Supplement 4

Patient Characteristics

Two studies correlated younger age and risk for LVAD infection. Goldstein et al ¹found a significant association between younger age and risk for LVAD infection and for risk of death due to LVAD infection. They postulated that this may have been related to a higher level of activity in younger patients, and, thus, a higher degree of local trauma at the driveline exit site, a recognized risk factor for subsequent driveline infection. For every decrease in patient age of 10 years, infection risk increased by 20%. A registry study by Kamdar et al ² similarly showed younger age to be a risk factor for infection, although notably, neither study controlled for duration of LVAD support.

In a secondary analysis of the HeartMate II LVAD bridge to transplant and destination therapy trials, extremely obese patients (BMI >35) had an increased risk of device-related infection and sepsis ³ There were more driveline infections and sepsis in obese patients than in underweight patients, but other types of infections did not differ in these groups ³. Four other studies of various devices showed that a higher BMI was a risk factor for infection. ⁴⁻⁷ These findings were similar to those in a study of the continuing access protocol for the HeartWare HVAD, where driveline infection was associated with both increased BMI and diabetes. ⁸ However, 1 study showed no infections in a cohort of 85 patients, including 21 patients with a BMI greater than 30, suggesting that BMI may not be a strong comorbidity. ⁹ In addition, a study from Japan showed an association with smaller BMI and risk of driveline infection. ¹⁰

References

- 1. Goldstein DJ, Naftel D, Holman W, et al: Continuous-flow devices and percutaneous site infections: clinical outcomes. *Journal of Heart & Lung Transplantation* 31 (11): 1151-7, 2012 doi: http://dx.doi.org/10.1016/j.healun.2012.05.004.
- 2. Kamdar F, Eckman P, Goldstein D, et al: 31 Pump-Related Infections (PRI) after Implantation of Continuous-Flow Left Ventricular Devices (CF LVADs): Analysis of 2900 Patients from the Interagency

Registry for Mechanically Assisted Circulatory Support (INTERMACS). *The Journal of Heart and Lung Transplantation* 31 (4): S19-S20doi: 10.1016/j.healun.2012.01.034.

- 3. Brewer RJ, Lanfear DE, Sai-Sudhakar CB, et al: Extremes of body mass index do not impact midterm survival after continuous-flow left ventricular assist device implantation. *Journal of Heart and Lung Transplantation* 31 (2): 167-172, 2012 doi: 10.1016/j.healun.2011.11.006.
- 4. Fleissner F, Avsar M, Malehsa D, *et al*: Reduction of driveline infections through doubled driveline tunneling of Left Ventricular Assist Devices (LVAD). *Artificial Organs* 36 (5): A23, 2012 doi: http://dx.doi.org/10.1111/j.1525-1594.2012.01477.x.
- 5. Raymer DS, Vader JM, Nassif ME, et al: Increased BMI is associated with left ventricular assist device-related infectious complications. *Journal of Heart and Lung Transplantation* 1): S197, 2014 doi: http://dx.doi.org/10.1016/j.healun.2014.01.536.
- 6. Henderson C, Patel K, Sayer G, et al: Extremes of Obesity and LVAD Patient Morbidity and Mortality. *The Journal of Heart and Lung Transplantation* 34 (4): S189doi: 10.1016/j.healun.2015.01.517.
- 7. Imamura T, Kinugawa K, Nitta D, et al: Readmission due to driveline infection can be predicted by new score by using serum albumin and body mass index during long-term left ventricular assist device support. *J Artif Organs* 18 (2): 120-7, 2015 doi: 10.1007/s10047-015-0816-2.
- 8. John R, Aaronson KD, Pae WE, et al: Drive-line infections and sepsis in patients receiving the HVAD system as a left ventricular assist device. *J Heart Lung Transplant* 33 (10): 1066-73, 2014 doi: 10.1016/j.healun.2014.05.010.
- 9. McMenamy M, Arabia F, Czer L, et al: Breaking the Myth of Obesity as a Contraindication to Continuous Flow Left Ventricular Assist Devices. *The Journal of Heart and Lung Transplantation* 34 (4): S193doi: 10.1016/j.healun.2015.01.528.
- 10. Ono M, Sawa Y, Nakatani T, et al: (547) Japanese Multi-Center Outcomes With the HeartMate II in the Post-Approval Era: Focusing on Results in Patients With Small Body Size. *The Journal of Heart and Lung Transplantation* 34 (4, Supplement): S205, 2015 doi: http://dx.doi.org/10.1016/j.healun.2015.01.563.