## STS/EACTS Latin America Cardiovascular Surgery Conference

November 15-17, 2018 Hilton Cartagena | Cartagena, Colombia





#### Christian Bermudez MD.

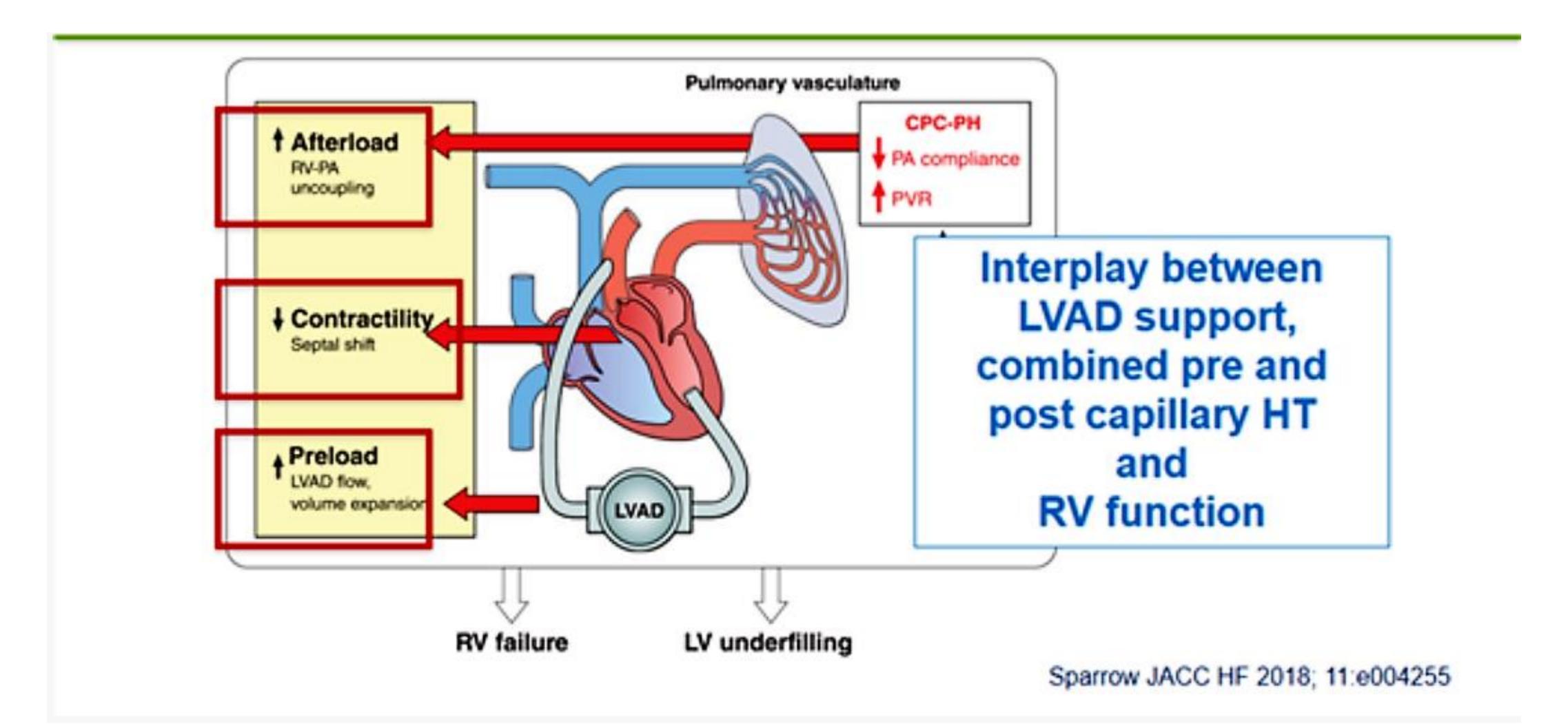
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#### **Conflict of Interest**

No Financial Disclosures.

# Interaction RV and LVAD support



#### INTERMACS definition of RVF

• Symptoms and Signs of persistent RVF following LVAD implantation characterized by:

#### Elevated CVP documented by:

- Right atrial pressure >16 mmHg on right heart catheterization
- Significantly dilated inferior vena cava with no inspiratory variation on echocardiography
- Elevated jugular venous pressure
- Manifestations of elevated CVP characterized by:
- Peripheral edema(>2+)
- Ascites or hepatomegaly on exam or diagnostic imaging
- Laboratory evidence of worsening hepatic (total bilirubin >2.0 mg/dl) or renal dysfunction (creatinine >2.0 mg/dl)

# Severity of Post-op RV Failure

#### MILD

 RHF requiring IV inotropes or vasodilators and/or iNO used for less than 7 days post-implantation

#### MODERATE

 Persisting RHF requiring IV inotropes or vasodilators and/or iNO used for > 7 days post-implantation but ≤ 14 days post-implantation

#### SEVERE

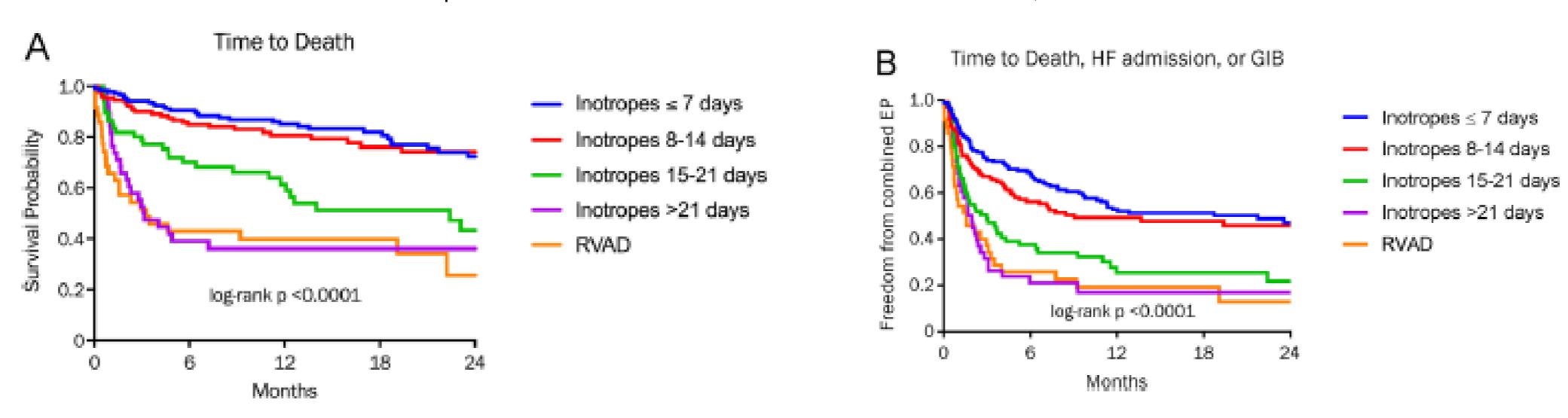


Persisting RHF requiring IV inotropes or vasodilators and/or iNO used for > 14 days post-implantation or implantation of MCS device for RV support at any time.
 2.6 fold increase in mortality at 6 months



# Clinical outcomes associated with INTERMACS-defined right heart failure after left ventricular assist device implantation

306 pt with less than severe RVD and 139 with severe RVD, St Louis

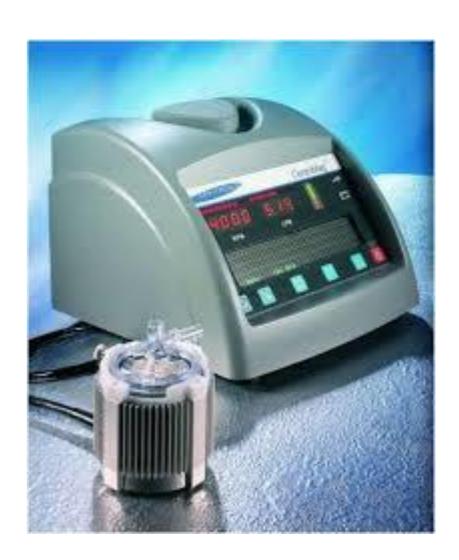


#### Severe RVD has profound effect in survival and clinical outcomes

Larue JHLT 2017

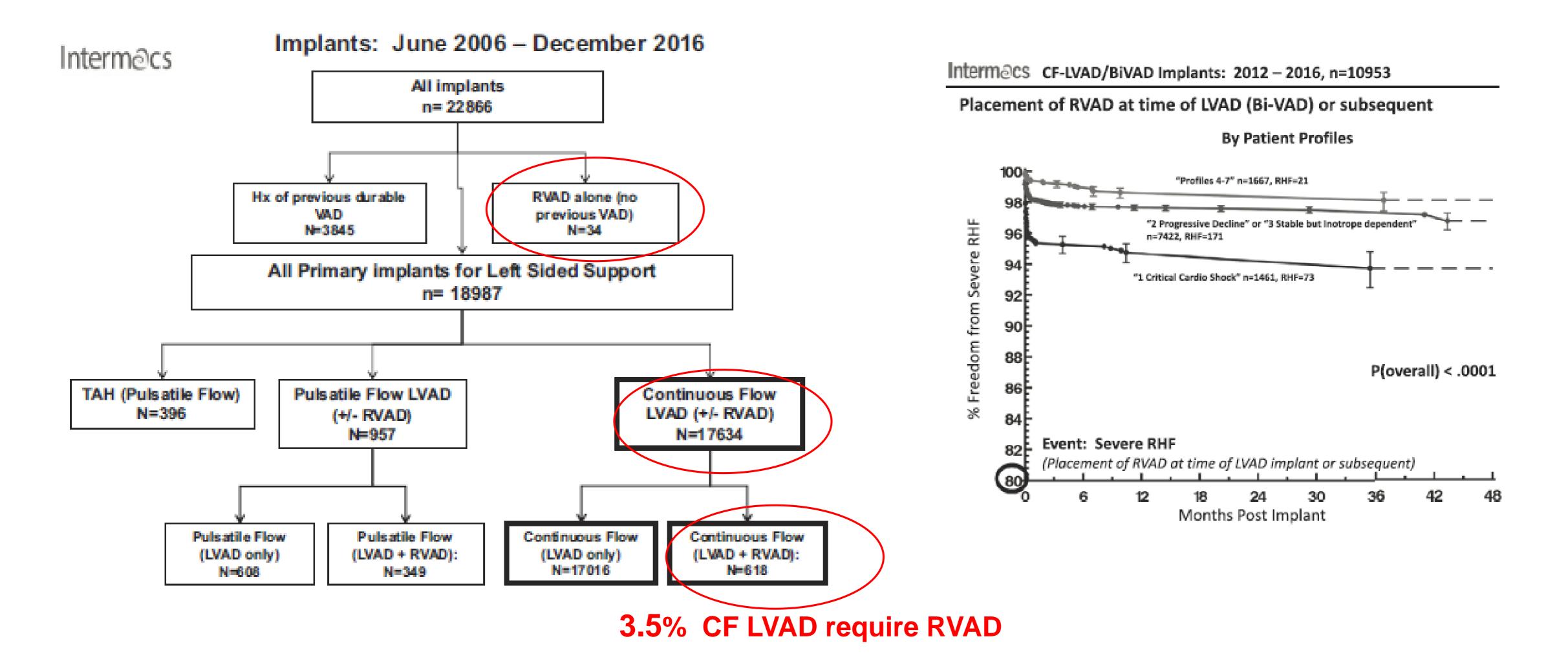
# Right Ventricular Failure

- 9-44% incidence in VAD eligible
- 5-20% post-LVAD incidence
- RVF:
  - Increased mortality
  - Multi-system organ failure
  - Coagulopathy
  - Hemorrhage
  - Pulmonary failure
  - Thromboembolic complications



Circ Cardiovasc Imaging 2014
Kalogeropoulos JHLT 2015
Kormos JTCVS 2010
Genovese Ann Thor Surg 2009
Fitzpatrick JHLT 2008
Morgan Ann Thor Surg 2004
Slaughter JHLT 2010

#### Surgical RVAD's in the US: Eighth INTERMACS Reports



J Heart LungTransplant 2017;36:1080–1086

#### **RV Risk Assessment**

- Risk Scores:
  - Michigan
  - Penn BIVAD
  - Penn CRITT
  - Berlin
  - Utah
  - U. Pitt
  - HM II

- Clinical: MV,RF, LVD, INTMCS
- Hemodynamics: CVP, RVSWI, CVP:PCWP, PVR, TPG, PA pressure
- Echo: RV Failure, TAPSE, TR, 3D TEE

Matthews JC JACC 2009
Fitzpatrick JR JHLT 2008
Drakos SGAm J Card 2010
Atluri P Ann Thor Surg 2014
Potapov JHLT 2008
Wang Y JHLT 2012
Kormos JTCVS 2010
Kiernan J Card Failure 2015

#### Clinical Tools for Assessing Risk for Right Ventricular Failure or Mortality After LVAD Since 2008

|                          | Publication |     | Devices                            |  |   |  |
|--------------------------|-------------|-----|------------------------------------|--|---|--|
| First author             | date        | No. | implanted                          | Components of score <sup>a</sup>   | Definition of RV failure  | Major findings   |
| Fitzpatrick <sup>5</sup> | 2008        | 167 | Pulsatile 98%<br>Continuous 2%     | Cardiac index     RV stroke work index     Severe RV dysfunction     Preoperative creatinine     Previous cardiac surgery  | Need for biventricular support  | Sensitivity of 83% and specificity of 80% to predict successful LVAD support using a cutoff of 50 points.  |
| Matthews <sup>8</sup>    | 2008        | 197 | Pulsatile 86%<br>Continuous<br>14% | Vasopressor requirement     Aspartate     aminotransferase     Bilirubin     Creatinine  | Need for post-operative intravenous inotrope support for > 14 days, inhaled nitric oxide for > 48 h, right-sided circulatory support, or hospital discharge on an inotrope                                    |  |
| Pota pov <sup>10</sup>   | 2008        | 54  | Pulsatile 31%<br>Continuous<br>69% | Tricuspid incompetence     RV end-diastolic     diameter > 35 mm     RV ejection fraction     <30%     Right atrial dimension     <50 mm     Short-/long-axis ratio     > 0.6        | Within 48 hours: RVAD implant or 2 of the following:  1. Mean arterial pressure <55 mmHg 2. CVP > 16 mmHg 3. Mixed venous saturation < 55% 4. Cardiac index < 2 liters/min/m² 5. Inotropic support > 20 units | OR for RV failure after LVAD implantation for Grade III or IV tricuspid regurgitation was 4.7 ( $p=0.012$ )  |
| Puwanant <sup>11</sup>   | 2008        | 33  | Pulsatile 45%<br>Continuous<br>55% | Tricuspid annular plane motion   | Need for inotropic support or pulmonary vasodilators for<br>>14 days post-operatively   | A cutoff of 7.5 mm yields a sensitivity of 48%, specificity of 91%, and area under the ROC curve of 0.81   |
| Drakos <sup>4</sup>      | 2011        | 175 | Pulsatile 86%<br>Continuous<br>14% | 1. Preoperative need for IABP 2. Increased PVR 3. Destination Therapy 4. Inotrope dependency 5. Obesity 6. ACE inhibitor and/or angiotensin II receptor blocker use 7. β-blocker use | Need for inhaled nitric oxide for > 48 hours, IV inotropes > 14 days and/or RV device insertion   | Area under the ROC curve to predict RV failure was 0.743 ± 0.037   |
| Kormos <sup>9</sup>      | 2011        | 484 | Continuous<br>100%                 | CVP     Need for     preoperative vent     BUN >39 mg/dl   | Need for RVAD, continuous inotropic support for at least<br>14 days or late inotropic support starting 14 days<br>after implantation  | The following were associated with RV failure after multivariate analysis:  1. CVP/pulmonary capillary wedge pressure ratio > 0.63 (OR, 2.3; 95% CI, 1.2-4.3)  2. Need for preoperative vent (OR, 5.5; 95% CI, 2.3-13.2)  3. BUN > 39 mg/dl (OR, 2.1; 95% CI, 1.1-4.1) |

|                       |      |     |                                    |   | White tell property and a fill fill i   |   |
|-----------------------|------|-----|------------------------------------|---|---|---|
| Kukucka 12            | 2011 | 115 | Pulsatile 56%<br>Continuous<br>44% | <ol> <li>RV-to-LV end-diastolic<br/>diameter (R/L) ratio<br/>obtained from<br/>transesophageal echo</li> </ol>                              | 1. Mean arterial pressure <55 mmHg 2. CVP pressure > 16 mm Hg 3. Mixed venous saturation < 55% 4. Cardiac index < 2 liters/min/m <sup>2</sup>                       | Using a cutoff of R/L ratio > 0.72 yielded an area under<br>the ROC curve of 0.742  |
| Grant <sup>13</sup>   | 2012 | 117 | Continuous<br>100%                 | 1. RV free wall peak<br>longitudinal strain   | <ol> <li>Inotropic support &gt;20 units.</li> <li>Unplanned insertion of an RVAD or the use of an intravenous inotrope for &gt; 14 days post-operatively</li> </ol> | A peak strain cutoff of -9.6% predicted RV failure with<br>sensitivity of 68% and specificity of 76% with an are<br>under the ROC curve of 0.70. When added to the<br>Michigan risk score, the area under the ROC curve<br>improved from 0.68 to 0.77   |
| Kato <sup>14</sup>    | 2012 | 111 | Pulsatile 29%<br>Continuous<br>71% | LVEDD     Left atrial diameter/     LVEDD     Total bilirubin     Albumin     RV stroke work index  | Need for inhaled nitric oxide for > 48 hours, IV inotropes > 14 days, and/or RVAD insertion   | Using a cutoff of 6 points provided a sensitivity of 68.69 specificity of 76.3%, and area under the ROC curve of 0.789  |
| Atluri <sup>15</sup>  | 2013 | 167 | Pulsatile 51%<br>Continuous<br>49% | CVP > 15 mm Hg     Severe RV dysfunction     Preoperative intubation     Severe tricuspid     regurgitation     Heart rate > 100 beats/ min | Need for biventricular support  | The components of the risk score were associated with the following odds of RV failure:  1. CVP > 15 mm Hg (OR, 2.0; 95% CI, 0.9-4.2)  2. Severe RV dysfunction (OR, 4.1; 95% CI, 1.4-12.4)  3. Preoperative intubation (OR, 4.3; 95% CI, 1.9-9.6)  4. Severe tricuspid regurgitation (OR, 3.7; 95% CI, 1.4-12.4)  5. Heart rate > 100 beats/min (OR, 2.0; 95% CI, 0.9-4.3) |
| Vivo <sup>16</sup>    | 2013 |     | Pulsatile 15%<br>Continuous<br>85% | <ol> <li>RV-to-LV end-diastolic<br/>diameter (R/L) ratio<br/>obtained from<br/>transthoracic echo</li> </ol>                                | Need of RVAD or ≥ 14 consecutive days of inotropic support ≤ 30 days  | Using a R/L ratio cutoff of 0.75 yielded an area under the ROC curve of 0.68  |
| Kiernan <sup>17</sup> | 2015 | 24  | Continuous<br>100%                 | RV end-systolic volume<br>index     RV end-diastolic volume<br>index  | Need of RVAD or ≥ 14 consecutive days of inotropic support  | <ol> <li>RV end-systolic volume index &gt;47 ml/m² had a sensitivity of 83%, specificity or 93%, and area under ROC curve of 0.88 (95% CI, 0.69-0.97; p &lt; 0.0001)</li> <li>RV end-diastolic volume index &gt;61 ml/m² had a sensitivity of 92%, specificity of 79%, and area under ROC curve of 0.90 (95% CI, 0.72-0.98; p &lt; 0.0001)</li> </ol>                       |

J HeartLungTransplant 2016;35:283–293

## EUROMACS Right Sided-HF Risk Score

ACHA

#### Risk score components:

#### 9.5-point risk score (5-item)

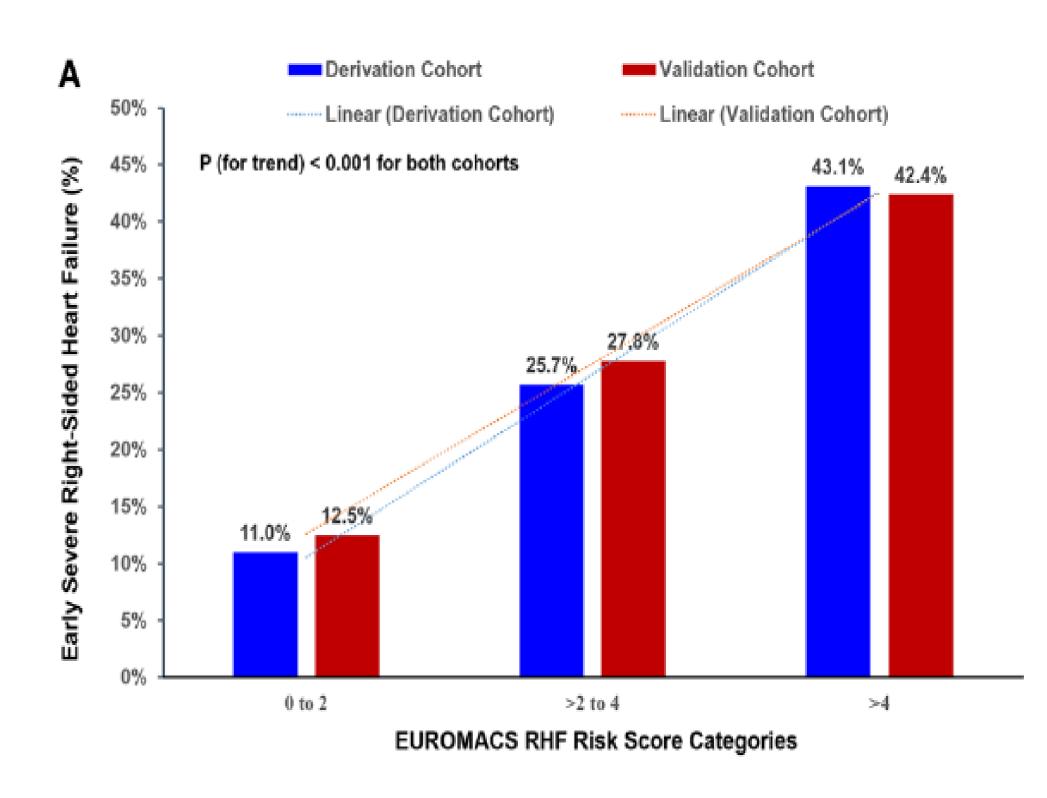
- Severe RV dysfunction on semi quantitative echocardiography (2 points)
- Ratio of RA to PCWP ≥ 0.54 (2 points)
- INTERMACS class 1 through 3 (2 points)
- Need of ≥3 inotropic agents (2.5 points)
- Hemoglobin ≤10 g/dL (1 point).

0-2: Low risk

2.5-5: Intermediate risk

> 4: High risk

Soliman et al Circulation. 2018;137:891-906.



Includes only the 3 most used CF pumps (HMII, HW, HMIII)

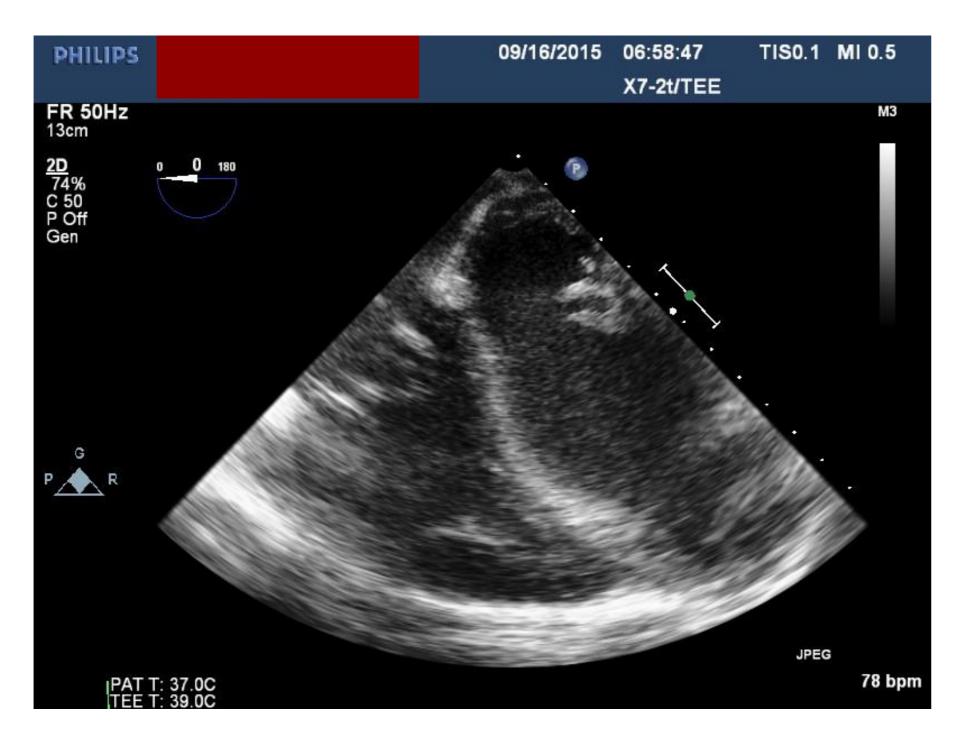


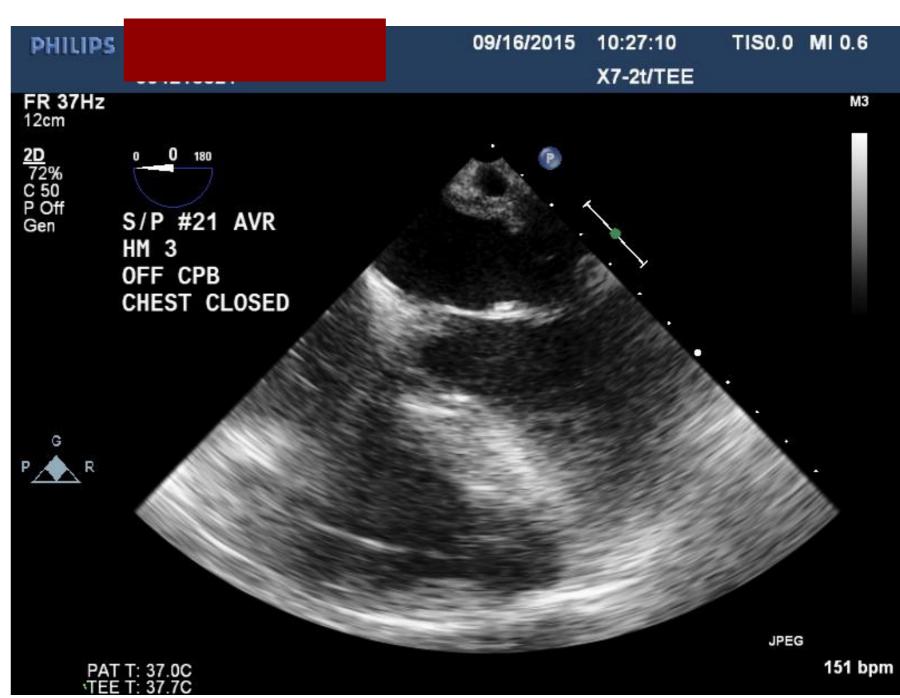
How do we prevent and manage acute perioperative RVF....

### **Pre-operative Optimization RV**

- Diuresis (Lasix Drip/ CVVH, target CVP<15 mmhg)</li>
- Preoperative Inotropic Support (Milrinone preferred over Dobutamine).
- IABP

# RV Pre- and Post-Optimization





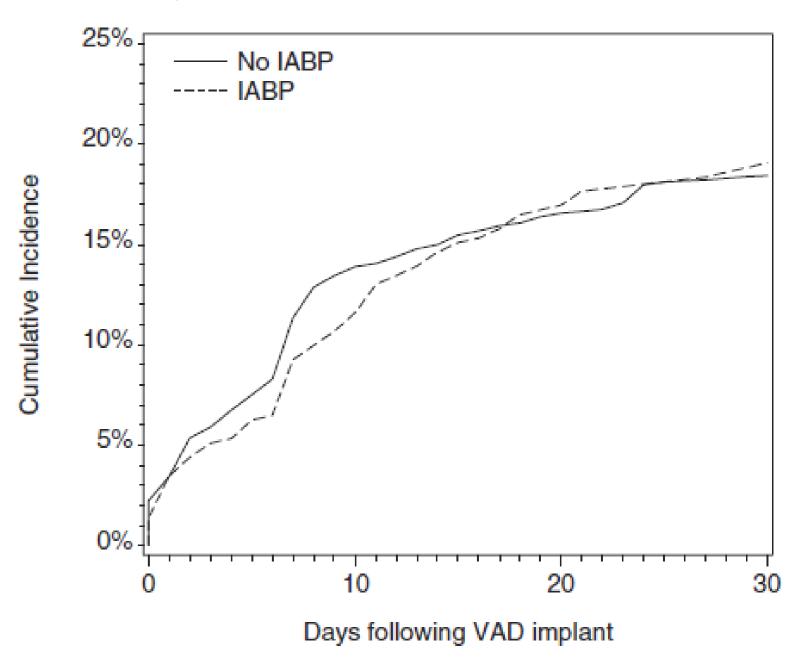
## **Preoperative IABP**

Intra-Aortic Balloon Pump Use Before Left Ventricular Assist Device Implantation: Insights From the INTERMACS Registry

| Intra-Aortic Balloon Pump Use Before LVAD |  |  |  |  |
|---|--|--|--|--|
| Implantation                              |  |  |  |  |

|  | No (n = 2013) | Yes (n = 433) | p       |
|--|---------------|---------------|---------|
| Right ventricular function, No. (%)            |               |               | <0.001  |
| Normal   | 327 (16.2)    | 51 (11.8)     |         |
| Mild dysfunction                               | 298 (14.8)    | 60 (13.9)     |         |
| Moderate dysfunction                           | 314 (15.6)    | 80 (18.5)     |         |
| Severe dysfunction                             | 125 (6.2)     | 48 (11.1)     |         |
| Unknown  | 949 (47.1)    | 194 (44.8)    |         |
| Cardiac arrest this hospitalization            | 11 (0.5)      | 14 (3.2)      | < 0.001 |
| Support within 48 hours after implant, No. (%) | • •           |               |         |
| Inotropes                                      | 1350 (67.1)   | 280 (64.7)    | 0.34    |
| Mechanical ventilation                         | 29 (1.4)      | 15 (3.5)      | 0.004   |
|  |               |               |         |

Cumulative incidence of right heart failure, hepatic dysfunction, renal dysfunction, or death



Despite markers of higher risk in patients with IABP use, we found no significant difference in 30 day outcomes compared to those without. The results suggest that IABP use may mitigate risk of early postoperative adverse outcomes in select patients.

## Intra-and Perioperative Strategies to Prevent/Treat RV Failure

#### **Surgical Strategies**

- TV Repair
- Minimize CPB
- Avoid bleeding /prevent transfusions
- Delayed chest closure
- Adjust LVAd flow (avoid septal shift)
- RVAD (early implantation)

#### Perioperative management

- Nitric Oxide or inhaled prostacyclin
- TEE monitoring of RVF
- Inotropic support to Maintain systolic BP and avoid vasodilation
  - Milrinone
  - Epinephrine
  - Isoproterenol
- Ventilator strategies
  - Maintain O2 and reduce CO2 (avoid hypercarbia)

#### Right heart failure and benefits of adjuvant tricuspid valve repair in patients undergoing left ventricular assist device implantation

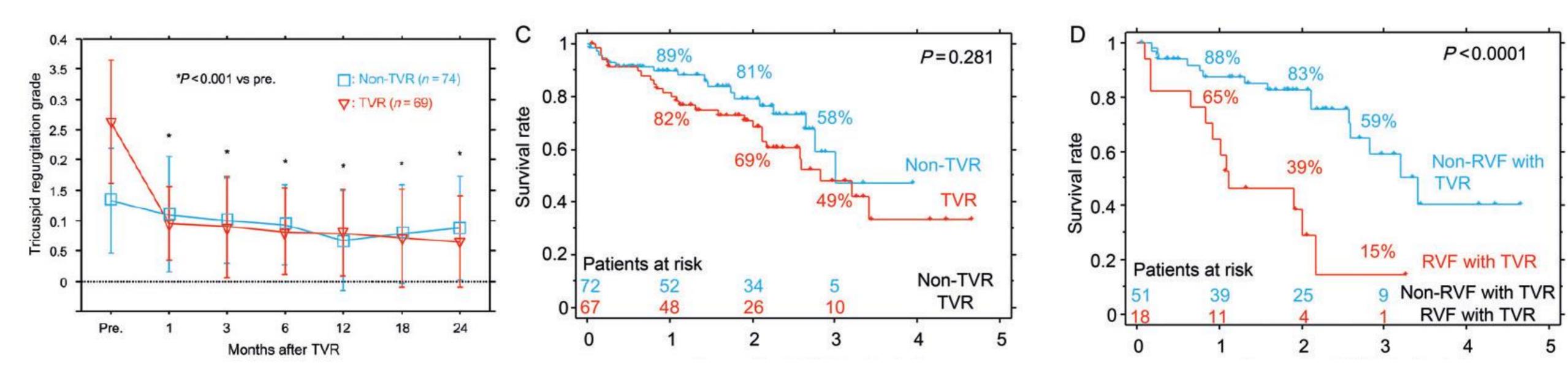
| Variables                            | TVR (n = 69)    | No TVR<br>(n = 72) | P-value |
|--------------------------------------|-----------------|--------------------|---------|
| Duration of heart<br>failure (years) | 4.4 ± 5.1       | 5.3 ± 5.4          | 0.405   |
| On ventilator                        | 13 (18%)        | 23 (32%)           | 0.101   |
| IABP support                         | 41 (58%)        | 46 (64%)           | 0.709   |
| On VA-ECMO                           | 13 (16%)        | 22 (32%)           | 0.157   |
| INTERMACS (Level 3)                  | 24 (42%)        | 30 (35%)           | 0.504   |
| Total bilirubin (mg/dl)              | 2.2 ± 1.5       | 2.2 ± 2.7          | 0.86    |
| Creatinine (mg/dl)                   | 1.6 ± 1.1       | 1.1 ± 0.6          | 0.006   |
| LVDd (mm)                            | 74 ± 12         | 73 ± 11            | 0.815   |
| LVDs (mm)                            | 67 ± 12         | 66 ± 12            | 0.645   |
| Ejection fraction (%)                | 16 ± 8          | 17 ± 8             | 0.892   |
| TR (Grades 0-4)                      | 2.6 ± 1.0       | $1.3 \pm 0.8$      | < 0.001 |
| Cardiac index                        | 2.0 ± 0.5       | 2.0 ± 0.5          | 0.717   |
| Mean PAP (mmHg)                      | 33 ± 10         | 31 ± 10            | 0.392   |
| PCWP (mmHg)                          | 24 ± 8          | 23 ± 9             | 0.738   |
| CVP (mmHg)                           | 12 ± 8          | 9 ± 6              | 0.006   |
| CVP/PCWP                             | $0.54 \pm 0.35$ | $0.38 \pm 0.19$    | 0.003   |
| RVSWI                                | 0.45 ± 0.27     | 0.46 ± 0.28        | 0.94    |
| Fibrosis (Scores 0-3)                | $2.4 \pm 0.7$   | $2.1 \pm 0.8$      | 0.009   |

#### 141 LVAD /69 TVr

| Table 2: Surgical procedures |              |                  |         |  |
|------------------------------|--------------|------------------|---------|--|
| Surgical procedures          | RVF (n = 27) | No RVF (n = 114) | P-value |  |
| LVAD implantation            |              |                  |         |  |
| Pulsatile                    | 26           | 93               | 0.109   |  |
| Continuous flow              | 1            | 21               |         |  |
| RVAD-ECMO                    | 3            |                  |         |  |
| TVR                          | 18 (67%)     | 51 (45%)         | 0.067   |  |
| Ring annuloplasty            | 14 (78%)     | 34 (67%)         |         |  |
| Flexible ring                | 11 (61%)     | 21 (41%)         |         |  |
| Semirigid ring               | 3 (17%)      | 13 (25%)         |         |  |
| DeVega method                | 4 (22%)      | 17 (33%)         |         |  |

#### Right heart failure and benefits of adjuvant tricuspid valve repair in patients undergoing left ventricular assist device implantation

#### 141 LVAD /69 TVR



Tricuspid valve repair is a useful and durable adjuvant procedure for restoring deteriorated right ventricular function in patients requiring LVAD implantation.

# Concomitant tricuspid valve surgery during implantation of continuous-flow left ventricular assist devices: A Society of Thoracic Surgeons database analysis.

Table 5 Sensitivity Analysis Comparing Results from Traditional Multivariate Regression Analysis to Inverse Probability Weighting Using Conditional Logistic Regression

|                       |                    | Before IPW adjustment |         | After IPW adjustment |                 |
|-----------------------|--------------------|-----------------------|---------|----------------------|-----------------|
| Variables             | No. (events/total) | OR for TVP (95% CI)   | p-value | OR for TVP (95% CI)  | <i>p</i> -value |
| Operative mortality   | 224/2,196          | 1.22 (0.83-1.80)      | 0.3050  | 0.95 (0.61-1.47)     | 0.8177          |
| Reoperation           |                    |                       |         |                      |                 |
| Any                   | 710/2,189          | 1.39 (1.08-1.79)      | 0.0099  | 1.46 (1.11-1.93)     | 0.0076          |
| Bleeding or tamponade | 350/2,189          | 1.67 (1.22-2.27)      | 0.0012  | 1.93 (1.37-2.72)     | 0.0002          |
| RVAD insertion        | 99/2,196           | 0.94 (0.54-1.64)      | 0.8170  | 0.69 (0.36-1.32)     | 0.2631          |
| Prolonged ventilation | 1,462/2,189        | 1.48 (1.13-1.940)     | 0.0039  | 1.40 (1.04-1.89)     | 0.0262          |
| New renal failure     | 214/1,851          | 1.66 (1.12-2.48)      | 0.0121  | 1.93 (1.37-2.72)     | 0.0002          |
| Stroke                | 67 /2 . 188        | 1.25 (0.63-2.50)      | 0.5227  | 1.22 (0.57-2.62)     | 0.6045          |

2196 cf LVADs, 588 (27%) LVAD-TVr (TVr in mod-severe TR, annulus >40 mm)

No difference in RVAD need or mortality

TVP was associated with an increased risk for postoperative renal failure (RR,1.53;95%CI,1.13–2.08; p =0.0061), dialysis (RR,1.49;95%CI,1.03–2.15; p = 0.0339), reoperation (RR,1.24;95%CI,1.07–1.45; p = 0.0056), greater total transfusion requirement (RR,1.03;95%CI,1.01–1.05; p = 0.0013), and hospital length of stay >21 days (RR,1.29;95%CI,1.16–1.43; p o 0.0001). Time on the ventilator and intensive care unit length of stay were also significantly prolonged for the LVAD -pTVP group.

The Journal of Heart and Lung Transplantation, Vol 33, No 6, June 2014

# Continuous Flow Left Ventricular Assist Device Implant Significantly ImprovesPulmonary Hypertension, Right Ventricular Contractility, and Tricuspid Valve Competence

TABLE 3

Mean Preoperative, Immediate Postoperative, and Follow-Up Right Ventricular Dysfunction and Tricuspid Regurgitation Following Continuous Flow Left Ventricular Assist Device Implant

|   | Pre-<br>Operative<br>(n = 114) | Post-<br>Operative<br>(n = 114) | 3-Month<br>Follow-Up<br>(n = 71) | 6-Month<br>Follow-Up<br>(n = 63) | 12-Month<br>Follow-Up<br>(n = 52) | P = (Post-<br>Op<br>vs. Pre-Op) |
|---|--------------------------------|---------------------------------|----------------------------------|----------------------------------|-----------------------------------|---------------------------------|
| Right ventricular dysfunction (all patients)                      | 2.09 ± 0.64                    | $1.65 \pm 0.71$                 | $1.67 \pm 0.77$                  | 1.36±0.88                        | 1.64±0.79                         | 0.001                           |
| Right ventricular dysfunction (pre-op moderate or severe, n = 58) | $2.46 \pm 0.49$                | $1.89 \pm 0.55$                 | 1.79±0.74                        | 1.48±0.80                        | 1.75±0.80                         | <0.00001                        |
| Tricuspid regurgitation (all patients)                            | $1.48 \pm 0.75$                | $1.24 \pm 0.50$                 | $1.05 \pm 0.53$                  | $1.04 \pm 0.42$                  | $0.75 \pm 0.58$                   | 0.001                           |
| Tricuspid regurgitation (pre-op moderate or severe, n = 59)       | 2.17 ± 0.28                    | 1.38 ± 0.60                     | 1.14±0.61                        | $1.17 \pm 0.47$                  | $0.71 \pm 0.57$                   | <0.000001                       |

There was an immediate improvement in TR grade and RV function following LVAD implant, which was sustained long term

Conclusion: Continuous flow LVAD implant improves pulmonary hypertension, RV function, and tricuspid regurgitation. TR may be managed non-operatively during CF LVAD implant.

J CARD SURG ATLURI, ET AL. 771 2013;28:770–775

# Inhaled nitric oxide after left ventricular assist device implantation: A prospective, randomized, double-blind, multicenter, placebo-controlled trial

# 105 patients randomized to receive 40ppm NO vs placebo at time of weaning from bypass

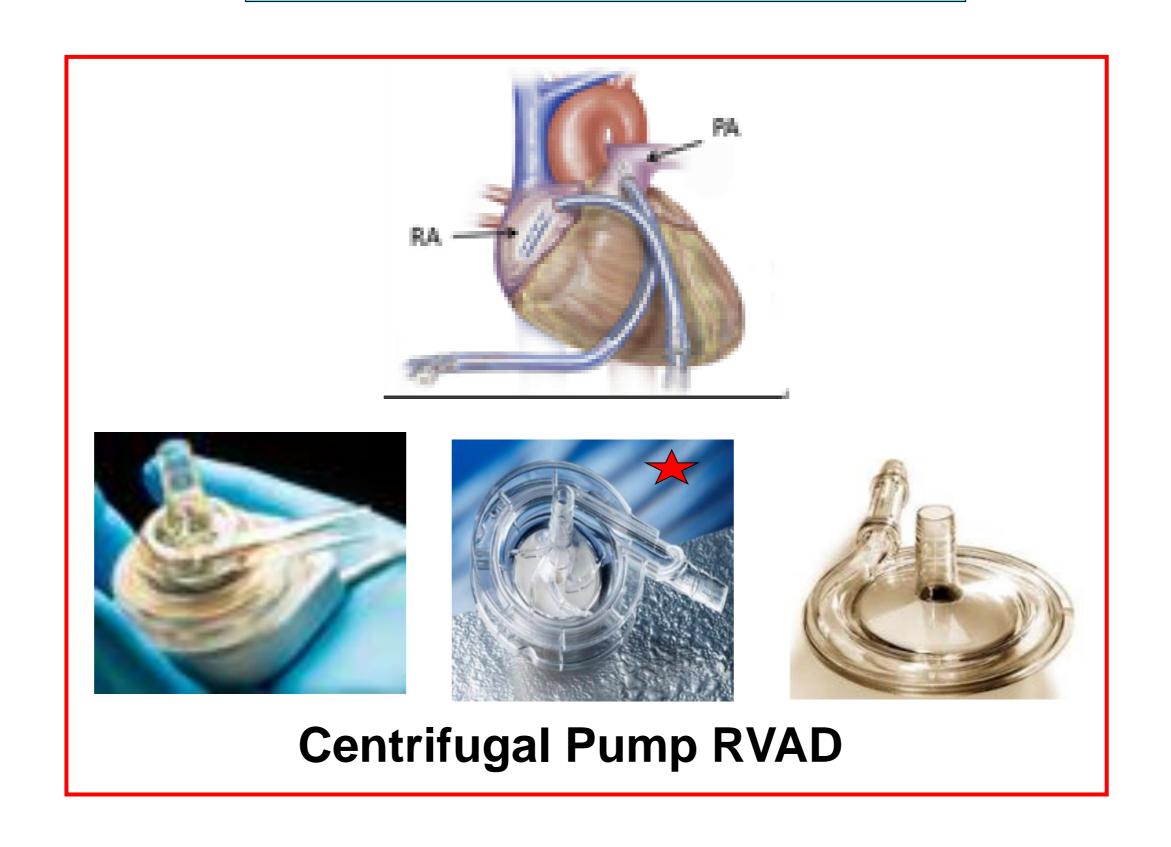
Use of iNO at 40 ppm given before separation from CPB did not reach statistical significance for the primary end point of reduction in RVD incidence. No statistically significant difference was found for secondary variables, including time on mechanical ventilation, ICU or hospital stay, and the need for RVAD after LVAD placement.

| Outcome Measure                             | iNO           | Placebo       | <i>p-v</i> alue |
|---|---------------|---------------|-----------------|
| Patients meeting RVD criteria ≤48 hours     |               |               | 0.330           |
| No. of total (%)                            | 7/73 (9.6)    | 12/77 (15.6)  |                 |
| 95% CI                                      | 2.8-16.3      | 7.5-23.7      |                 |
| Males, No. (%)                              | 7/64 (10.9)   | 7/65 (10.8)   | >0.99           |
| Females, No. (%)                            | 0/9 (0.0)     | 5/12 (41.7)   | 0.045           |
| PVRI <270.5 dyne/sec/cm <sup>-5</sup>       | 6/51 (11.8)   | 6/48 (12.5)   | >0.99           |
| PVRI ≥270.5 dyne/sec/cm <sup>-5</sup>       | 1/7 (14.3)    | 5/7 (71.4)    | 0.103           |
| Days on mechanical ventilation <sup>a</sup> | 70            | 67            | 0.077           |
| Mean (SD)                                   | 5.37 (7.72)   | 11.10 (24.81) |                 |
| Median (range)                              | 2.0 (1-30)    | 3.0 (0-160)   |                 |
| No. of ICU days <sup>b</sup>                | 60            | 58            | 0.630           |
| Mean (SD)                                   | 20.52 (32.31) | 19.90 (24.38) |                 |
| Median (range)                              | 11.0 (3-194)  | 9.0 (3-115)   |                 |
| No. of total hospital days <sup>c</sup>     | 58            | 58            | 0.979           |
| Mean (SD)                                   | 40.57 (32.19) | 40.76 (29.41) |                 |
| Median (range)                              | 32.0 (11-194) | 31.5 (10-156) |                 |
| Quantity of blood products used             | 73            | 77            |                 |
| Mean, ml (SD)                               | 4,232 (4675)  | 4,885 (7760)  | 0.226           |
| Patients requiring PRT, No. (%)d            | 10/71 (14.1)  | 8/70 (11.4)   | 0.637           |
| Non-survival at Day 28, No. (%)             | 8/71 (11.3)   | 8/70 (11.4)   | 0.924           |
| Patients needing RVAD by Day 28, No. (%)    | 4/71 (5.6)    | 7/70 (10.0)   | 0.468           |

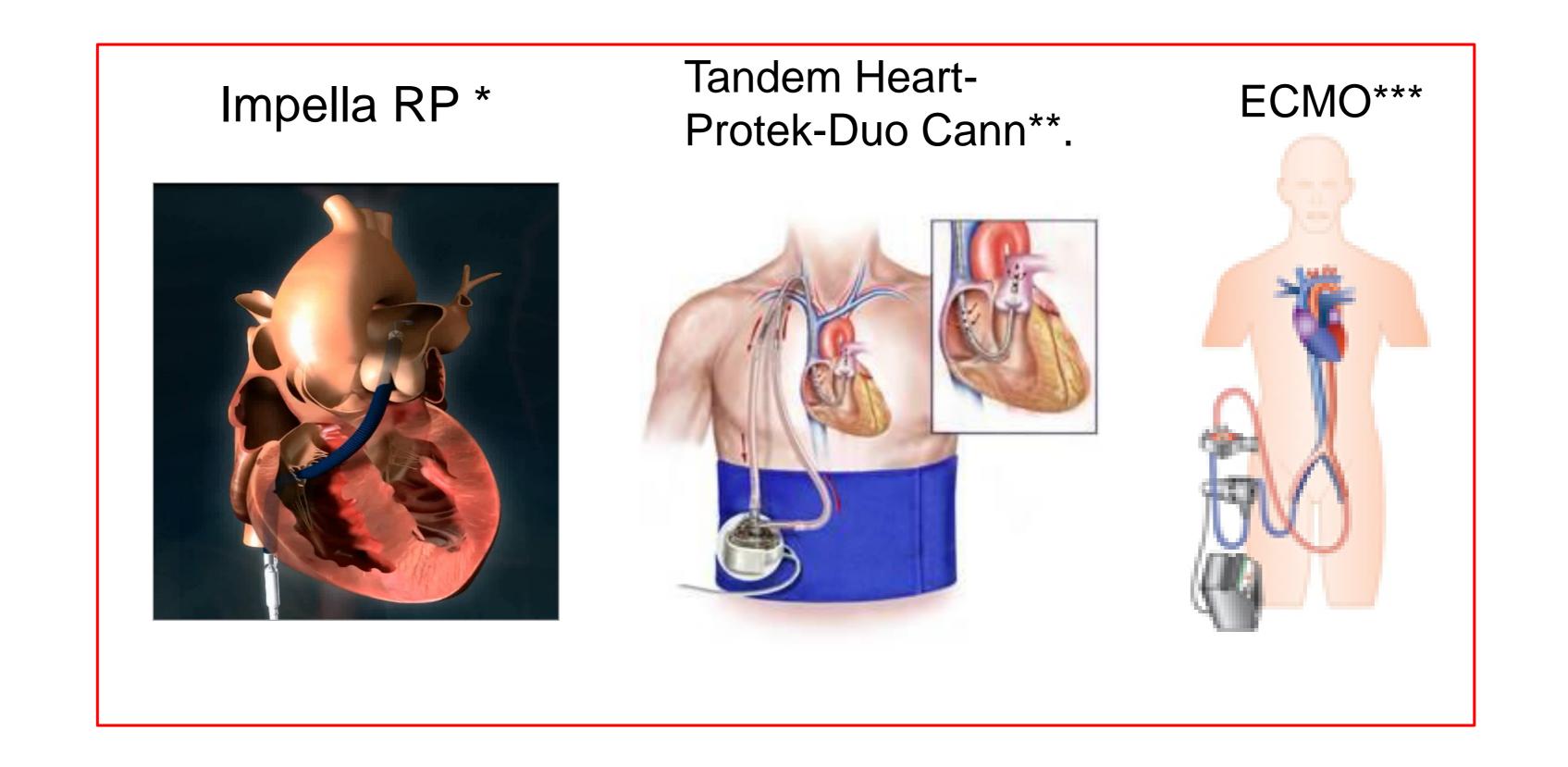
J Heart Lung Transplant 2011;30:870–8

#### Surgical Temporary Mechanical RV Support Options

#### Sternotomy/Thoracotomy



## Percutaneous Temporary RV Support Options



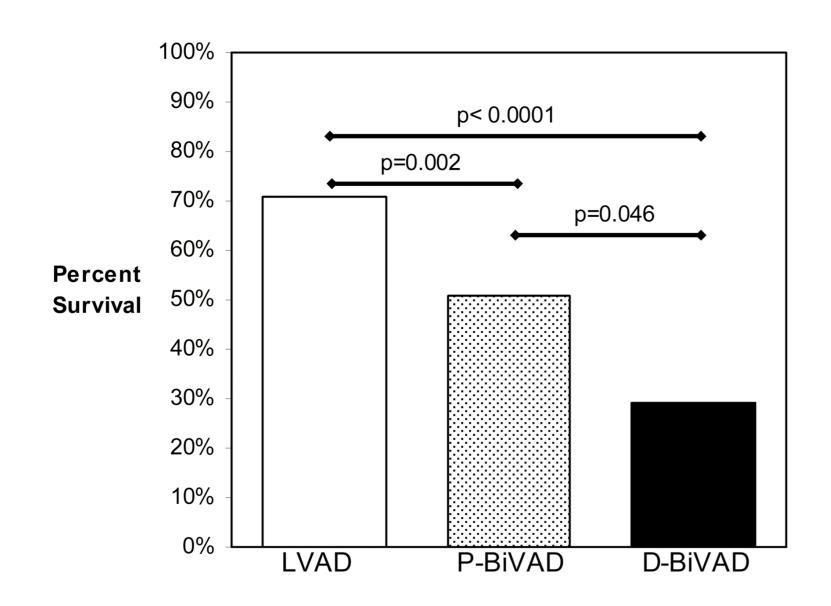
<sup>\*</sup>FDA Approval for RV support

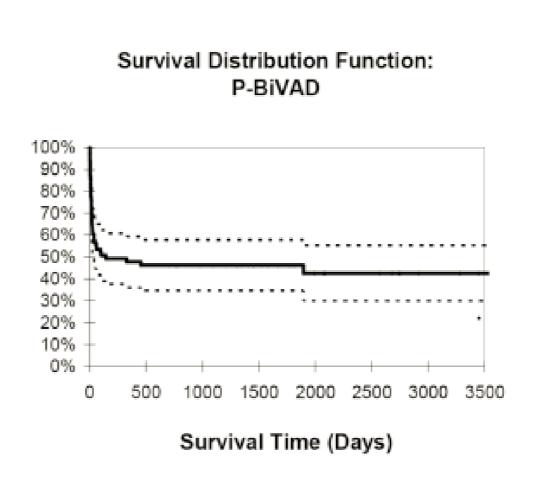
<sup>\*\*</sup> FDA Approval for Circulatory Support 6h

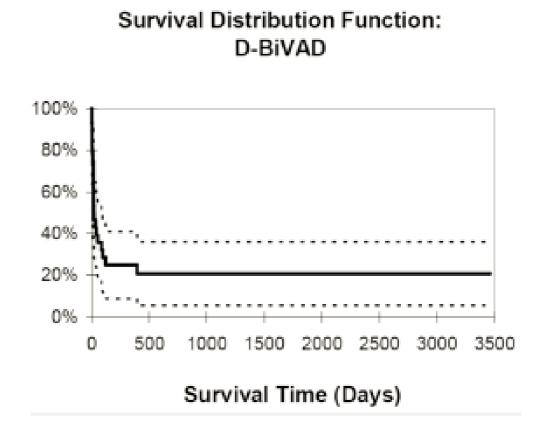
<sup>\*\*\*</sup> FDA Approval for Circulatory Support 6h

# Early, Planned Institution of Biventricular Mechanical Circulatory Support Results in Improved Outcomes Compared to Delayed Conversion of LVAD to BiVAD

167 LVAD alone ,71 Planned BIVAD and 28 delayed BIVAD (PVADS) Similar patient characteristics in the BIVAD group



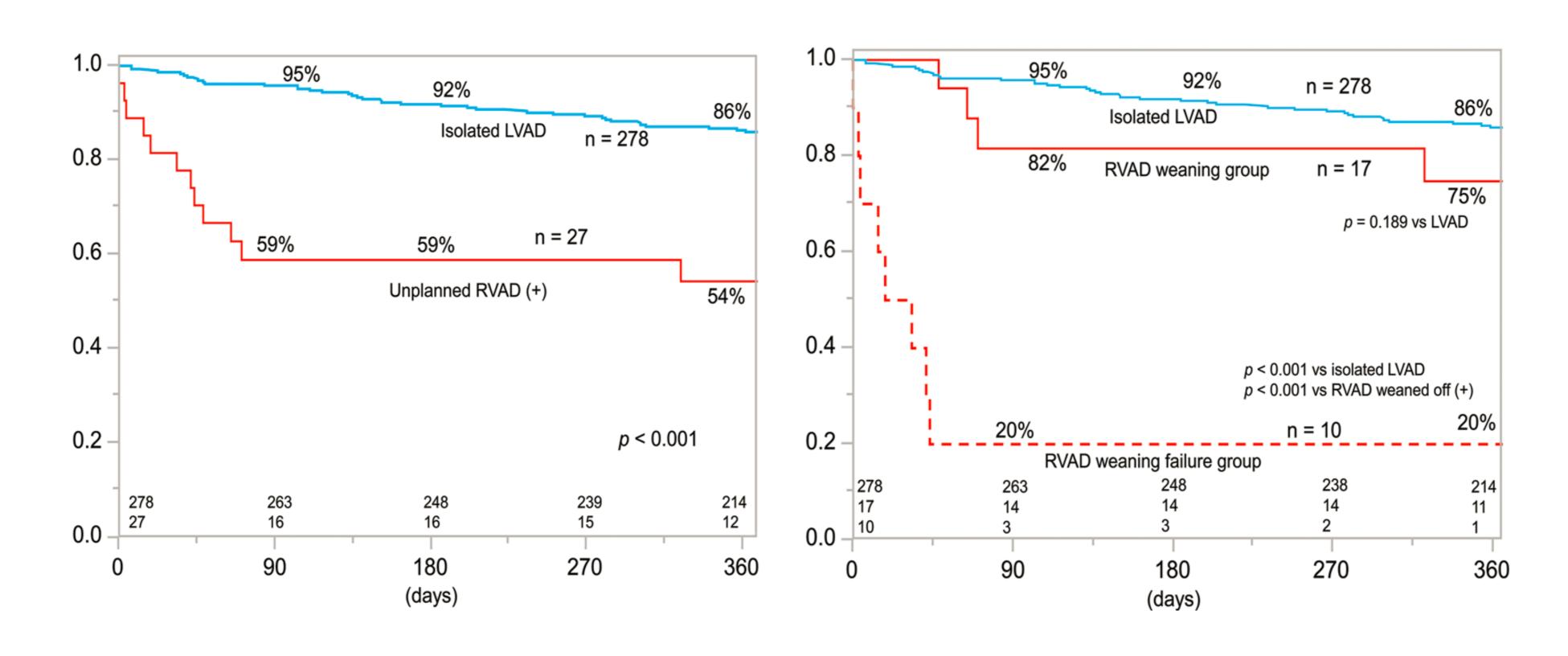




When patients at risk for isolated LVAD support failure are identified, proceeding directly to BiVAD implantation is advised, as early institution of biventricular support results in dramatic improvement in survival

J Thorac Cardiovasc Surg. 2009 April; 137(4): 971–977

# Outcome of unplanned right ventricular assist device support for severe right heart failure after implantable left ventricular assist device insertion.



# Clinical experience with Centrimag temporary right ventricular mechanical circulatory support

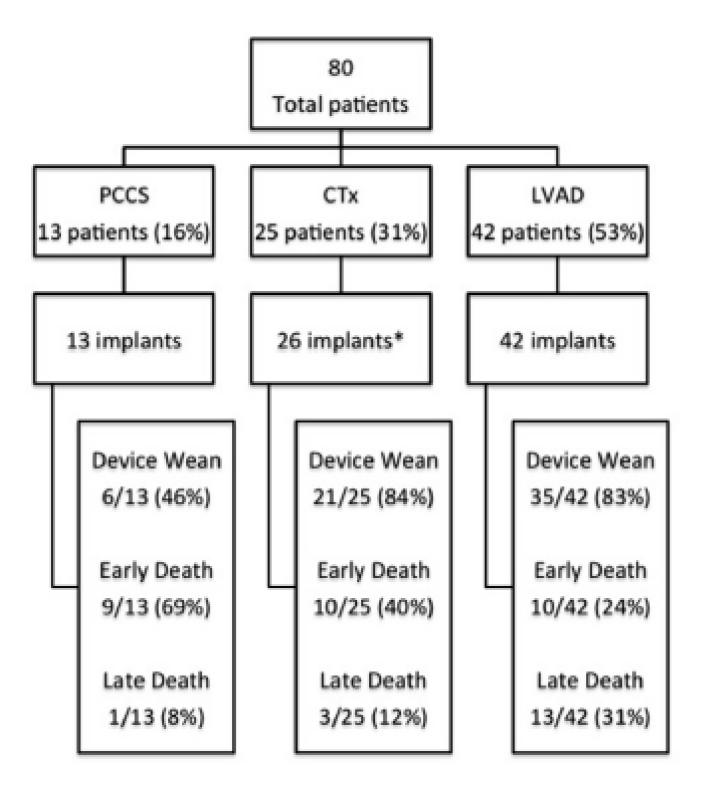


TABLE 2. Adverse events and causes of death in study patients

| Variable                 | PCCS (n = 13), (%) | CTx (n = 25), (%) | LVAD (n = 42), (%) | P value |
|--------------------------|--------------------|-------------------|--------------------|---------|
| Adverse event            |                    |                   |                    |         |
| Reoperation for bleeding | 3 (23)             | 9 (36)            | 10 (24)            | .52     |
| Major infection          | 8 (62)             | 13 (52)           | 23 (55)            | .85     |
| Arrhythmia               | 5 (38)             | 10 (40)           | 21 (50)            | .64     |
| Stroke/encephalopathy    | 1(8)               | 3 (12)            | 9 (21)             | 54      |
| Air embolism             | 0 (0)              | 0 (0)             | 1 (2)              | .63     |
| Causes of early death    |                    |                   |                    |         |
| MSOF/sepsis              | 1 (8)              | 5 (20)            | 3 (7)              | .25     |
| LV failure               | 1 (8)              | 1 (4)             | 0 (0)              | .22     |
| Stroke                   | 0 (0)              | 0 (0)             | 0 (0)              | _       |
| Care withdrawn           | 5 (38)             | 1 (4)             | 4 (10)             | .01     |
| Causes of late death     |                    |                   |                    |         |
| Stroke                   | 0 (0)              | 0 (0)             | 0 (0)              | _       |
| Care withdrawn           | 1 (8)              | 1 (4)             | 4 (10)             | .71     |

Risk factors for weaning RVAD

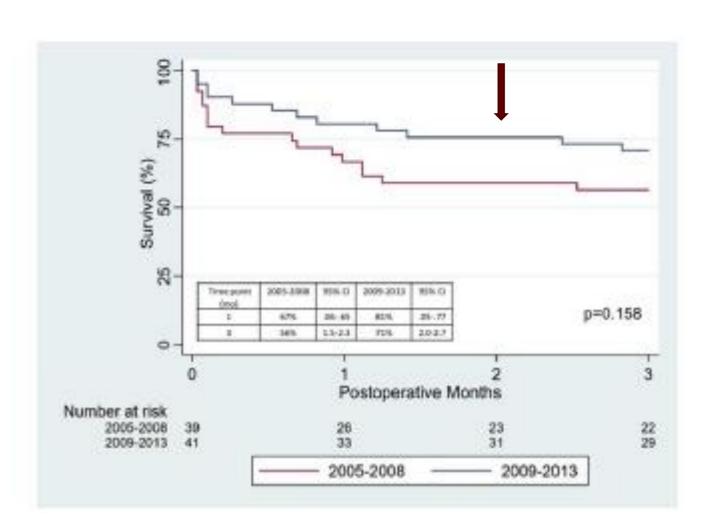
Centrimag Central cann.

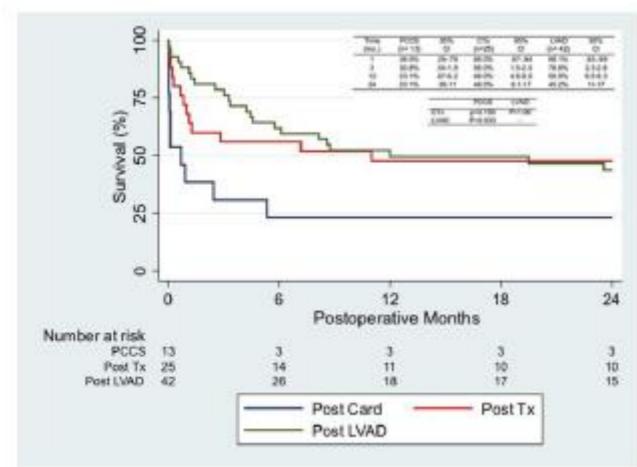
| Multivariate analysis |       |      |            |
|-----------------------|-------|------|------------|
| PCCS indication       | 0.161 | .007 | 0.043-0.60 |
| Female sex            | 0.313 | .056 | 0.095-1.03 |

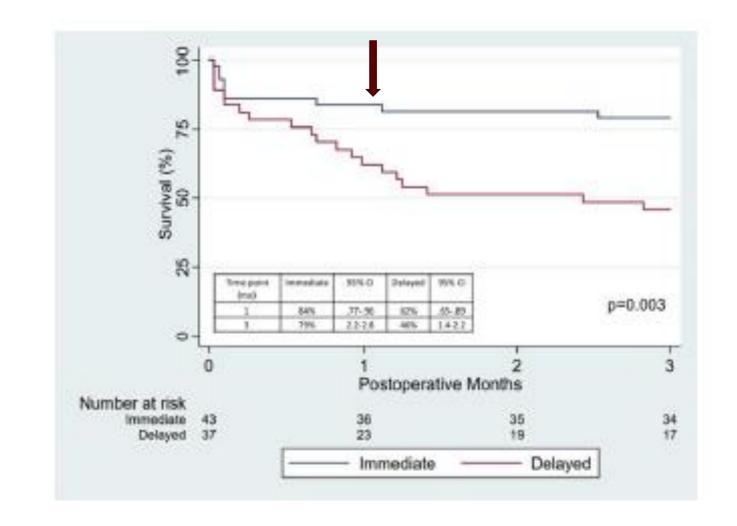
J.Thorac Cardiovasc Surg 2018;156:1885-91

# Clinical experience with temporary right ventricular mechanical circulatory support

Survival of Centrimag RVAD by Indication, Era and Timing of Implantation





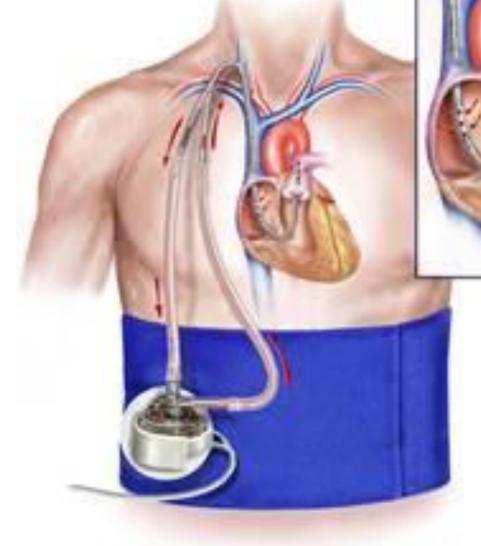


Conclusions: Temporary right ventricular mechanical support remains an effective treatment strategy after left ventricular assist device placement with immediate support resulting in superior short-term survival. Caution should be applied in postcardiotomy cardiogenic shock when weaning and survival are poor. Overall survival outcomes have remained relatively static over time.

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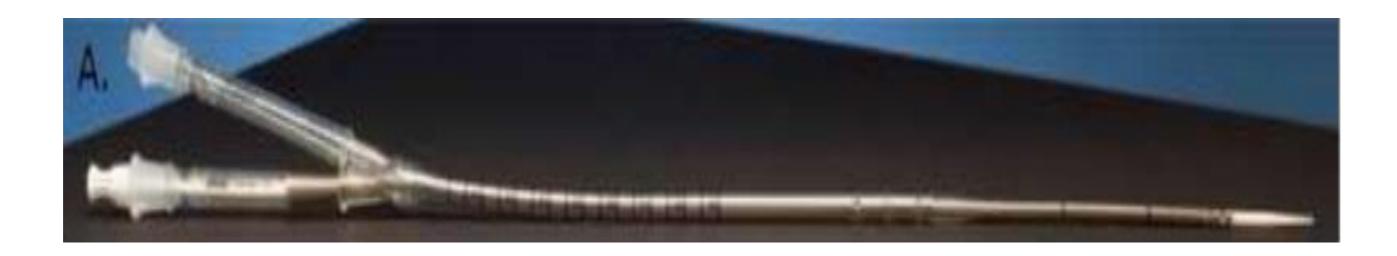
#### TandemHeart RVAD (TH pump and Dual Lumen Cannula)





Tandem Heart Pump

Placement under fluoroscopy using One flow directed PA catheter and COOK®.035 Lunderquist® guidewire used to advance the Cannula



PROTEK-DUO Cannula 29 and 31 FR

# Outcomes with the Tandem Protek Duo Dual-Lumen Percutaneous Right Ventricular Assist Device

Table 1. Demographics and Baseline Characteristics

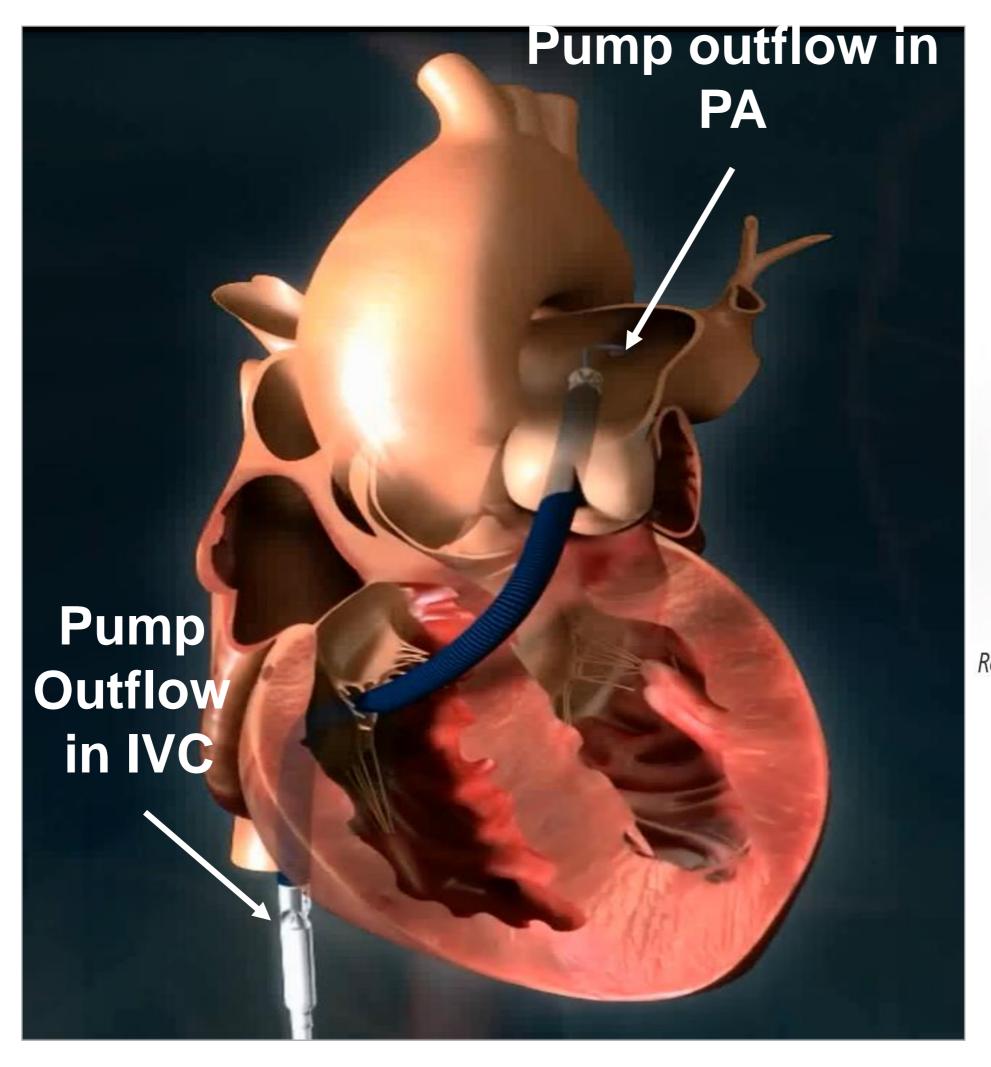
| Factor                   | Value ± SD      |
|--------------------------|-----------------|
| Age                      | 56.3±8          |
| Gender, male             | 13 pts (76%)    |
| Diabetes?                | 12 pts (71%)    |
| Smoker                   | 3 pts (18%)     |
| Ischemic etiology of CMP | 5 pts (29%)     |
| Hypertension             | 11 pts (65%)    |
| Serum sodium             | 133.9±3.7       |
| GFR                      | $60.8 \pm 37$   |
| Albumin                  | $2.4 \pm 0.4$   |
| ALT                      | $37.6 \pm 29.2$ |
| Total bilirubin          | $1.6 \pm 0.9$   |
| Wt (kg)                  | · 98.7±18.6     |
| LVEF                     | 17.5 ± 16.5     |
| RA pressure              | 21.6±6.9        |
| PA systolic              | $52 \pm 14.3$   |
| PA diastolic             | 27.8±7.1        |
| PA mean                  | $35.1 \pm 8.5$  |
| PCWP                     | $25.3 \pm 6.8$  |
| PA saturation            | $53.1 \pm 12.6$ |
| Cardiac output           | 4.8±1.3         |
| Cardiac index            | $2.2 \pm 0.7$   |
| Outcome weaned           | 4 (23%)         |
| Outcome: VAD             | 6 pts (35%)     |
| Outcome: Death           | 7 pts (41%)     |
| Days of TPD support      | 10.5±6.5        |

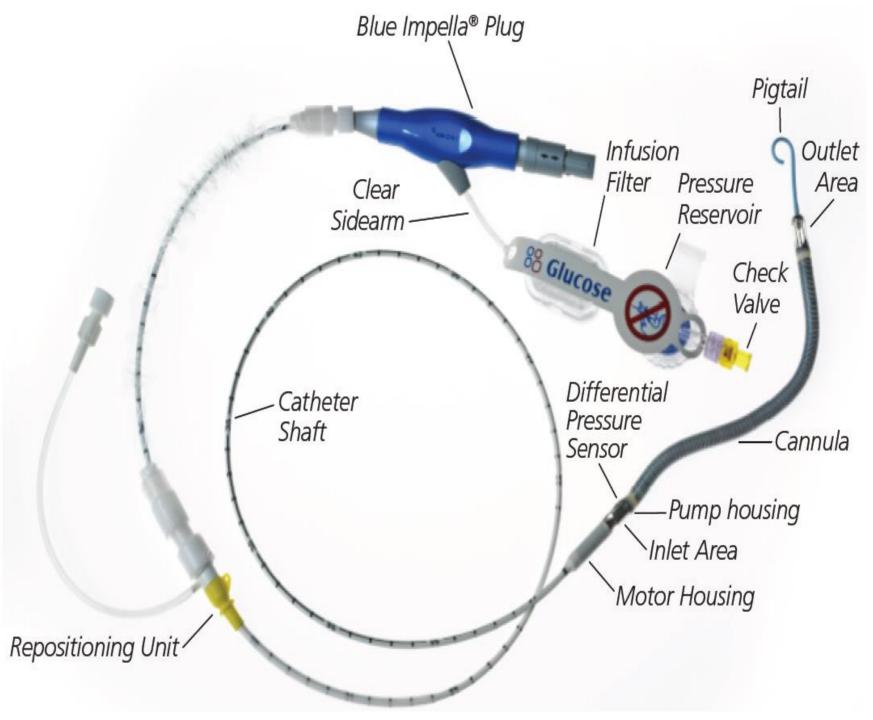
Two-center experience using the TPD in 17 patients with right ventricular(RV) failure (12 of whom were post-left ventricular assist device (LVAD) implantation)

Complications occurred in 6 (35%):

- 1 pt epistaxis and hematemesis.
- 1pt had injury to left internal jugular due to inability to advance the catheter past the RV due to tortuous anatomy.
- 2 intracranial bleeds
- 2 bleeding at the catheter insertion site after placement.

#### Impella RP: Percutaneous Device





- Axial Flow pump (22 Fr)
- Catheter based (11Fr)
- IVC implant .
- RPM up to 33000.

#### **RECOVER Trial: Patient Outcomes and Adverse Events**

#### **Primary End Points**

| Event                          | All patients<br>(N = 30)<br>% (No.) | Cohort A<br>(n = 18)<br>% (No.) | Cohort B<br>(n = 12)<br>% (No.) | <i>p</i> -value |
|--------------------------------|-------------------------------------|---------------------------------|---------------------------------|-----------------|
| Alive at                       |                                     |                                 |                                 |                 |
| 30 Days                        | 73.3 (22)                           | 83.3 (15)                       | 58.3 (7)                        | 0.129           |
| Discharge                      | 70.0 (21)                           | 77.8 (14)                       | 58.3 (7)                        | 0.255           |
| 30 days/discharge/next therapy | 73.3 (22)                           | 83.3 (15)                       | 58.3 (7)                        | 0.129           |
| 180 days                       | 70.0 (21)                           | 77.8 (14)                       | 58.3 (7)                        | 0.255           |

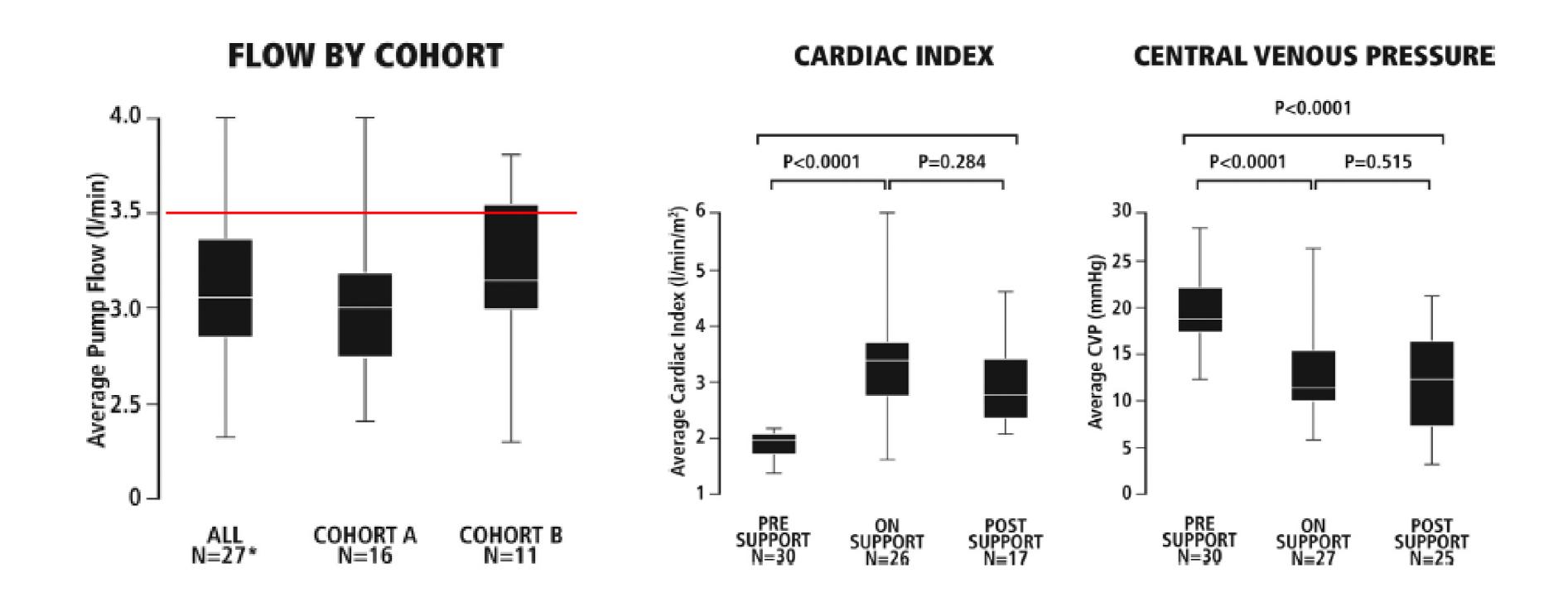
#### Secondary EndPoints

| Safety end points                                      | All patients<br>(N = 30)<br>% (No.) | Cohort A<br>(n = 18)<br>% (No.) | Cohort B<br>(n = 12)<br>% (No.) | <i>p-</i> value |
|--|-------------------------------------|---------------------------------|---------------------------------|-----------------|
| Death  | 26.7 (8)                            | 16.7 (3)                        | 41.7 (5)                        | 0.129           |
| Major bleeding   | 60.0 (18)                           | 55.6 (10)                       | 66.7 (8)                        | 0.543           |
| Device access site                                     | 3.3                                 | 0.0                             | 8.3                             |                 |
| Postoperative <sup>a</sup>                             | 36.7                                | 33.3                            | 41.7                            |                 |
| Transfusion with no overt bleeding                     | 16.7                                | 22.2                            | 8.3                             |                 |
| Other  | 3.3                                 | 0.0                             | 8.3                             |                 |
| Hemolysis  | 13.3 (4)                            | 16.7 (3)                        | 8.3 (1)                         | 0.511           |
| Pulmonary embolism                                     | 0.0 (0)                             | 0.0 (0)                         | 0.0 (0)                         |                 |
| Tricuspid and pulmonary valve dysfunction <sup>b</sup> | 3.3 (1)                             | 5.6 (1)                         | 0.0 (0)                         | 0.406           |

<sup>&</sup>lt;sup>a</sup>Chest or mediastinal re-exploration, tamponade, hemothorax.

<sup>b</sup>Increase in valve regurgitation by more than one grade on a 4-grade scale compared with baseline.

## Flows and Hemodynamics



## Summary

- ➤ The presence of acute severe RV failure is associated with increased risk of mortality and morbidity.
- Preoperative, intraoperative and postoperative management are key to prevent and avoid progression of RVF and may be critical to prevent poor outcomes.
- There is an increasing number of surgical and percutaneous RVAD options that seem to be efficacious and safe, but timing implantation seems to be a critical step to prevent progression to MOF.

# STS/EACTS Latin America Cardiovascular Surgery Conference

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### Post-Operative/ICU Management

- Bleeding
- Nitric Oxide
- Inotropes
- Maintain MAP
- Watch CVP/PA ratio go to RVAD early if any doubts
- Role of Pump Speed? Don't know, do not over pump