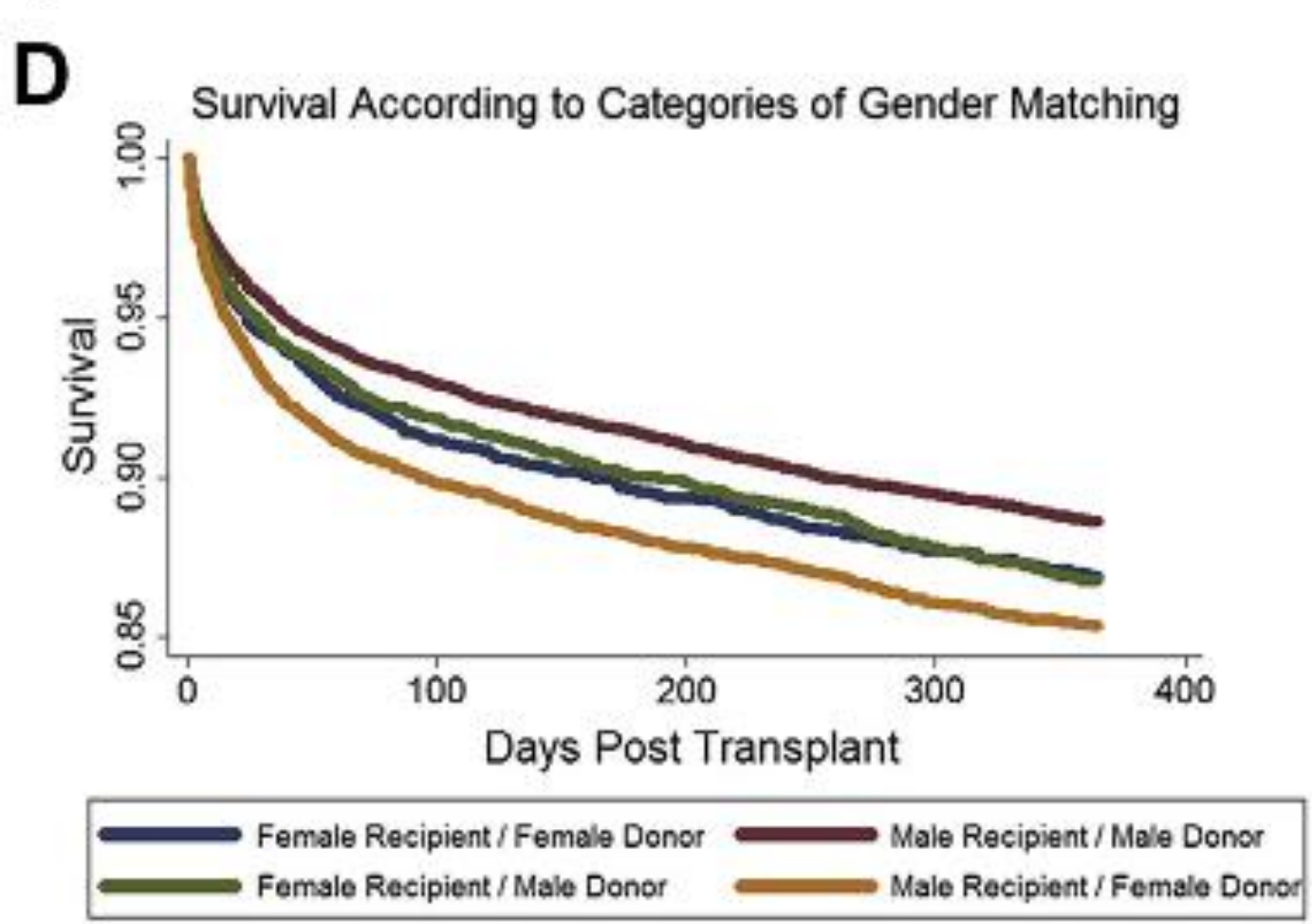
$$[1]\ \text{Predicted left ventricular mass}(\text{g}) = \text{a} \cdot \text{Height}^{0.54}(\text{m}) \cdot \text{Weight}^{0.61}(\text{kg})$$

where $a = 6.82$ for women and 8.25 for men; and

$$[2]\ \text{Predicted right ventricular mass}(\text{g}) = \text{a} \cdot \text{Age}^{-0.32}(\text{years}) \cdot \text{Height}^{1.135}(\text{m}) \cdot \text{Weight}^{0.315}(\text{kg})$$

Reed. JACC Heart Fail. 2014;2.

A-Survival by difference in weight
B-Survival by difference in predicted heart size
D-Survival by gender matching



Reed. JACC Heart Fail. 2014;2.

These « others » antibodies…

A Reevaluation of the Role of IgM Non-HLA Antibodies in Cardiac Transplantation

Smith, John D.[1]; Hamour, Iman M.[1]; Burke, Margaret M.[2]; Mahesh, Balikrishnan[3]; Stanford, Rachel E.[1]; Haj-Yahia, Saleem[1] Magdi H.[3]; Banner, Nicholas R.[1]; Rose, Marlene L.[3,5]

- Retrospective 616 patients HTx, UK 1 center (91-2003)
- 59/616 non-HLA IgM+ and no HLA-Ab
- 25/59 died ≤ 1 year
  - 6 from PGD; 10% mortality associated to PGD

55.9% survival 1st year vs 75.8% no antibody

John. Transplantation 2009;87.

These « others » antibodies…

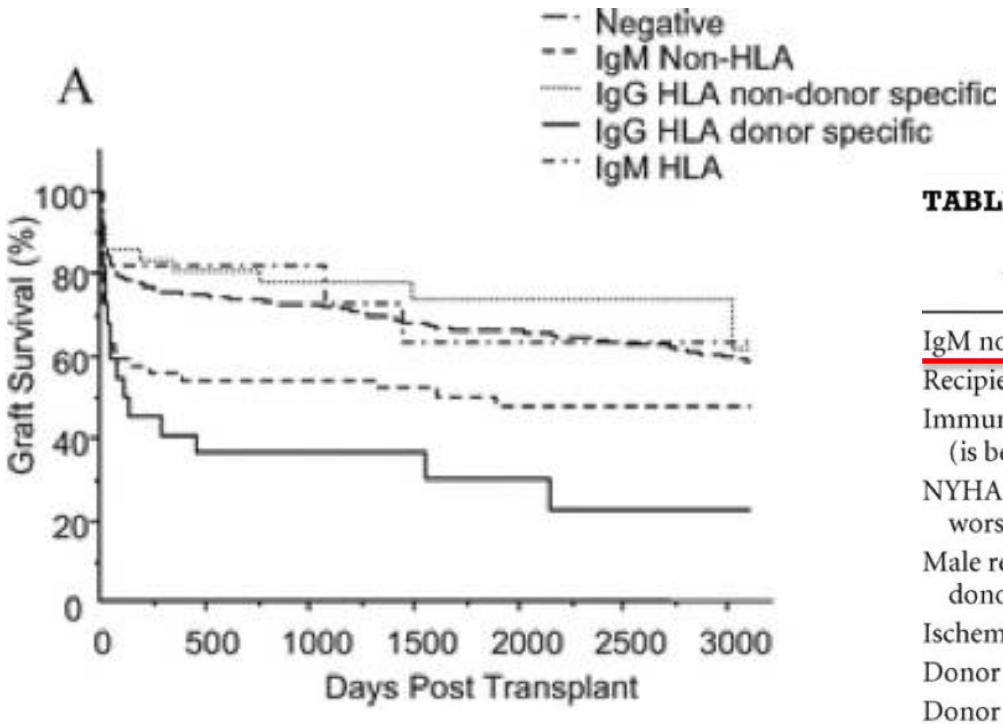


TABLE 3. Multivariate analysis

Variable	Parameter estimate	Standard error	*P*	Hazard ratio
IgM non-HLA	0.8583	0.2281	0.0002	2.359
Recipient age[a]	0.02908	0.00863	0.0008	1.030
Immunosuppression 2 (is better than 1)	−0.3926	0.1820	0.031	0.675
NYHA class IV (is worse)	0.3357	0.0996	0.0007	1.399
Male recipient, female donor (is worse)	0.3517	0.1620	0.030	1.421
Ischemic time	0.00261	0.00125	0.037	1.003
Donor age[a,b]	−0.05600	0.02840	0.049	0.523
Donor age[a,b,c]	0.00104	0.0004349	0.017	1.127

John. Transplantation 2009;87.

Is AMR possible without DSA?

- 17 HTx recipients with late AMR
  - 15 DSA +
  - 2 no DSA but anti-vimentin IgG+ [1]

- 37 HTx recipients with AMR
  - 15/37 no DSA
  - 19 of AMR tested for MICA Ab; 3/19 DSA- MICA-[2]

1-Rose. Human Immunology 2013.
2-Zhang. Transplantation 2011;91.

Characterization of immune responses to cardiac self-antigens myosin and vimentin in human cardiac allograft recipients with antibody-mediated rejection and cardiac allograft vasculopathy

Dilip S. Nath, MD,[a] Haseeb Ilias Basha, MD,[b] Venkataswarup Tiriveedhi, MD, PhD,[b] Chiraag Alur, BS,[b] Donna Phelan, BA,[c] Gregory A. Ewald, MD,[d] Nader Moazami, MD,[a] and Thalachallour Mohanakumar, PhD[b,e]

Table 2 Characteristics of AMR$^+$ Patients

Pt	Symptoms	Abnormal echocardiography	Inotropes	Histology	Immunopathology		DSA	Anti-MYO	Anti-VIM
					CD4	CD68			
1	+	+	+	+	+	−	+	+	+
2	+	+	−	+	+	+	+	+	+
3	−	+	+	+	+	+	−	+	−
4	+	+	+	+	−	+	−	+	+
5	+	+	+	−	+	+	+	−	−
6	−	+	+	−	−	+	+	+	+
7	−	+	+	+	+	+	+	+	+
8	+	+	+	+	+	−	+	+	+
9	+	−	+	+	+	+	−	+	+
10	−	+	+	+	−	+	+	+	+

Pt, patient.

Nath. JHLT 2010;29.

Biomarkers of PGD

- The role of biomarkers in PGD remains controversial.
- Brain death -> Biomarkers↑
- Can we use them to define whether a heart is acceptable or not ?
- Can they predict long-term outcomes in recipients with regard to PGD?

What to choose ?

- A **composite of the biomarkers** has been proposed as a better method of predicting PGD.
- Combination of **NT-proBNP and cTnT** (n= 63) for an early diagnosis of LV systolic dysfunction, ↑**sensitivity** (0.78–0.9 VS 1.0)[1]
- Combination of **PCT and cTnT** in donors is a better predictor of early graft dysfunction in recipients than lone biomarkers.
- More research is needed in this area to try different combinations.

1. Nicolas-Robin et al; Intensive Care Med 2007
2. Potapov et al; Int J Cardiol 2003

Levosimendan *not available in Canada

- a calcium sensitizer
- PGD -despite inotropic support with **epinephrine** > 0.1 µg/kg/min & **milrinone** > 0.3 µg/kg/min.
- 30-day survival rate was 93%.
- Subsequent 3-year follow-up of this study showed a significantly lower 1-year and 3-year survival rate.

		Post-levosimendan	
Variable	Pre-levosimendan	24 hours	48 hours
Ejection fraction, %	27 ± 4	38 ± 8[a]	45 ± 10[a]
Cardiac output, liter/min	5.2 ± 0.6	6.2 ± 0.7[a]	5.9 ± 0.6
MAP, mm Hg	67 ± 10	80 ± 9[a]	83 ± 9[a]
MPAP, mm Hg	31 ± 7	24 ± 6	23 ± 6
Epinephrine,[b] mg/hours	1.3 ± 1.2	0.4 ± 0.4[a]	0.3 ± 0.4[a]
Norepinephrine,[b] mg/hours	1.0 ± 0.8	0.3 ± 0.3[a]	0.15 ± 0.2[a]
Milrinone,[b] mg/hours	1.5 ± 0.6	0.9 ± 0.7[a]	0.8 ± 0.9[a]
Iloprost,[c] µ/day	54 ± 10	43 ± 11[a]	32 ± 20[a]

MAP, mean arterial pressure; MPAP, mean pulmonary arterial pressure.
[a]Value of $p < 0.05$ for comparison to the pre-levosimendan figures.
[b]Maximum dose used on the respective day.
[c]Cumulative dose used on the respective day.

Weis et al; J Heart Lung Transplant 2009

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EUROPEAN JOURNAL OF CARDIO-THORACIC SURGERY

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Extra-corporeal membrane oxygenation temporary support for early graft failure after cardiac transplantation☆

Cosimo D'Alessandro [a,*], Stéphane Aubert [a], Jean Louis Golmard [b], Beltran Levy Praschker [a], Charles Edouard Luyt [c], Alain Pavie [a], Iradj Gandjbakhch [a,b,c], Pascal Leprince [a]

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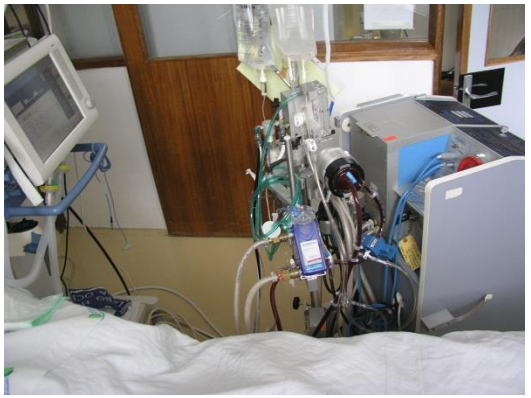
Received 12 September 2008; received in revised form 8 May 2009; accepted 16 May 2009; Available online 17 July 2009



90 patients
54 – ECMO
8 - assist devices
2 biventricular assist devices
6 centrifugal RV assist
28 were on maximal inotropes alone
Medically treated – 46% survival
Mechanical support -25% survival
ECMO - 50% survival

1 year survival:
PGD 37%
No PGD 78%

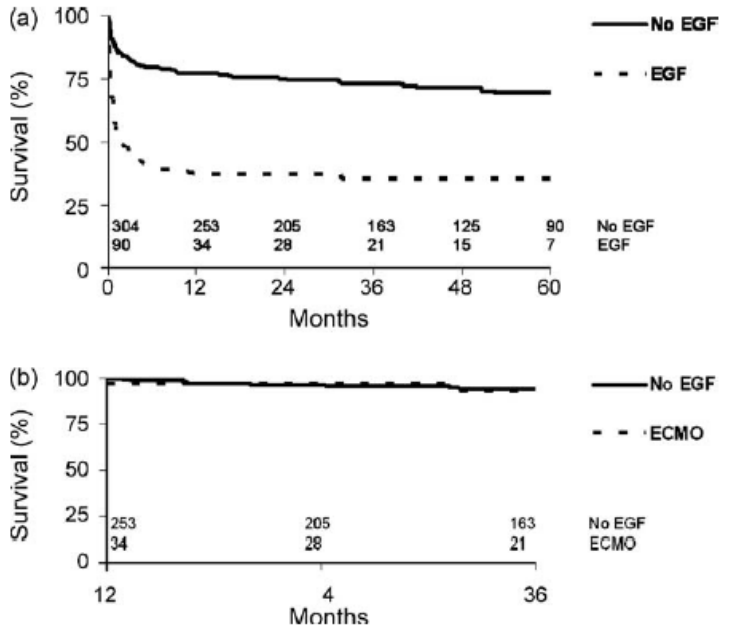


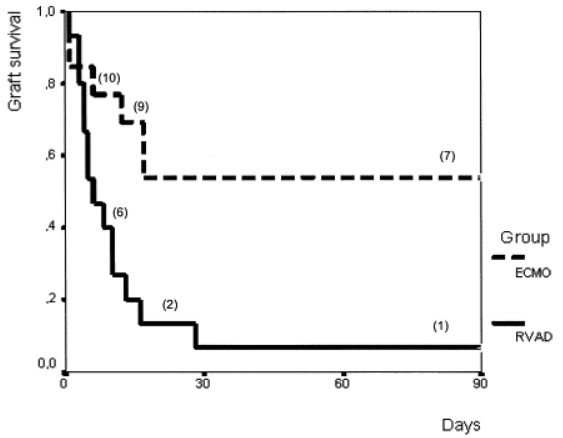
Fig. 1. (a) Kaplan—Meier 5-year survival. Absence of EGF was correlated with a better long-term survival: 78% at 1 year and 70% at 5 years without EGF vs 37% at 1 year and 35% at 5 years with EGF ($p < 0.001$). (b) Kaplan—Meier 1-year conditional survival. Patients treated with ECMO have the same 1-year conditional survival as patients not having suffered EGF: 94% at 3 years.

Extracorporeal Membrane Oxygenation is Superior to Right Ventricular Assist Device for Acute Right Ventricular Failure After Heart Transplantation

Shahrokh Taghavi, MD, Andreas Zuckermann, MD, Jan Ankersmit, MD, Georg Wieselthaler, MD, Angela Rajek, MD, Günther Laufer, MD, Ernst Wolner, MD, and Michael Grimm, MD

Departments of Cardiothoracic Surgery and Cardiothoracic Anesthesiology, University of Vienna, Vienna, Austria

- 28 patients - acute RV failure
  - 13 pt -ECMO
  - 15 pt -RVAD
- Patient survival was similar
- Graft survival was markedly improved (7 compared with 1)
- Retransplantation was less often required (1 compared with 6)
- Weaning rates were significantly higher (10 compared with 2)



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European Journal of Cardio-thoracic Surgery 40 (2011) 1348–1354

EUROPEAN JOURNAL OF CARDIO-THORACIC SURGERY

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Incidence and outcome of Levitronix CentriMag support as rescue therapy for early cardiac allograft failure: a United Kingdom national study

Helen L. Thomas [a,b,*], Vamsidhar B. Dronavalli [c,d], Jayan Parameshwar [a,e], Robert S. Bonser [a,c,d], Nicholas R. Banner [a,f,g]
and on behalf of the Steering Group of the UK Cardiothoracic Transplant Audit [1]

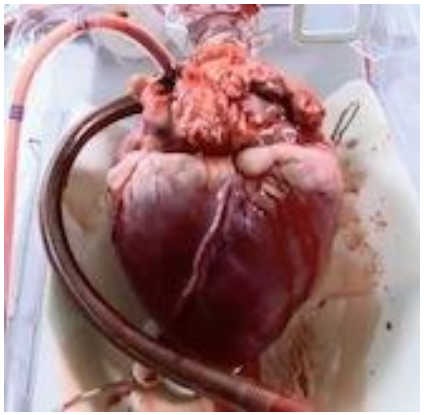
- 38 patients from 2003 to 2008
- CentriMag device for PGD survival was 50% at 30 days and 32% at 1 year.
- Earlier implantation of the device after transplant appeared to correlate with improved survival.
- All survivors were supported with the device for no more than 30 days.

Organ preservation

- How can we reduce the incidence of PGD and increase graft and patient survival ?
  - Reduction of the ischemic time
  - Better preservation of older donor hearts (potentially)

Ex vivo perfusion

- Potentially **avoid the limitation of cold storage** by providing warm blood perfusion to the donor organ.
- Better preservation of the **endothelium integrity**
- Reduce the incidence of coronary artery vasculopathy (**CAV**)?
- **Increase the donor heart utilization** and weeding out sub-optimal organs



Ex vivo perfusion

- **PROCEED II is a global clinical trial that compares standard cold storage of donor hearts to warm oxygenated blood perfusion using the Organ Care System.**
- 92 patients (43 OCS and 49 SOC patients)
- Total cross clamp-time :
  - OCS group 5.4 ± 1.4 hours↑
  - SOC group 3.4 ± 1.1 hours
- Total ischemic time:
  - OCS group 1.8 ± 0.4 hours↓
  - SOC group 3.4 ± 1.1 hours
- No statistical differences in : 30-day patient survival, 30-day graft survival, all reported SAEs, reported cardiac SAEs, early graft dysfunction, and episodes of rejection.
- Development of more effective donor management and donor heart preservation strategies may reduce the incidence of PGD.

S. Ullah, Perfusion 2006

Effect of intraoperative blood cardioplegia

- Single cold flush preservation is the gold standard
- Reliable protection as long as total ischemic time of the heart does not exceed 3 to 4 hours and donor age is < 40 years.
- Clinical reality today often challenges these limits due to changes in the donor population and altered non-regional organ allocation.

Improve preservation-intraoperative blood cardioplegia

- Group 1 : standard filtrated cold **University of Wisconsin** (UW) single flush perfusion - served as the historical control.
- Group 2 : after initial UW preservation, additional Buckberg cold blood **cardioplegia** was administered **antegrade by aortic root** after completion of each anastomosis or at least **every 20 minutes** during implantation.
- Group 3 :preservation was as in Group 2, but starting with graft implantation, perfusate of extracorporeal circulation blood cardioplegia was **leucocyte-depleted** by 40×10^{-6} by inline filtration.

F.M. Wagner, Thorac Cardiovasc Surg,2013

Improve preservation-intraoperative blood cardioplegia

- PGD:
  - Group 1 5.2%
  - Group 2 4.1%
  - Group 3 0% ($p < 0.05$ Group 3 vs Group 1).

- **epinephrine** use & **IABP support** significantly ↓ in Group 3 (0.2 vs 0.3 vs. 0.3 µg/kg/min and 2% vs 10% vs 17% in Group 3 vs Group 2 vs Group 1, respectively; $p < 0.05$).
- Need for **permanent pacemaker** implantation before hospital discharge was ↓ in Group 3 (0% vs 2.0% vs 5.5% in Group 3 vs 2 vs 1, respectively; $p < 0.05$).

Size and sex mismatch

Table 2 Survival by Quantiles of Difference in pHM

	Unadjusted Models		Adjusted Models (	
	Survival 1 yr		Survival 1 yr	
	HR (95% CI)	p Value	HR (95% CI)	p Value
1 (most-undersized donor)	1.27 (1.13–1.43)	<0.001	1.25 (1.02–1.54)	0.03
2	1.10 (0.98–1.24)	0.1	1.14 (0.95–1.36)	0.1
3	0.96 (0.85–1.09)	0.5	1.02 (0.85–1.23)	0.8
4 (best fit)	Referent		Referent	
5	1.00 (0.88–1.13)	1.0	1.06 (0.89–1.26)	0.5
6	1.06 (0.94–1.19)	0.4	1.03 (0.86–1.24)	0.7
7 (most-oversized donor)	1.08 (0.96–1.22)	0.2	0.95 (0.78–1.16)	0.6
MR/MD	Referent		Referent	
MR/FD	1.32 (1.22–1.43)	<0.001	1.00 (0.85–1.17)	1.0
FR/FD	1.17 (1.06–1.29)	0.002	1.26 (1.08–1.47)	0.003
FR/MD	1.17 (1.06–1.30)	0.002	1.62 (1.36–1.92)	<0.001
FR/MD†	1.00 (0.88–1.14)	1.0	1.28 (1.04–1.57)	0.02

Reed. JACC Heart Fail. 2014;2.

PLEX in PGD; reasonable if any suspicion of AMR

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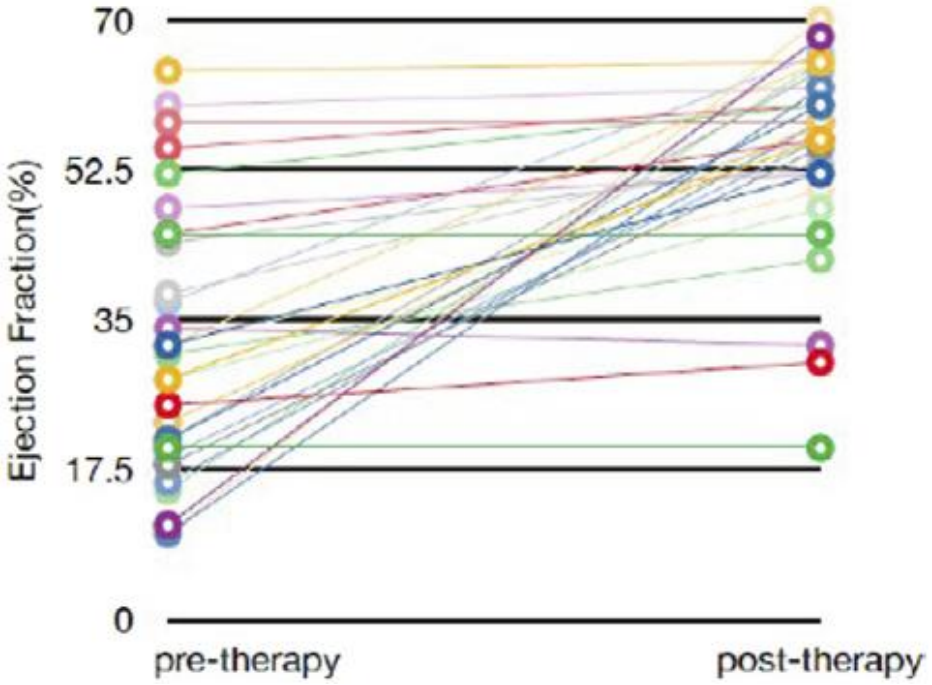
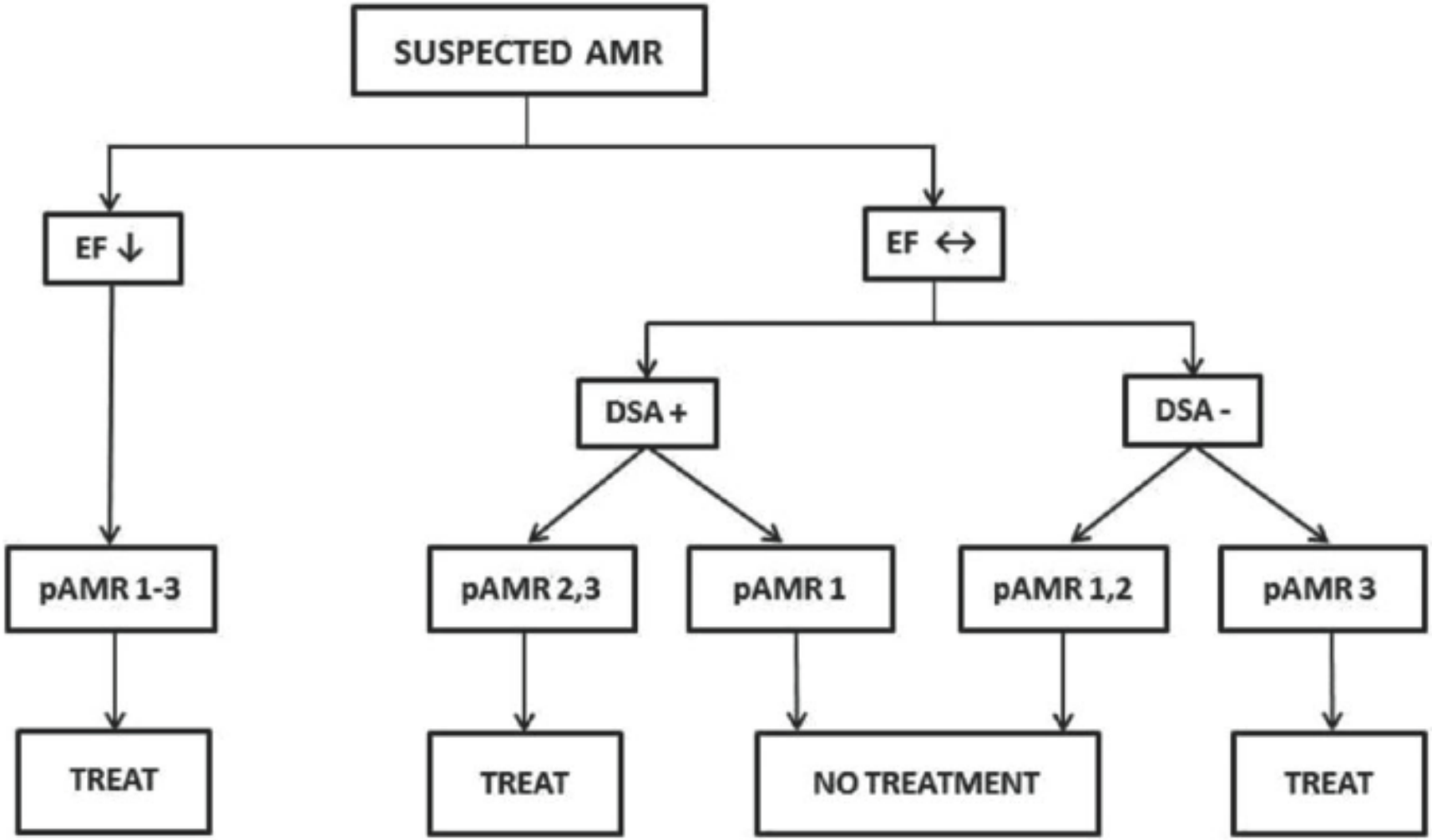
Steroid Pulse Therapy Combined with Plasmapheresis for Clinically Compromised Patients after Heart Transplantation

H.-W. Chou, N.-H. Chi, M.-H. Lin, N.-K. Chou, C.-I. Tsao, H.-Y. Yu, Y.-S. Chen, and S.-S. Wang



Chou. Transplantation Proceedings 2012;44.

PLEX in PGD; reasonable if any suspicion of AMR



Chih. American Journal of Transplantation 2012;12.

PLEX in PGD; also done in other organs Tx

ELSEVIER

Comparison of the Molecular Adsorbent Recirculating System and Plasmapheresis for Patients With Graft Dysfunction After Liver Transplantation

J.Y. Lee, S.B. Kim, J.W. Chang, S.-K. Park, S.-W. Kwon, K.W. Song, S. Hwang, and S.G. Lee

- 31 OLT with graft dysfunction 2002-2007; MARS vs PLEX
- 90 days survival not different: 53% vs 56%
- Cause of graft dysfunction:
  - MARS: PGD 2, Rejection 7, Ischemia 5, HBV 1
  - PLEX: PGD 3, Rejection 6, Ischemia 7

Lee. Transplantation Proceedings 2012;42.