Chronic Drive Line Infections: More than a Pain in the Side

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Disclosures

• Co-PI, MOMENTUM 3 Trial, Abbott Laboratories
Chronic Drive Line Infections - Case

• 65 year old male who underwent an uncomplicated LVAD Implantation

• 3 Months Post Surgery

• “Getting out of the car – I dropped my controller”

• 5 days after dropping the controller, he notices pain, a new discharge at the exit site, and presents to the VAD Clinic for evaluation
Question

• This patient has a drive line infection
  • A.) TRUE
  • B.) FALSE
Major Infection
A clinical infection accompanied by pain, fever, drainage and/or leukocytosis that is treated by anti-microbial agents (non-prophylactic). A positive culture from the infected site or organ should be present unless strong clinical evidence indicates the need for treatment despite negative cultures. The general categories of infection are listed below:

Localized Non-Device Infection
Infection localized to any organ system or region (e.g. mediastinitis) without evidence of systemic involvement (See sepsis definition), ascertained by standard clinical methods and either associated with evidence of bacterial, viral, fungal or protozoal infection, and/or requiring empirical treatment.

Percutaneous Site and/or Pocket Infection
A positive culture from the skin and/or tissue surrounding the drive line or from the tissue surrounding the external housing of a pump implanted within the body, coupled with the need to treat with antimicrobial therapy when there is clinical evidence of infection such as pain, fever, drainage, or leukocytosis.

Internal Pump Component, Inflow or Outflow Tract Infection
Infection of blood-contacting surfaces of the LVAD documented by positive site culture. (There should be a separate data field for paracorporeal pump that describes infection at the percutaneous cannula site, e.g. Thoratec PVAD).

Sepsis
Evidence of systemic involvement by infection, manifested by positive blood cultures and/or hypotension.
What Next?

• Site is cultured and appropriate antimicrobial therapy is initiated
• Patient will likely now live with this problem for the remainder of time on this device
Options for Treatment

• Chronic Suppressive Antibiotic Therapy
• Surgical Debridement
• VAD Exchange
• Transplantation with LVAD Removal
• Recovery with Removal of Driveline
### Historical Perspective

<table>
<thead>
<tr>
<th></th>
<th>CF LVAD (n=133)</th>
<th></th>
<th>PF LVAD (n=59)</th>
<th></th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[211 pt-years]</td>
<td>[211 pt-years]</td>
<td>[41 pt-years]</td>
<td>[41 pt-years]</td>
<td>[95% CI]</td>
</tr>
<tr>
<td># Pts (%)</td>
<td>12 (9%)</td>
<td>13 (9%)</td>
<td>20 (34%)</td>
<td>21 (34%)</td>
<td>0.12 [0.06-0.26]***</td>
</tr>
<tr>
<td># Events</td>
<td>13</td>
<td>13</td>
<td>21</td>
<td>21</td>
<td>0.12 [0.06-0.26]***</td>
</tr>
<tr>
<td>Events/pt yr</td>
<td>0.06</td>
<td>0.06</td>
<td>0.51</td>
<td>0.51</td>
<td>0.51 [0.47-1.03]</td>
</tr>
<tr>
<td>Pump Replacements</td>
<td>118 (89%)</td>
<td>398 (89%)</td>
<td>51 (86%)</td>
<td>113 (86%)</td>
<td>0.69 [0.47-1.03]</td>
</tr>
<tr>
<td>Bleeding</td>
<td>108 (81%)</td>
<td>349 (81%)</td>
<td>45 (76%)</td>
<td>101 (76%)</td>
<td>0.68 [0.46-1.02]</td>
</tr>
<tr>
<td>Bleeding requiring PRBC¹</td>
<td>40 (30%)</td>
<td>49 (30%)</td>
<td>9 (15%)</td>
<td>12 (15%)</td>
<td>0.80 [0.39-1.64]</td>
</tr>
<tr>
<td>Ischemic</td>
<td>24 (18%)</td>
<td>27 (18%)</td>
<td>8 (14%)</td>
<td>9 (14%)</td>
<td>0.59 [0.26-1.35]</td>
</tr>
<tr>
<td>Hemorrhagic</td>
<td>22 (17%)</td>
<td>25 (17%)</td>
<td>5 (8%)</td>
<td>6 (8%)</td>
<td>0.59 [0.20-1.71]</td>
</tr>
<tr>
<td>Other Neurological²</td>
<td>29 (22%)</td>
<td>35 (22%)</td>
<td>10 (17%)</td>
<td>12 (17%)</td>
<td>0.57 [0.28-1.20]</td>
</tr>
<tr>
<td>Local Infection</td>
<td>65 (49%)</td>
<td>160 (49%)</td>
<td>27 (46%)</td>
<td>55 (46%)</td>
<td>0.57 [0.36-0.90]**</td>
</tr>
<tr>
<td>Percutaneous Lead Infection</td>
<td>42 (32%)</td>
<td>80 (32%)</td>
<td>16 (27%)</td>
<td>25 (27%)</td>
<td>0.63 [0.36-1.10]</td>
</tr>
</tbody>
</table>

HVAD

- Driveline Exit Site Infections (16.9% of patients) with 0.25 Event/per patient Year

Contemporary Scope of the Problem


<table>
<thead>
<tr>
<th>Event</th>
<th>Centrifugal-Flow Pump (N=515)</th>
<th>Axial-Flow Pump (N=505)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of patients (%)</td>
<td>EPPY (95% CI)</td>
</tr>
<tr>
<td>Major infection</td>
<td>300 (58.3)</td>
<td>0.82 (0.76 - 0.89)</td>
</tr>
<tr>
<td>Any infection</td>
<td>78 (15.1)</td>
<td>0.13 (0.11 - 0.16)</td>
</tr>
<tr>
<td>Sepsis</td>
<td>120 (23.3)</td>
<td>0.23 (0.20 - 0.27)</td>
</tr>
<tr>
<td>LVAS driveline infection</td>
<td>210 (40.8)</td>
<td>0.46 (0.41 - 0.51)</td>
</tr>
</tbody>
</table>
Continuous-flow left ventricular assist devices and usefulness of a standardized strategy to reduce drive-line infections

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How to Code This Chronic Problem – Help?

• If patient is placed on chronic suppressive antibiotics and is re-admitted with the same organism and receives IV antibiotics = the same infection. This situation is not a new AE

• If patient undergoes an escalation in therapy – fails suppressive antibiotic therapy, needs surgical debridement, or pump exchange because they now have a pocket infection – then this situation represents a new AE
Summary

• The Existence of a Driveline represents one of the major limitations of LVAD therapy at present
• At best, chronic driveline infections will occur in 1 out of 4 patients
• Battery Technology Improvement (Electric Vehicles) will lead to an fully implantable system