Society of Thoracic Surgeons

Intermacs & Pedimacs User Group Webinar

August 30, 2023
User Group Webinar

- Welcome and Introductions
- STS Updates
- AQO 2023
- Dr. Kiernan
- User Feedback
The Intermacs Data Warehouse Team

Rama Rudraraju, PhD, Director of Programming, Intermacs Data Warehouse

Maceo Cleggett, Clinical Data Analyst, Intermacs Data Warehouse

Jeanne Anne Love, Patient Management Director, Intermacs Data Warehouse

John Pennington, MSHI, Senior Data Manager, Intermacs Data Warehouse

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Database Operational Questions
• intermacsfaq@sts.org
2023 Advances in Quality & Outcomes: A Data Managers Meeting

Discussions on valuable research and important clinical findings with the goal of improving data collection and patient outcomes.

📅 Sep 26—29, 2023
📍 Virtual
AQO Registration Is Open!

<table>
<thead>
<tr>
<th>Registration Type</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>One Day: STS Member</td>
<td>$200</td>
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<tr>
<td>One Day: Non-Member</td>
<td>$250</td>
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<tr>
<td>Multi-day: STS Member</td>
<td>$300</td>
</tr>
<tr>
<td>Multi-day: Non-Member</td>
<td>$400</td>
</tr>
<tr>
<td>Multi-day: STS Industry/vendor</td>
<td>$500</td>
</tr>
</tbody>
</table>
Upcoming Intermacs Webinars

Intermacs User Group Webinar

• October 25th @ 1 pm CT
Intermacs Database

Intermacs Webinars

Intermacs User Group Call
August 30 at 2 p.m. ET • 1 p.m. CT
Call In: 888-475-4499 or 877-853-5257 or 312-626-6799
Meeting ID: 557 707 151
International Dial-in Numbers

Join Webinar

Most Recent Intermacs Webinar
View Webinar Recording
View Slides - Intermacs/Pedimacs Quality Assurance Report Overview Quarterly Webinar - April 20, 2023

View Past Intermacs Webinars
PreImplant form

ECMO: Present at the time of durable MCS device implant

- Yes
- No
- Unknown

Total Number of days on ECMO

ST: Unknown
### Implant form

**Concomitant surgery**
- None
- ASD closure
- PFO closure
- CABG
- VSD closure
- Congenital cardiac surgery, other
- Aortic Valve Procedure
  - Aortic Valve Surgery - Replacement - Biological
  - Aortic Valve Surgery - Replacement - Mechanical
- Mitral Valve Surgery - Repair
- Mitral Valve Surgery - Replacement - Biological
- Mitral Valve Surgery - Replacement - Mechanical
- Tricuspid Valve Surgery - Repair - De/Vega
- Tricuspid Valve Surgery - Repair - Ring
- Tricuspid Valve Surgery - Repair - Other
- Tricuspid Valve Surgery - Replacement - Biological
- Tricuspid Valve Surgery - Replacement - Mechanical
- Tricuspid Valve Surgery - Excision
- Pulmonary Valve Surgery - Repair
- Pulmonary Valve Surgery - Replacement - Biological
- Pulmonary Valve Surgery - Replacement - Mechanical
- Left ventricular aneurysmectomy
- Other, specify
- Arrhythmia surgery (ablation)
- Ligation of left atrial appendage
- Temporary MCS Removal (ECMO, IABP removal documented here)

---

**Extracorporeal Membrane Oxygenation (ECMO Insertion)**

**Total Number of days the patient was on ECMO: 0**

**ST: Unknown**

[sts.org](http://sts.org)
## Explant form

**Yes**  ○ Unknown

<table>
<thead>
<tr>
<th>Was the patient on ECMO at any time since implant of their durable LVAD?</th>
</tr>
</thead>
<tbody>
<tr>
<td>○ Yes</td>
</tr>
<tr>
<td>○ No</td>
</tr>
<tr>
<td>○ Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total number of days on ECMO</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ST= ○ Unknown
Death form

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was the patient on ECMO at any time since implant of their durable LVAD?</td>
<td>Yes, No, Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question</th>
<th>Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of days on ECMO</td>
<td>Unknown</td>
</tr>
</tbody>
</table>

| ST= Unknown
Implant Discharge form

Was ECMO initiated at any time after VAD implant?
- Yes
- No
- Unknown

Total Number of days on ECMO?

ST= Unknown
Open Discussion

Please use the Q&A Function.

We will answer as many questions as possible.

We encourage your feedback and want to hear from you!
THANK YOU FOR JOINING!
STS-Intermacs & Pedimacs User’s Webinar

Early Acute Right Heart Failure: RVAD use in LVAD Recipients

Michael Kiernan, MD, MS, MBA
Associate Professor of Medicine, TUSM
Associate Chief, Division of Cardiology, Tufts Medical Center
Objectives

• Define the incidence of right heart failure
• Differentiate types of right ventricular assist devices
• Describe outcomes following RVAD implant
Improving AE Profile with Current Technologies: Adverse events by device type

- GIB
- CVA
- Infxn
- RHF

Incidence of early RHF

<table>
<thead>
<tr>
<th>Early RHF Incidence (%)</th>
<th>HM II 2007</th>
<th>HVAD ADVANCE 2012</th>
<th>HVAD ENDURANCE 2017</th>
<th>HM II 2018</th>
<th>HM 3 MOMENTUM 3 2018</th>
<th>HM II 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>20</td>
<td>19.3</td>
<td>38.5</td>
<td>26.8</td>
<td>31.7</td>
<td>27.9</td>
</tr>
</tbody>
</table>
Functional capacity after LVAD implantation: 20% with persistent NYHA III/VI symptoms

Proportion of Patients who are NYHA I or II over Time

Mehra. NEJM 2018;378:1386
The Vexing Problem of Right Heart Failure

• Given known worse survival of BiVAD recipients, there is *generally* a preference to avoid RVAD unless it is clearly necessary – *inexact science*

• Ability to identify right heart failure (RHF) prior to or during LVAD implant that is severe enough to warrant an RVAD is *imprecise*

• Many patients with marginal RV function are deemed days to weeks after initial LVAD to warrant 2nd procedure – sequential RVAD

• Decision-making further complicated by choice of temporary or durable (*off-label*) RVAD, depending on expected duration of support

• *No commercially available FDA approved DURABLE RVADs!*
Prediction: is really difficult!!

ROCs for RHF Models

AUC of 0.5 suggests no discrimination (test not helpful)
0.7 to 0.8 considered acceptable
0.8 to 0.9 considered excellent
> 0.9 considered outstanding.

Kalogeropoulos JHLT 2015;34(12):1595

- All Patients (N=11,162)
  - Primary CF-LVAD (N=9976)
    - Any RVAD (5.2%) (N=521)
      - Early RVAD (≤ 14 d) (3.9%) (N=386)
      - No RVAD (94.8%) (N=9455)
  - No RVAD (94.8%) (N=9455)

Kiernan ISHLT 2017
Kiernan Circ Heart Fail 2017;10
Survival for CF-LVAD recipients with and without early RVAD

<table>
<thead>
<tr>
<th>Hazard Ratio (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adjusted 2.76 (2.34, 3.24)</td>
<td>&lt;.0001</td>
</tr>
</tbody>
</table>

Product Limit Survival Estimates
With Number of Subjects at Risk

Kiernan Circ Heart Fail 2017;10
Patient characteristics by prediction of risk

<table>
<thead>
<tr>
<th></th>
<th>Estimated probability of RVAD within 14 days of CF-LVAD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;1%</td>
</tr>
<tr>
<td>TOTAL N</td>
<td>1359</td>
</tr>
<tr>
<td>Creatinine (mg/dL)</td>
<td>Median</td>
</tr>
<tr>
<td>Total Bili (mg/dL)</td>
<td>Median</td>
</tr>
<tr>
<td>INR</td>
<td>Median</td>
</tr>
<tr>
<td>WBC (x10^3/µL)</td>
<td>Median</td>
</tr>
<tr>
<td>RAP</td>
<td>Median</td>
</tr>
<tr>
<td>PA pulse pressure</td>
<td>Median</td>
</tr>
<tr>
<td>Stroke volume (x100)</td>
<td>Median</td>
</tr>
<tr>
<td>LVEDD</td>
<td>Median</td>
</tr>
</tbody>
</table>
Receiver operating characteristic for early RVAD INTERMACS model

AUC = 0.78

(A) Sens=22%, Spec=97%, ppv=25%, npv=97%

(B) Sens=34%, Spec=94%, ppv=19%, npv=97%

(C) Sens=61%, Spec=81%, ppv=12%, npv=98%

(D) Sens=87%, Spec=46%, ppv=6%, npv=99%
Survival following LVAD and BIVAD implantation

Figure 7   Actuarial survival curve for continuous-flow LVAD and BiVAD patients, stratified by pump type. The depiction is as shown in Figure 6.
Temporary mechanical circulatory support device options for acute right ventricular support

Durable mechanical circulatory support device options for acute right ventricular support

Figure 1  Chest X-ray of a patient displaying both VADs.
Other durable mechanical circulatory support devices for right ventricular support

<table>
<thead>
<tr>
<th>Device Type</th>
<th>2021 Q4</th>
<th>2022 Q1</th>
<th>2022 Q2</th>
<th>2022 Q3</th>
<th>2022 Q4</th>
<th>2023 Q1</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>n</td>
<td>n</td>
<td>n</td>
<td>n</td>
<td>n</td>
<td>n</td>
</tr>
<tr>
<td>LVAD</td>
<td>618</td>
<td>92.1 %</td>
<td>657</td>
<td>91.8 %</td>
<td>658</td>
<td>92.1 %</td>
<td>536</td>
</tr>
<tr>
<td>BiVAD</td>
<td>50</td>
<td>7.4 %</td>
<td>55</td>
<td>7.6 %</td>
<td>54</td>
<td>7.5 %</td>
<td>48</td>
</tr>
<tr>
<td>TAH</td>
<td>3</td>
<td>0.4 %</td>
<td>3</td>
<td>0.4 %</td>
<td>2</td>
<td>0.2 %</td>
<td>1</td>
</tr>
<tr>
<td>TOTAL</td>
<td>671</td>
<td>100.0 %</td>
<td>715</td>
<td>100.0 %</td>
<td>714</td>
<td>100.0 %</td>
<td>685</td>
</tr>
</tbody>
</table>
Updated Analysis of RVAD Use and Outcomes from INTERMACS: Focus on Timing and Device Type

**Sequential** = separate surgical encounter
**Concurrent** = same surgical encounter

LVAD or BiVAD Patients
Implant Dates: 1/1/2010-12/31/2020
N=29,384

- Concurrent BiVAD
  - N=1,090
  - LVAD + tRVAD
    - N=997
  - LVAD + dRVAD
    - N=93
  - 68%

- Sequential RVAD
  - N=566
  - LVAD + Sequential tRVAD
    - N=523
  - LVAD + Sequential dRVAD
    - N=43
  - 32%

- LVAD Only
  - N=27,325
  - 5.6%

Risk of death over time by cause

- Continuous Flow LVAD/BiVAD Implants: 2008 – 2013, n = 9372

Causes of Death:
- Infection
- Bleeding
- RHF
- Neurological
- Device Malfunction
- MSOF

Kirklin. JHLT 2014;33:555-564.
Prevalence of RVAD use over time

RVAD Support in Patients' First INTERMACS Device by Year (RVADs Include both Isolated and Biventricular Support)

<table>
<thead>
<tr>
<th>Implant Year</th>
<th>RVAD Type 0</th>
<th>RVAD Type 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>64</td>
<td>34</td>
</tr>
<tr>
<td>2011</td>
<td>69</td>
<td>64</td>
</tr>
<tr>
<td>2012</td>
<td>62</td>
<td>36</td>
</tr>
<tr>
<td>2013</td>
<td>94</td>
<td>35</td>
</tr>
<tr>
<td>2014</td>
<td>107</td>
<td>42</td>
</tr>
<tr>
<td>2015</td>
<td>116</td>
<td>33</td>
</tr>
<tr>
<td>2016</td>
<td>95</td>
<td>21</td>
</tr>
<tr>
<td>2017</td>
<td>120</td>
<td>11</td>
</tr>
<tr>
<td>2018</td>
<td>125</td>
<td>14</td>
</tr>
<tr>
<td>2019</td>
<td>142</td>
<td>10</td>
</tr>
<tr>
<td>2020</td>
<td>136</td>
<td>13</td>
</tr>
<tr>
<td>2021</td>
<td>197</td>
<td>13</td>
</tr>
<tr>
<td>2022</td>
<td>199</td>
<td>10</td>
</tr>
</tbody>
</table>

Frequency Count
Worse Survival following BiVAD vs LVAD alone

HR = 3.95 (3.66-4.26)

Missing: Comparison of survival by era

Survival following *Concurrent* BiVAD: Temporary vs Durable
(Device Type: No survival difference)

Kaplan-Meier Survival for Concurrent BiVADs Temporary vs Durable
Intermacs: 1/1/2010 - 12/31/2020

HR = 1.28 (0.9-1.81)

Shaded areas indicate 70% confidence limits
p (log-rank) = 0.1700
Event: Death (censored at transplant or cessation of support)

No statistical adjustment made for differing patient characteristics

Survival \textbf{Sequential BiVADs: Temporary vs Durable}  
(Device Type: No survival difference)

Missing: Time to RVAD implant (hours, days, weeks?)

\begin{figure}
\centering
\includegraphics[width=\textwidth]{SurvivalGraph.png}
\caption{Kaplan-Meier Survival for Sequential BiVADs (≤27 Days) Temporary vs Durable \protect\cite{Ahmed2023}.}
\end{figure}

\begin{table}
\centering
\begin{tabular}{|c|c|c|}
\hline
Months after Device Implant & Sequential tempRVAD & Sequential durRVAD \\
\hline
0 & 100.0\% (100.0\%-100.0\%) & 100.0\% (100.0\%-100.0\%) \\
3 & 53.6\% (51.4\%-55.8\%) & 48.8\% (41.0\%-56.2\%) \\
6 & 48.0\% (45.8\%-50.2\%) & 38.0\% (30.4\%-45.5\%) \\
9 & 44.2\% (42.0\%-46.4\%) & 38.0\% (30.4\%-45.5\%) \\
12 & 42.6\% (40.3\%-44.7\%) & 33.2\% (25.4\%-41.3\%) \\
\hline
\end{tabular}
\end{table}

Shaded areas indicate 70\% confidence limits  
\( p \) (log-rank) = 0.3787  
Event: Death (censored at transplant or cessation of support)
Survival Durable BiVADs: Concurrent vs Sequential
(Device Timing: lower survival with delayed implant)

Kaplan-Meier Survival for Durable Concurrent vs Sequential BiVADS
Intermacs: 1/1/2018-12/31/2020

HR=2.49 (1.5-4.14)

Months after Device Implant | Concurrent Durable BiVAD | Sequential Durable BiVAD
---|---|---
0 | 100.0% (100.0%-100.0%) | 100.0% (100.0%-100.0%)
3 | 79.4% (74.8%-83.3%) | 48.8% (41.0%-56.2%)
5 | 73.3% (68.2%-77.7%) | 38.0% (30.4%-45.5%)
9 | 60.5% (54.8%-65.8%) | 38.0% (30.4%-45.5%)
12 | 68.9% (63.1%-74.2%) | 33.2% (25.4%-41.3%)

Shaded areas indicate 70% confidence limits
p (log-rank) = 0.0003
Event: Death (censored at transplant or cessation of support)

Survival Temporary BiVADs: Concurrent vs Sequential
(Device Timing: lower survival with delayed implant)

Outcomes in \textit{temporary} RVAD recipients

LVAD + tempRVAD
\textit{N}=997

- Explanted RVAD to LVAD Only
  - \textit{N}=421 (42.2\%)

- Exchange tempRVAD to durRVAD
  - \textit{N}=18 (1.8\%)

- Cessation of Support
  - \textit{N}=4 (0.4\%)

- Died
  - \textit{N}=303 (30.4\%)

- Alive on Device
  - \textit{N}=64 (6.4\%)

- Transplanted
  - \textit{N}=206 (20.7\%)

- Died
  - \textit{N}=238 (56\%)

- Alive on Device
  - \textit{N}=204

Survival BiVADs: Concurrent vs Sequential
Adjusted for baseline characteristics (Propensity Matched)

Kaplan-Meier Survival for Concurrent BiVADs vs Sequential RVAD (<=27 Days) (Matched 1:1)
Intermacs: 1/1/2010-12/31/2020

HR = 1.59 (1.34-1.87)

<table>
<thead>
<tr>
<th>Months after Device Implant</th>
<th>Concurrent BiVADs</th>
<th>Sequential RVAD (&lt;=27 Days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>100.0% (100.0%-100.0%)</td>
<td>100.0% (100.0%-100.0%)</td>
</tr>
<tr>
<td>3</td>
<td>57.8% (55.8%-59.7%)</td>
<td>53.2% (51.0%-55.3%)</td>
</tr>
<tr>
<td>6</td>
<td>52.9% (50.8%-54.9%)</td>
<td>47.2% (45.0%-49.3%)</td>
</tr>
<tr>
<td>9</td>
<td>56.6% (56.6%-60.7%)</td>
<td>43.6% (41.5%-45.7%)</td>
</tr>
<tr>
<td>12</td>
<td>56.8% (53.6%-57.9%)</td>
<td>41.8% (39.7%-43.9%)</td>
</tr>
</tbody>
</table>

Shaded areas indicate 70% confidence limits
p (log-rank) = < 0.001
Event Death (censored at transplant or cessation of support)

Missing: timing of subsequent operation

## Concurrent vs Sequential: 3m Adverse Events
Temporary RVADs

### TABLE 3  Adverse Event Profile: Concurrent vs Sequential Biventricular Assist Devices With the Use of Temporary Right Ventricular Assist Device

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Concurrent BiVAD with Temporary RVAD (n = 997)</th>
<th>Sequential BiVAD with Temporary RVAD (n = 523)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Episodes, n (%)</td>
<td>Rate (per 100 patient-months)</td>
</tr>
<tr>
<td>Early (≤3 months)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bleeding</td>
<td>956 (51.5)</td>
<td>42.2</td>
</tr>
<tr>
<td>Device malfunction/pump thrombosis</td>
<td>91 (3.2)</td>
<td>4.02</td>
</tr>
<tr>
<td>Infection</td>
<td>691 (42.6)</td>
<td>30.51</td>
</tr>
<tr>
<td>Neurologic dysfunction</td>
<td>171 (14.7)</td>
<td>7.55</td>
</tr>
<tr>
<td>Renal dysfunction</td>
<td>284 (26.3)</td>
<td>12.54</td>
</tr>
</tbody>
</table>
Concurrent vs Sequential 3m Adverse Events: Durable RVADs

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>Concurrent BiVAD With Durable RVAD (n = 93)</th>
<th>Sequential BiVAD With Durable RVAD (n = 43)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Episodes, n (%)</td>
<td>Rate (per 100 patient-months)</td>
<td>Episodes, n (%)</td>
</tr>
<tr>
<td>Early (≤3 months)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bleeding</td>
<td>54 (36.6)</td>
<td>22.59</td>
<td>44 (65.1)</td>
</tr>
<tr>
<td>Device malfunction/pump thrombosis</td>
<td>26 (22.6)</td>
<td>10.88</td>
<td>10 (20.9)</td>
</tr>
<tr>
<td>Infection</td>
<td>60 (43.0)</td>
<td>25.10</td>
<td>41 (58.1)</td>
</tr>
<tr>
<td>Neurologic dysfunction</td>
<td>21 (20.4)</td>
<td>8.79</td>
<td>14 (23.3)</td>
</tr>
<tr>
<td>Renal dysfunction</td>
<td>16 (17.2)</td>
<td>6.69</td>
<td>25 (51.2)</td>
</tr>
</tbody>
</table>
Conclusions

• Incidence of RVAD use: 5.6% - stable over time
• Majority (68%) are concurrent with index surgery
• Majority (91%) temporary
• Mortality high in RVAD recipients (6m month survival 63%) – 60% more likely to die than those with isolated LVAD within a year
• AE (bleeding, cva, infection, renal failure) more common in RVAD recipients
Questions?

Michael Kiernan, MD, MS, MBA
Associate Professor of Medicine, TUSM
Associate Chief, Division of Cardiology, Tufts Medical Center