APPLICATION OF THE SEATTLE HEART FAILURE MODEL TO THE HEARTWARE BRIDGE TO TRANSPLANT US TRIAL

ACC Poster Contributions
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Background: The Seattle Heart Failure Model (SHFM) is a well-validated and calibrated risk model. We sought to estimate the impact of ventricular assist device (VAD) therapy in the HeartWare HVAD Bridge- to- Transplant ADVANCE trial by comparing observed survival to that predicted with medical therapy by the SHFM in 140 patients.

Methods: The SHFM was calculated with the inclusion of inotropes, intra-aortic balloon pumps (IABP) and a diminished benefit of the ICD as the annual mortality increases (J Heart Lung Transplant 2010:1021-5). A t statistic was used to estimate the P value of the observed HVAD survival vs. SHFM estimated survival with continued medical therapy..

Results: The patients were high risk with 26% on IABP/ventilator, 76% on inotropes, systolic blood pressure 104±1mmHg, and a high diuretic requirement (furosemide 7.0±1.8 mg/kg/day). The overall estimated hazard ratio for HVAD benefit was ~0.15 at 30, 90, 180 and 365 days, consistent with an ~85% reduction in mortality vs. the SHFM estimated survival with medical therapy (all P<0.0001). Patients with an IABP (n=35) had an estimated ~95% reduction in mortality at 1 year with the HVAD (P<0.0001). Patients with (n=77) and without inotropes (n=28) had an ~85% and ~80% reduction in mortality at 1 year with the HVAD (p<0.0001 and p=0.002). There was no evidence that the post VAD survival varied with the pre VAD SHFM estimated risk. The SHFM model predicted survival and the observed HVAD outcomes will be presented.

Conclusions: The SHFM can be used to describe patients who are currently receiving VADs and may potentially serve as a virtual control arm in single arm trials. The survival with the HVAD did not vary by the baseline risk of the SHFM. It is estimated that the HVAD reduced mortality by ~85% vs. continued medical therapy.