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OMICS Group has organized 500 conferences, workshops and national symposiums across the major cities including San Francisco, Las Vegas, San Antonio, Omaha, Orlando, Raleigh, Santa Clara, Chicago, Philadelphia, Baltimore, United Kingdom, Valencia, Dubai, Beijing, Hyderabad, Bengaluru and Mumbai.
A Prospective, Multicenter Study to Evaluate a New Percutaneous Ventricular Assist Device for Right Ventricular Failure:
The RECOVER RIGHT Study

Louis Samuels, MD
Surgical Director of Heart Failure
Lankenau Medical Center
Lankenau Heart Institute

On behalf of all RECOVER RIGHT Investigators
Background

• Right Ventricular Failure (RVF) refractory to medical treatment carries a high risk for mortality.

• Surgical right ventricular assist devices (RVAD) have been used as a last resort to save patient lives but mortality remains ~50%. In addition, these devices remain invasive, complex to use and therefore indicated for a limited population.

• The Impella RP is the first percutaneous, single vascular access pump designed for right heart support.

• RECOVER RIGHT* is an FDA approved, prospective, multicenter, single arm study that evaluates the safety and probable benefit of the Impella RP in patients with RVF refractory to medical treatment and deemed to require hemodynamic support.

*clinicaltrials.gov: NCT01777607
Impella RP: Percutaneous Right Ventricular Assist Device (RVAD)

- Transfemoral venous insertion
  - 3D shaped cannula
  - 22 Fr motor housing
  - Pump mounted on a 11Fr catheter
  - Flow: 4 L/min @ 33,000 rpm
  - Anticoagulation: ACT ~ 160-180 sec

Impella RP is an investigational device in the United States, not approved by the FDA. Impella RP is CE Marked in Europe.
Patients who develop RVF deemed to require hemodynamic support within 48 hours:

**Cohort A**
Post implantation of a durable LVAD

**Cohort B**
Post-cardiotomy or post myocardial infarction

RVF defined as CI < 2.2 l/min/m² (despite continuous infusion of ≥ 1 high dose inotropes (i.e Dopamine/Dobutamine ≥ 10µg/kg/min or equivalent) and any of the following:
  • CVP > 15 mmHg or CVP/PCWP or LAP ratio > 0.63 or,
  • RV dysfunction on echo (TAPSE score of ≤ 14 mm)

*HDE Study, Humanitarian Device Exemption*
Study Endpoints

**Primary Endpoint:**
Survival at 30 days or hospital discharge (whichever is longer) or to the next therapy (heart transplant, surgical RVAD)

**Secondary Endpoints:**

- Efficacy Endpoints:
  - Hemodynamic improvement (CVP and CI)
  - Decreased use of inotropes

- Safety Endpoints:
  - Death
  - Bleeding
  - Hemolysis
  - Pulmonary Embolism
  - Tricuspid and Pulmonary valve Dysfunction*

*increase valve regurgitation by more than one grade on a 4-grade scale compared to baseline
Trial Committees & Partners

**EXECUTIVE STEERING COMMITTEE**

- William O’Neill (Co-PI)
- Mark Anderson (Co-PI)
- James Goldstein (Exec. member)

**SPONSOR**

ABIOMED

**INVESTIGATOR SITES**

15

**INDEPENDENT SAFETY MEDICAL MONITOR**

Louis Samuels, MD

**INDEPENDENT CLINICAL EVENTS COMMITTEE & STAT ANALYSES**

- Donald Cutlip, MD
- Joseph Massaro, PhD (HCRI)

**ECHO CORELAB**

- Pamela Douglas, MD (DCRI)

**SITE and DATA MANAGEMENT (ABIOMED)**

**SPONSOR**

ABIOMED
Study Participating Centers

- Cedars Sinai
- Banner Good Sam
- Henry Ford Medical Center
- Mass General Hosp
- Tufts Medical Ctr
- Barnes Jewish Hosp
- Washington Univ.
- Integris Baptist
- UT Hermann
- Ochsner Health System
- Texas Heart Institute
- Detroit MC
- Albert Einstein
- UPMC
- Duke University
- Univ. of Alabama
- Birmingham
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- Albert Einstein
- UPMC
- Duke University
- Univ. of Alabama
- Birmingham
- UT Hermann
- Ochsner Health System
- Texas Heart Institute
Study Flow

Assessed For Eligibility
N=175

Not Eligible: N=145
- 53.8% No RV Failure
- 8.2% INTERMACS 1 or EOF
- 4.2% on another RVAD
- 2.8% DVT, IVC Filter
- 2.8% HIT/Thrombocytopenia
- 2.1% AMI with complications
- 26.6% Other exclusion criteria

Enrolled
N= 30

Cohort A
N=18
RVF Post implantation of a durable LVAD

Cohort B
N=12
- 5 RVF post AMI-CS
- 5 RVF post heart transplant
- 2 RVF post valve surgery
## Baseline Patient Characteristics

<table>
<thead>
<tr>
<th></th>
<th>All (N=30)</th>
<th>Cohort A (N=18)</th>
<th>Cohort B (N=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>59±15</td>
<td>56±14</td>
<td>64±16</td>
</tr>
<tr>
<td><strong>Gender-Male</strong></td>
<td>76.7%</td>
<td>83.3%</td>
<td>66.7%</td>
</tr>
<tr>
<td><strong>History of CHF</strong></td>
<td>88.5%</td>
<td>100.0%</td>
<td>62.5%</td>
</tr>
<tr>
<td><strong>Current NYHA (Class IV)</strong></td>
<td>78.6%</td>
<td>77.8%</td>
<td>80%</td>
</tr>
<tr>
<td><strong>Diabetes Mellitus</strong></td>
<td>53.3%</td>
<td>61.1%</td>
<td>41.7%</td>
</tr>
<tr>
<td><strong>Chronic Kidney Disease</strong></td>
<td>37.5%</td>
<td>37.5%</td>
<td>37.5%</td>
</tr>
<tr>
<td><strong>History of CVA</strong></td>
<td>20.0%</td>
<td>6.3%</td>
<td>44.4%</td>
</tr>
<tr>
<td><strong>LVEF %</strong></td>
<td>23±17</td>
<td>14±7</td>
<td>40±17</td>
</tr>
<tr>
<td><strong>TAPSE (mm)</strong></td>
<td>8.9±4.7</td>
<td>8.1±4.2</td>
<td>10.3±5.5</td>
</tr>
<tr>
<td><strong>Successful Impella RP</strong></td>
<td>96.7%</td>
<td>94.4%</td>
<td>100.0%</td>
</tr>
<tr>
<td><strong>Implantation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Impella RP Pump Flow Performance

Duration of Support: 3.04±1.5 days [0.5, 7.8 days]

Flow as a Function of Performance Settings

Flow by Cohort

- 3 patients did not have device flow data (1 failed implant, 2 patients with no pump flow data recorded)
Hemodynamic Improvement Was Reproducible in Most Patients*

* N=25, 5 patients did not have paired hemodynamic data recorded)
Sustained Hemodynamic Improvement After Impella RP Removal

Cardiac Index

- Pre Support: N=30
- On Support: N=26
- Post Support: N=17

Average Cardiac Index (l/min/m²)

- Pre Support: 2
- On Support: 3
- Post Support: 5

P<0.0001 P=0.284

Central Venous Pressure

- Pre Support: N=30
- On Support: N=27
- Post Support: N=25

Average CVP (mmHg)

- Pre Support: 10
- On Support: 15
- Post Support: 20

P<0.0001 P=0.515
Primary Endpoint
Survival to 30 Day, Discharge or Next Therapy
(N=30)

Benchmark Reference:
Survival Rates observed in the Surgical HDE approved RVAD device

*http://www.accessdata.fda.gov/cdrh_docs/pdf7/H070004b.pdf
### Secondary Safety Endpoint:
**Major Adverse Events at 30 day or Discharge** (whichever is longer)

<table>
<thead>
<tr>
<th></th>
<th>All (N=30)</th>
<th>Cohort A (N=18)</th>
<th>Cohort B (N=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Death</strong></td>
<td>26.7%</td>
<td>16.7%</td>
<td>41.7%</td>
</tr>
<tr>
<td><strong>Pulmonary Embolism</strong></td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td><strong>Hemolysis</strong></td>
<td>13.3%</td>
<td>16.7%</td>
<td>8.3%</td>
</tr>
<tr>
<td><strong>Tricuspid and Pulmonary Valve Dysfunction</strong></td>
<td>3.3%</td>
<td>5.6%</td>
<td>0.0%</td>
</tr>
<tr>
<td><strong>Bleeding (Transfusion or re-intervention)</strong></td>
<td>60.0%</td>
<td>55.6%</td>
<td>66.7%</td>
</tr>
<tr>
<td>. Device access site bleeding</td>
<td>3.3%</td>
<td>0.0%</td>
<td>8.3%*</td>
</tr>
<tr>
<td>. Postoperative bleeding (chest or mediastinal re-exploration, tamponade, hemothorax)</td>
<td>36.7%</td>
<td>33.3%</td>
<td>41.7%</td>
</tr>
<tr>
<td>. Transfusion with no overt bleeding</td>
<td>16.7%</td>
<td>22.2%</td>
<td>8.3%</td>
</tr>
<tr>
<td>. Other</td>
<td>3.3%</td>
<td>0.0%</td>
<td>8.3%</td>
</tr>
</tbody>
</table>

*1 patient had bleeding after sheath positioning;  
**Based on echocardiographic core lab analysis
## Benchmark Adverse Events @ 30days

<table>
<thead>
<tr>
<th>Event</th>
<th>Impella RP (N=30)</th>
<th>HDE RVAD Device* (N=32)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>26.7%</td>
<td>53.0%</td>
</tr>
<tr>
<td>Bleeding (Transfusion or re-intervention)</td>
<td>60.0%</td>
<td>84.4%</td>
</tr>
<tr>
<td>Hemolysis</td>
<td>13.3%</td>
<td>15.6%</td>
</tr>
<tr>
<td>Neurologic dysfunction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>3.3%</td>
<td>25.0%</td>
</tr>
<tr>
<td>Metabolic encephalopathy</td>
<td>0.0%</td>
<td>6.2%</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Limb ischemia</td>
<td>3.3%</td>
<td>6.2%</td>
</tr>
</tbody>
</table>

*Adverse events data available only for the entire cohort of the HDE RVAD device (N=32). Of those, N=24 were RVAD.*
Secondary Effectiveness Endpoint:
Decrease in Use of Inotropes and Pressors After Impella RP Support
Conclusions

- RECOVER RIGHT is the first percutaneous RVAD FDA study. The use of Impella RP device was:
  - Reliably deliverable and safe
  - Improved the hemodynamics
  - Led to favorable outcomes

- The Impella RP may play a pivotal role in the treatment of RVF.
THANK YOU
Major Exclusion Criteria

**Cohort A**
- INTERMACS 1 patients
- Severe end organ failure
- Neurological injury post LVAD implant

**Cohort B**
- Profound cardiogenic shock (SBP< 75mmHg, CI<1.3 l/min/m² despite ≥2 inotropes±mechanical support or PH<7.1)
- AMI with mechanical complications
- Unsuccessful RCA revascularization

**Both Cohorts**
- Presence of RA, RV or PA thrombus
- Prosthetic valves in the right heart (tricuspid or pulmonary valves)
- Severe pulmonary valve stenosis or insufficiency
- Severe pulmonary hypertension (PAP>60mmHg)
- Documented DVT and/or presence of IVC filter
Benchmark of the Primary Endpoint
To The HDE Approved Surgical RVAD

RECOVER RIGHT (Impella RP)
HDE Approved Surgical RVAD

All Patients
- 30% 50% 70% 89%
  N=30
- 58% 73% 89%
  N=24

Cohort A
- 31% 60% 89%
  N=18
- 60% 83% 94%
  N=10

Cohort B
- 21% 42% 67%
  N=12
- 58% 80%
  N=14
Thanks' for your kind attention!
Let Us Meet Again

We welcome you all to our future conferences of OMICS International

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