Diagnosis and Treatment of Infection in Mechanical Circulatory Support

M Hannan MD
IE Workshop ESCMID, Amsterdam 2019
Disclosure slide

• I have no disclosures
Outline

• Epidemiology
• Definitions
• Metrics in IMACS and international data bases
• Bloodstream infection and mortality
• Diagnosis of infection
  – Clinical, microbiological, radiological
• Management of infection
  – medical and surgical
• Recent developments in MCS
Working formulation for the standardization of definitions of infections in patients using ventricular assist devices

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Technical development
Improved biocompatibility and minimization

Source: Thoratec, HeartWare Inc
LVAD switch from Heart Mate II to 3
from second to third generation pump
## Definition of Infection in MCS

<table>
<thead>
<tr>
<th>Category of Major Infection</th>
<th>Location of Infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAD specific</td>
<td>Pump and /or cannula (includes pump interior from INTERMACS)</td>
</tr>
<tr>
<td></td>
<td>Pocket</td>
</tr>
<tr>
<td></td>
<td>VAD driveline</td>
</tr>
<tr>
<td>VAD-related</td>
<td>VAD related bacteraemia</td>
</tr>
<tr>
<td></td>
<td>VAD related mediastinitis</td>
</tr>
<tr>
<td></td>
<td>VAD related mediastinitis pocket</td>
</tr>
<tr>
<td>Non VAD</td>
<td>Pulmonary/pneumonia</td>
</tr>
<tr>
<td></td>
<td>Non VAD bacteraemia</td>
</tr>
<tr>
<td></td>
<td>UTI</td>
</tr>
<tr>
<td></td>
<td>GI</td>
</tr>
</tbody>
</table>

Hannan MM et al JHLT 2011 30(4) p375-384
Hazard function curve indicating the instantaneous risk of death over time.

**Continuous Flow LVAD/BiVAD Implants: 2008 – 2014, n=12030**

**Instantaneous Death Rate (Hazard) for selected causes**

- **Cause of Death**
  - Infection
  - RHFR
  - Neurological
  - Device Malfunction
  - MSOF

### Deaths/Month

- 0.010
- 0.009
- 0.008
- 0.007
- 0.006
- 0.005
- 0.004
- 0.003
- 0.002
- 0.001
- 0.000

### Months post implant

0  6  12  18  24  30  36  42  48

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Epidemiology of infection in mechanical circulatory support: A global analysis from the ISHLT Mechanically Assisted Circulatory Support Registry

Margaret M. Hannan, MD, a Rongbing Xie, DrPH, MPH, b Jennifer Cowger, MD, MS, c Stephan Schueler, MD, PhD, d Theo de By, MBA, e Anne I. Dipchand, MD, f Vivian H. Chu, MD, g Ryan S. Cantor, MSPH, b Christine E. Koval, MD, h Thomas Krabatsch, MD, i Christopher S. Hayward, MD, j Takeshi Nakatani, MD, PhD, k and James K. Kirklin, MD
Epidemiology of infection in MCS: A global analysis from the IMACS Registry

Patients Implanted in IMACS 2013-2015

- Bi-VAD
  - Pulsatile Flow or Unspecified: 72
  - Axial: 202
  - Centrifugal: 185
  - Continuous Flow: 387
- RVAD
  - Pulsatile Flow or Unspecified: 21
  - Axial: 69
  - Centrifugal: 185
- TAH
  - Pulsatile Flow or Unspecified: 214
  - Axial: 6455
  - Centrifugal: 2953
- LVAD
  - Continuous Flow: 9408
  - Axial: 6455
  - Centrifugal: 2953

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Epidemiology of infection in MCS: A global analysis from the IMACS Registry

<table>
<thead>
<tr>
<th>MAJOR INFECTION CATEGORY</th>
<th>NO OF INFECTIONS(% OF TOTAL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAD SPECIFIC</td>
<td>1,756(26%)</td>
</tr>
<tr>
<td>VAD RELATED</td>
<td>501(7.4%)</td>
</tr>
<tr>
<td>NON VAD</td>
<td>4,501(66.6%)</td>
</tr>
<tr>
<td>TOTAL</td>
<td>6,758</td>
</tr>
</tbody>
</table>

*The Journal of Heart and Lung Transplantation* DOI: (10.1016/j.healun.2019.01.007)
41% of patients will have had a major infection after one year
Table 6. Microbiology genus and location of Non-VAD infection. IMACS registry: January 2013 through December 2015, n=10,171

<table>
<thead>
<tr>
<th>Category of VAD infection</th>
<th>Location of Infection</th>
<th>Bacterial</th>
<th>Fungal</th>
<th>Viral</th>
<th>Protozoal</th>
<th>Unknown</th>
<th>Total n of infections by location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non VAD</td>
<td>Pneumonia</td>
<td>1,203 (78.5%)</td>
<td>107 (7%)</td>
<td>73 (4.8%)</td>
<td>4 (&lt;1%)</td>
<td>146 (9.5%)</td>
<td>1,533 (34.0%)</td>
</tr>
<tr>
<td></td>
<td>Non VAD related BSI</td>
<td>1,252 (91%)</td>
<td>81 (6%)</td>
<td>8 (&lt;1%)</td>
<td>1</td>
<td>34 (2%)</td>
<td>1,376 (30.6%)</td>
</tr>
<tr>
<td></td>
<td>UTI</td>
<td>1,018 (90%)</td>
<td>71 (6.3%)</td>
<td>0</td>
<td>4 (&lt;1%)</td>
<td>39 (3.4%)</td>
<td>1,132 (24.2%)</td>
</tr>
<tr>
<td></td>
<td>GI</td>
<td>398 (86.5%)</td>
<td>21 (4.5%)</td>
<td>10 (2%)</td>
<td>4 (&lt;1%)</td>
<td>27 (6%)</td>
<td>460 (10.2%)</td>
</tr>
<tr>
<td></td>
<td>Non VAD infection by genus</td>
<td>3,871 (86%)</td>
<td>280 (6%)</td>
<td>91 (2%)</td>
<td>13 (&lt;1%)</td>
<td>246 (5.5%)</td>
<td>4501</td>
</tr>
<tr>
<td></td>
<td>Total number of non VAD infections</td>
<td>4,501</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total N of infection

* BSI = Bloodstream infection,
Table 3. Summary of all Non VAD infection rates, by category, location, and timeline. IMACS registry: January 2013 through December 2015, n=10,171.

<table>
<thead>
<tr>
<th>Location</th>
<th>Early (≤ 3 months)</th>
<th>Late (&gt; 3 months)</th>
<th>p-values^b</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Event</td>
<td>Rate^a</td>
<td>%pts</td>
</tr>
<tr>
<td>Non VAD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pneumonia</td>
<td>1122</td>
<td>4.18</td>
<td>29.6</td>
</tr>
<tr>
<td>Non VAD-related BSI</td>
<td>594</td>
<td>2.21</td>
<td>15.9</td>
</tr>
<tr>
<td>UTI</td>
<td>730</td>
<td>2.72</td>
<td>19.2</td>
</tr>
<tr>
<td>GI</td>
<td>279</td>
<td>1.0</td>
<td>7.4</td>
</tr>
</tbody>
</table>

^a Infection rates per 100 person months

^b p-value compares early to late infection rates
Figure 4a. Survival after first VAD-specific infection by infection location; DL, pump and/or cannula and pocket infection. **IMACS registry: January 2013 through December 2015, n=10171**
Figure 4b. Survival after first VAD-related infection by infection location; VAD-related BSI, VAD-related mediastinitis, or VAD-Related mediastinitis/pocket infection. IMACS registry: January 2013 through December 2015, n=10171
Figure 4c. Survival after first non-VAD related infection by infection location; pneumonia, non-VAD related BSI, GI infection and UTI’s. IMACS registry: January 2013 through December 2015, n=10,171
Outcomes, and Effects of Device Flow Type on VAD Infections: An IMACS Registry Analysis: Xie et al  ISHLT Orlando FL 2019

- VAD infection rates were higher in axial devices (early and late)

- Younger pts (<40 yrs with axial) had a higher risk of developing VAD infection

- VAD infection was associated with
  a) higher mortality rates in both flow type groups
  b) higher rate of hemorrhagic CVA in axial flow
  c) higher rate of pump thrombosis in axial flow
IMACS Registry Geographic Distribution Xie et al ISHLT Orlando FL 2019.

Axial: 70%  
Centrifugal: 30%

Axial: 26%  
Centrifugal: 74%

Axial: 66%  
Centrifugal: 34%

P<0.0001
Microbiology of infection in summary

• Bacterial infections, predominate, early and late
  • Most common pathogens overall Gram-pos S. aureus & S epidermidis >50%, colonize the skin, adhere to implants & create biofilms. Enterococcus sp are the third most common Gram-pos 2%
  • Most common Gram-neg P. aeruginosus 22-28% followed by Enterobacteriacea such as Klebsiella sp 2% and Enterobacter sp 2%
• Fungal infection uncommon 1-10%
  • C. albicans >70% C. glabrata 10%, Aspergillus sp infection documented

— MRSA, VRE, CRE infection rates vary by regional and institutional

Bloodstream infections in mechanical circulatory support device recipients in the International Society of Heart and Lung Transplantation Mechanically Assisted Circulation Support Registry: Epidemiology, risk factors, and mortality

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BSI in MCS device recipients in the IMACS: Epidemiology, risk factors and mortality.

Figure 1: Timing of onset of mechanical circulatory support (MCS)–related and non–MCS-related bloodstream infection (BSI) based on early or late onset of infection in International Society of Heart and Lung Transplantation Mechanically Assisted Circulation Support Registry, January 2013 to December 2015 (n = 10,171).
Table 4(B)  Multivariate Model Demonstrating Independent Factors Associated With Blood Stream Infection Not Related to Mechanical Circulatory Support\(^a\)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>HR</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at implant (10 years)</td>
<td>1.09</td>
<td>1.02-1.14</td>
<td>0.0016</td>
</tr>
<tr>
<td>Body mass index (10 kg/m(^2))</td>
<td>1.31</td>
<td>1.21-1.43</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Previous cardiac surgery</td>
<td>1.39</td>
<td>1.22-1.58</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Pre-implant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dialysis</td>
<td>1.99</td>
<td>1.51-2.63</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>1.26</td>
<td>1.09-1.46</td>
<td>0.0014</td>
</tr>
<tr>
<td>Frailty</td>
<td>1.28</td>
<td>1.02 - 1.62</td>
<td>0.0344</td>
</tr>
<tr>
<td>BiVAD/TAH/RVAD</td>
<td>2.31</td>
<td>1.88 - 2.85</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>INTERMACS Category 1</td>
<td>1.46</td>
<td>1.25 - 1.70</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

BiVAD, biventricular assist device; CI, confidence interval; HR, hazard ratio; INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; RVAD, right ventricular assist device; TAH, total artificial heart.

\(^a\)Data are reported for International Society of Heart and Lung Transplantation Mechanically Assisted Circulation Support patients, January 2013 through December 2015 (\(n = 10,171\)).
Bloodstream infection in MCS device recipients in the IMACS: Epidemiology, risk factors and mortality. JHLT Vol38, No 8, August 2018
<table>
<thead>
<tr>
<th>BSI</th>
<th>Bacteria</th>
<th>Fungus</th>
<th>Other/unknown</th>
<th>Total (n = 1,606)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. (%)</td>
<td>No. (%)</td>
<td>No. (%)</td>
<td>No. (%)</td>
</tr>
<tr>
<td>MCS-related</td>
<td>222 (13.8)</td>
<td>4 (0.25)</td>
<td>2 (0.12)</td>
<td>228 (14.2)</td>
</tr>
<tr>
<td>Non-MCS-related</td>
<td>1,252 (78.0)</td>
<td>81 (5.0)</td>
<td>45 (3.3)</td>
<td>1,378 (85.8)</td>
</tr>
</tbody>
</table>

BSI, bloodstream infection; MCS, mechanical circulatory support.

*Infections occurred in 1,231 patients among 10,171 International Society of Heart and Lung Transplantation Mechanically Assisted Circulation Support, from January 2013 to December 2015.*
MECHANICAL CIRCULATORY SUPPORT INFECTIONS

An ISHLT consensus document for prevention and management strategies for mechanical circulatory support infection

Shimon Kusne, MD, a Martha Mooney, MD, FACP, b Lara Danziger-Isakov, MD, MPH, c Annemarie Kaan, MCN, RN, d Lars H. Lund, MD, PhD, e Haifa Lyster, MSc, f Georg Wieselthaler, MD, g Saima Aslam, MD, MS, h Barbara Cagliostro, RN, MSN, i Jonathan Chen, MD, j Pamela Combs, PhD, RN, k Adam Cochrane, PharmD, l Jennifer Conway, MD, m Jennifer Cowger, MD, MS, n Maria Frigerio, MD, o Rochelle Gellatly, PharmD, p Paolo Grossi, MD, PhD, q Finn Gustafsson, MD, PhD, r Margaret Hannan, MD, s Angela Lorts, MD, t Stanley Martin, MD, u Sean Pinney, MD, v Fernanda P. Silveira, MD, w Stephan Schubert, MD, x Stephan Schueler, MD, PhD, FRCS, y Martin Strueber, MD, z Nir Uriel, MD, za Neil Wrightson, RN, zb Rachel Zabner, MD, zc and Shirish Huprikar, MD zd
Diagnosis of MCS infection-Clinical

• In pts with unexplained fever and/or leukocytosis, evaluation should include
  – Blood cultures PVC and CVC before antibiotics are commenced and repeated as per IE guidelines
  – Urinalysis
  – Urine culture
  – Chest X ray
  – Wound culture
  – Additional imaging as needed

Hannan MM et al JHLT 2011 30(4) p375-384
Radiological diagnosis of MCS infection

- CT or US are recommended for deep seated drive-line, pocket, pump and cannula abnormalities in a specific anatomical space, may lack specificity.

- Leukocytes radio-labeled scintigraphy may also lack specificity.

- Combining SPECT/CT with radio-labeled leukocytes has increased the sensitivity for infection detection, and specificity for anatomical location including distant foci/infected emboli.

- TEE recommended in BSI to look for vegetations and turbulent flow.

Litzler et al, J Nucl Med 2010;51:1044-8
# Management of MCS infection

<table>
<thead>
<tr>
<th>Therapeutic options for Driveline bacterial infections</th>
<th>Medical intervention</th>
<th>Surgical intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MCS specific</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Superficial Driveline</strong></td>
<td>2 weeks IV antibiotics</td>
<td></td>
</tr>
<tr>
<td><strong>Deep-seated Driveline</strong></td>
<td>6-8 weeks IV antibiotics</td>
<td>Surgical debridement +/- VAC. New driveline exit site may be required.</td>
</tr>
<tr>
<td><strong>Depth unknown</strong></td>
<td>Clinical call, may need to treat as deep.</td>
<td></td>
</tr>
</tbody>
</table>

Kusne et al. The Journal of Heart and Lung Transplantation, Vol 36, No 10, October 2017
Management of MCS infection

<table>
<thead>
<tr>
<th>Therapeutic options for Cannula/Pump bacterial infection</th>
<th>Medical Intervention</th>
<th>Surgical intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial treatment</strong></td>
<td>Empiric antibiotic covering staphylococcal and pseudomonal based on local susceptibility patterns 4-6 weeks IV antibiotics</td>
<td>Surgical drainage and surgical debridement may be required depending on strategy BTT, DT, HT,</td>
</tr>
<tr>
<td><strong>Persistent bacteraemia, septic emboli, sepsis despite adequate antimicrobial and surgical therapy</strong></td>
<td>In BTT continue until after HT. In DT IV antibiotics for 6-8 weeks followed by long term suppression therapy. Duration will depend on pathogen and intra-operative cultures.</td>
<td>BTT replace device before MOF. DT may need to exchange the device to control infection</td>
</tr>
</tbody>
</table>
## Management of MCS infection

### Therapeutic options for MCS-related infection

<table>
<thead>
<tr>
<th>Medical Intervention</th>
<th>Surgical intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial treatment</strong></td>
<td><strong>Empiric antibiotic covering staphylococcal and pseudomonal based on local susceptibility patterns 4-6 weeks IV antibiotics</strong></td>
</tr>
<tr>
<td><strong>MCS-related bacteraemia, Bacterial mediastinitis and infective endocarditis.</strong></td>
<td><strong>Duration of antibiotics same as for Pump or cannula infection.</strong></td>
</tr>
</tbody>
</table>

Kusne et al. The Journal of Heart and Lung Transplantation, Vol 36, No 10, October 2017
Pump Exchange outcomes

  - Infection recurrence rates of 26% versus 38% for pump exchange compared to non exchange
  - One year survival >60%
Summary

- Infection still challenging but decreasing
- Majority of infections are non VAD infection
- Majority of infections are preventable
New studies

• Biofilm studies Anton Peleg et al, Melbourne

• First human study published JHLT, a fully implantable wireless device, NO DRIVELINE
Biofilm formation and migration on ventricular assist device drivelines

Yue Qu, PhD, David McGiffin, MD, Christina Kure, PhD, Berkay Ozcelik, PhD, John Fraser, MD, PhD, Helmut Thissen, PhD, and Anton Y. Peleg, MD, PhD

ABSTRACT

Objectives: Driveline infections remain an important complication of ventricular assist device therapy, with biofilm formation being a major contributor. This study aimed to elucidate factors that govern biofilm formation and migration on clinically relevant ventricular assist device drivelines.

Methods: Experimental analyses were performed on HeartWare HVAD (HeartWare International Inc, Framingham, Mass) drivelines to assess surface chemistry and biofilm formation. To mimic the driveline exit site, a drip-flow biofilm reactor assay was used. To mimic a subcutaneous tissue environment, a tunnel-based interstitial biofilm assay was developed. Clinical HVAD drivelines explanted at the time of cardiac transplantation were also examined by scanning electron microscopy.

Results: Common causative pathogens of driveline infections were able to adhere to the smooth and velour sections of the HVAD driveline and formed robust biofilms in the drip-flow biofilm reactor; however, Pseudomonas aeruginosa and Candida albicans had greater biomass. Biofilm migration within the interstitial driveline tunnel was evident for Staphylococcus epidermidis, Staphylococcus aureus, and C albicans, but not P aeruginosa. Biofilm formation by staphylococci was 500 to 10,000 times higher in the tunnel-based model compared with our exit site model. The 3-dimensional structure of the driveline velour and the use of silicone adhesive in driveline manufacturing were found to promote biofilm growth, and explanted patient drivelines demonstrated inadequate tissue in-growth along the entire velour with micro-gaps between velour fibers.

Conclusions: This work highlights the predilection of pathogens to different parts of the driveline, the importance of the subcutaneous tunnel to biofilm formation and migration, and the presence of micro-gaps in clinical drivelines that could facilitate invasive driveline infections. (J Thorac Cardiovasc Surg 2019; :1-12)
Driveline skin exit site

A

Smooth section (2 cm)  Velour section
First human use of a wireless coplanar energy transfer coupled with a continuous-flow left ventricular assist device

Yuryi Pya, MD, a Jiri Maly, MD, PhD, b Mahabbit Bekbossynova, MD, a Roman Salov, MBA, a Stephan Schueler, MD, PhD, FRCS, c Bart Meyns, MD, PhD, d Yigal Kassif, MD, e Massimo Massetti, MD, PhD, f Michael Zilbershlag, BSc, g and Ivan Netuka, MD, PhD b

From the a National Research Cardiac Surgery Center, Astana, Kazakhstan; b Department of Cardiovascular Surgery, Institute for Clinical and Experimental Medicine, Prague, Czech Republic; c Department of Cardiovascular Surgery, Freeman Hospital, The Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle, UK; d Cardiac Surgery Department, The University Hospitals Leuven, Leuven, Belgium; e Cardiac Surgery Department, Sheba Medical Center, Tel Aviv, Israel; f Cardio Vascular Department, Catholic University of the Sacred Heart Rome, Policlinico A. Gemelli Foundation, Rome, Italy; and the g LeviticusCardio, Ltd., Petach Tikva, Israel.
Figure 1  (A) Chest X-ray depicting implantable components topography. (B) Implantable components. (C) External components.
Thank you
Effect of Left Ventricular Assist Device Infection on Post-transplant Outcomes

Allison R. Schulman, BA, Timothy P. Martens, MD, Mark J. Russo, MD, MS, Paul J. Christos, MPH, MS, Rachel J. Gordon, MD, MPH, Franklin D. Lowy, MD, Mehmet C. Oz, MD, and Yoshifumi Naka, MD, PhD

Background: In this study, we sought to confirm which types of device-related infections impact bridge-to-transplant rates. We also aimed to determine the effect of device-related infections on post-transplant survival and post-transplant infection.

Methods: We retrospectively reviewed paper and electronic medical records for 149 patients undergoing left ventricular assist device (LVAD) implantation as a bridge to transplantation at the Columbia Presbyterian Medical Center between 2000 and 2006. The primary outcome measures were survival to transplantation, post-transplant infection and post-transplant survival.

Results: Patients with sepsis were less likely to be successfully bridged to cardiac transplantation (7 of 22 vs 103 of 127, 31.8% vs 81.1%, p = 0.01). However, if transplanted, their survival rates at 1 year were not decreased (6 of 7 vs 85 of 103, 85.7% vs 82.5%, p = 1.00). No other pre-transplant device-related infection affected post-transplant survival at 1 year (22 of 27 vs 69 of 83, 81.5% vs 83.1%, p = 1.00). Pre-transplant drive-line infections predicted post-transplant infection in former drive-line or pocket sites (11 of 16 vs 14 of 94, 68.8% vs 14.9%, p = 0.01) and increased overall post-transplant hospital length of stay (16 vs 19 days, p = 0.04). They did not, however, affect post-transplant survival at 1 year (22 of 25 vs 69 of 85, 88% vs 81.2%, p = 0.56).

Conclusions: Although survival to transplantation was diminished in LVAD patients with sepsis, if successfully transplanted, post-transplant survival was unaffected. Patients with local device infections and signs of early sepsis may warrant evaluation for urgent transplantation. A pre-transplant drive-line infection was associated with post-transplant infection in either the former pocket or drive-line site, and increased overall length of stay, but it did not decrease post-transplant survival. J Heart Lung Transplant 2009;28:237-42. Copyright © 2009 by the International Society for Heart and Lung Transplantation.
2019 EACTS Expert Consensus on long-term mechanical circulatory support

The Task force on long-term mechanical circulatory support of the European Association for Cardio-Thoracic Surgery (EACTS)

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C Diff studies in and cardiac surgery

- Evaluation of risk factors for a fulminant CDI after cardiac surgery: a single centre retrospective study. April 1999-2011, 41,466 patients underwent cardiac surgery in Germany
  - 3% of patient developed CDI
- Management Practices and Major Infection after Cardiac Surgery, multi centre >5,000 in US
  - Prospective study
  - 1% developed a C Diff infection
  - Higher in LVAD/transplant patients

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